

INSMED INC  
Form 10-Q  
November 07, 2012

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2012

OR

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  
(State or other jurisdiction of incorporation or organization)

54-1972729  
(I.R.S. employer identification no.)

9 Deer Park Drive, Suite C  
Monmouth Junction, NJ  
(Address of principal executive offices)

08852  
(Zip Code)

(732) 997-4600  
(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  No

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  No

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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  Accelerated filer  Non-accelerated filer  Small Reporting Company

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

As of November 2, 2012, there were 31,352,554 shares of the registrant’s common stock, \$0.01 par value, outstanding.

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## INSMED INCORPORATED

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In this Form 10-Q, we use the words the "Company," "Insmmed," "Insmmed Incorporated," "we," "us" and "our" to refer to Insmmed Incorporated, a Virginia corporation.

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PART I  
FINANCIAL INFORMATION  
ITEM 1. FINANCIAL STATEMENTS

INSMED INCORPORATED  
Consolidated Balance Sheets (Unaudited)  
(in thousands, except share and per share data)

|  | September<br>30,<br>2012 | December<br>31,<br>2011 |
|--|--------------------------|-------------------------|
| Assets   |                          |                         |
| Current assets:  |                          |                         |
| Cash and cash equivalents  | \$44,989                 | \$14,848                |
| Short-term investments   | 44,759                   | 61,424                  |
| Accounts receivable  | -                        | 757                     |
| Prepaid expenses and other current assets  | 605                      | 370                     |
| Total current assets   | 90,353                   | 77,399                  |
| Certificate of deposit   | 2,132                    | 2,085                   |
| In-process research and development  | 58,200                   | 58,200                  |
| Other  | 125                      | 212                     |
| Fixed assets, net  | 1,647                    | 1,937                   |
| Total assets   | \$152,457                | \$139,833               |
| Liabilities and stockholders' equity   |                          |                         |
| Current liabilities:   |                          |                         |
| Accounts payable   | \$2,985                  | \$2,334                 |
| Accrued expenses   | 836                      | 800                     |
| Accrued compensation   | 1,581                    | 795                     |
| Accrued lease expense, current   | 291                      | 278                     |
| Deferred rent  | 151                      | 156                     |
| Capital lease obligations, current   | 109                      | 114                     |
| Debt, current  | 592                      | -                       |
| Total current liabilities  | 6,545                    | 4,477                   |
| Accrued lease expense, long-term   | 717                      | 923                     |
| Capital lease obligations, long-term   | 80                       | 166                     |
| Debt, long-term  | 8,503                    | -                       |
| Total liabilities  | 15,845                   | 5,566                   |
| Stockholders' equity:  |                          |                         |
| Common stock; \$.01 par value; authorized shares 500,000,000; issued and outstanding shares, 31,178,954 in 2012 and 24,833,301 in 2011 | 312                      | 248                     |
| Additional paid-in capital   | 455,560                  | 427,743                 |
| Accumulated deficit  | (320,095 )               | (294,174 )              |
| Accumulated other comprehensive income:  |                          |                         |
| Unrealized gain on investments   | 835                      | 450                     |
| Total stockholders' equity   | 136,612                  | 134,267                 |

|  |           |           |
|--|-----------|-----------|
| Total liabilities and stockholders' equity | \$152,457 | \$139,833 |
|--|-----------|-----------|

See accompanying notes to unaudited consolidated financial statements

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INSMED INCORPORATED  
Consolidated Statements of Comprehensive Operations (Unaudited)  
(in thousands, except per share data)

|   | Three Months Ended<br>September 30, |              | Nine Months Ended<br>September 30, |              |
|---|-------------------------------------|--------------|------------------------------------|--------------|
|   | 2012                                | 2011         | 2012                               | 2011         |
| License fees  | \$ -                                | \$ 1         | \$ -                               | \$ 252       |
| Other expanded access program income, net                                       | -                                   | 434          | -                                  | 2,762        |
| Total revenues  | -                                   | 435          | -                                  | 3,014        |
| Operating expenses:   |                                     |              |                                    |              |
| Research and development  | 5,539                               | 6,933        | 17,553                             | 21,399       |
| General and administrative  | 3,814                               | 2,472        | 9,047                              | 8,474        |
| Impairment loss   | -                                   | 25,990       | -                                  | 25,990       |
| Total operating expenses  | 9,353                               | 35,395       | 26,600                             | 55,863       |
| Operating loss  | (9,353 )                            | (34,960 )    | (26,600 )                          | (52,849 )    |
| Investment income   | 193                                 | 371          | 901                                | 1,358        |
| Interest expense  | (222 )                              | (2 )         | (225 )                             | (9 )         |
| Gain on sale of asset, net  | -                                   | -            | 5                                  | -            |
| Loss before income taxes  | (9,382 )                            | (34,591 )    | (25,919 )                          | (51,500 )    |
| Income tax expense  | -                                   | -            | 4                                  | 2            |
| Net loss  | (9,382 )                            | (34,591 )    | (25,923 )                          | (51,502 )    |
| Accretion of beneficial conversion charge                                       | -                                   | -            | -                                  | (9,175 )     |
| Net loss attributable to common stockholders                                    | \$ (9,382 )                         | \$ (34,591 ) | \$ (25,923 )                       | \$ (60,677 ) |
| Basic and diluted net loss attributable to common stockholders per common share | \$ (0.38 )                          | \$ (1.39 )   | \$ (1.04 )                         | \$ (2.66 )   |
| Weighted average basic and diluted common shares outstanding                    | 25,013                              | 24,833       | 24,916                             | 22,848       |
| Comprehensive loss  | \$ (9,183 )                         | \$ (34,837 ) | \$ (25,538 )                       | \$ (51,624 ) |

See accompanying notes to unaudited consolidated financial statements

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INSMED INCORPORATED  
Consolidated Statements of Cash Flows (Unaudited)  
(in thousands)

|   | Nine Months Ended<br>September 30, |             |
|---|------------------------------------|-------------|
|   | 2012                               | 2011        |
| <b>Operating activities</b>   |                                    |             |
| Net loss  | \$(25,923 )                        | \$(51,502 ) |
| Adjustments to reconcile net loss to net cash (used in) provided by operating activities: |                                    |             |
| Depreciation and amortization   | 412                                | 233         |
| Stock based compensation expense  | 1,518                              | 1,091       |
| Gain on sale of asset, net  | (5 )                               | -           |
| Impairment loss   | -                                  | 25,990      |
| Amortization of financing costs   | 55                                 | -           |
| Changes in operating assets and liabilities:  |                                    |             |
| Accounts receivable   | 757                                | 31          |
| Prepaid expenses and other assets   | (175 )                             | (352 )      |
| Accounts payable  | 651                                | 54          |
| Accrued expenses and deferred rent  | 31                                 | 296         |
| Accrued lease expenses  | (193 )                             | -           |
| Accrued compensation  | 786                                | -           |
| Deferred revenue  | -                                  | 19          |
| Net cash used in operating activities   | (22,086 )                          | (24,140 )   |
| <b>Investing activities</b>   |                                    |             |
| Purchase of fixed assets  | (122 )                             | (555 )      |
| Proceeds from sale of asset   | 5                                  | -           |
| Sales of short-term investments   | 17,050                             | 26,018      |
| Purchases of short-term investments   | -                                  | (1,585 )    |
| Net cash provided by investing activities   | 16,933                             | 23,878      |
| <b>Financing activities</b>   |                                    |             |
| Payments on capital lease obligations   | (91 )                              | (64 )       |
| Proceeds from issuance of debt, net of issuance and financing costs                       | 9,726                              | -           |
| Proceeds from issuance of common stock  | 25,659                             | 32          |
| Net cash provided by (used in) financing activities                                       | 35,294                             | (32 )       |
| Increase in cash and cash equivalents   | 30,141                             | (294 )      |
| Cash and cash equivalents at beginning of period  | 14,848                             | 10,743      |
| Cash and cash equivalents at end of period  | \$44,989                           | \$10,449    |
| <b>Supplemental disclosures of cash flow information</b>                                  |                                    |             |
| Cash paid for interest  | \$164                              | \$9         |
| Cash paid for taxes, net  | \$4                                | \$2         |
| <b>Supplemental disclosures of non-cash investing and financing activities</b>            |                                    |             |
| Unrealized gain on investments  | \$385                              | \$(122 )    |

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|  |       |            |
|--|-------|------------|
| Accretion of beneficial conversion charge      | \$-   | \$(9,175 ) |
| Fair value of warrants in connection with debt | \$790 | \$-        |

See accompanying notes to unaudited consolidated financial statements

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INSMED INCORPORATED

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Description of the Business

Insmmed® is a biopharmaceutical company focused on developing and commercializing novel, targeted inhaled therapies for patients with high unmet need battling serious orphan lung diseases. Our lead product candidate, ARIKACE® (liposomal amikacin for inhalation), is a differentiated, inhaled antibiotic engineered to deliver a proven and potent anti-infective directly to the site of serious lung infections to improve the efficacy, safety and convenience of treatment for patients.

Currently, we are continuing late-stage clinical trials for two initial primary target indications for this product: lung infections caused by *Pseudomonas aeruginosa*, which we refer to as *Pseudomonas*, in cystic fibrosis (CF) patients and lung infections caused by non-tuberculous mycobacteria (NTM). Our ongoing ARIKACE clinical development program includes a European and Canadian registration phase 3 clinical study of ARIKACE in CF patients with *Pseudomonas* lung infections (CLEAR-108) and an optional longer term open-label safety study (CLEAR-110), as well as a phase 2 clinical study of ARIKACE in patients with NTM lung disease (TARGET-NTM). We expect to report clinical results from both the CLEAR-108 and TARGET-NTM studies in 2013. Our sole development focus is to obtain regulatory approval for, and to prepare for commercialization of, ARIKACE in the U.S. and Europe.

Corporate History

We were incorporated in the Commonwealth of Virginia on November 29, 1999. On December 1, 2010, we completed a business combination with Transave, Inc., or Transave, a privately held, New Jersey-based pharmaceutical company focused on the development of differentiated and innovative inhaled pharmaceuticals for the site-specific treatment of serious lung infections. Our integration with Transave was completed in 2011.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012. The consolidated balance sheet at December 31, 2011 has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by GAAP for complete financial statements. For further information, refer to the consolidated financial statements and footnotes thereto included in the Company's annual report on Form 10-K for the year ended December 31, 2011 filed with the Securities and Exchange Commission on March 13, 2012.

Principles of Consolidation

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



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### Use of Estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company bases its estimates and judgments on historical experience and on various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's balance sheets and the amounts of revenue and expenses reported for each of the periods presented are affected by estimates and assumptions, which are used for, but not limited to, the accounting for revenue recognition, stock-based compensation, income taxes, loss contingencies and accounting for research and development costs. Actual results could differ from those estimates.

### Debt Issuance and Deferred Financing Costs

Debt issuance and deferred financing costs are amortized using the effective interest rate method, and amortized to interest expense over the term of the debt. Debt issuance costs are reflected as a discount to the debt, and deferred financing costs as other assets in the consolidated balance sheets.

### Identified Intangible Assets

As part of the merger, we recorded in-process research and development as identified intangible assets. Identifiable intangible assets are measured at their respective fair values as of the acquisition date and are not amortized until commercialization. Once commercialization occurs, these intangible assets will be amortized over their estimated useful lives. While we believe the fair values assigned to our acquired intangible assets are based on reasonable estimates and assumptions given the available facts and circumstances as of the acquisition date, unanticipated events or circumstances may occur that require us to review the assets for impairment. Events or circumstances that may require an impairment assessment include negative clinical trial results, the non-approval of a new drug application (NDA) by the U.S. Food and Drug Administration, or the FDA, material delays in our development program or a sustained decline in market capitalization.

Indefinite-lived intangible assets are not subject to periodic amortization. Rather, indefinite-lived intangibles are reviewed for impairment by applying a fair value based test on an annual basis or more frequently if events or circumstances indicate impairment may have occurred. Events or circumstances that may require an interim impairment assessment are consistent with those described above. The Company has elected to perform its annual impairment test as of October 1 of each year.

### Revenue Recognition and Collaboration Agreements

Our historic revenues reflected principally secondary revenue streams for IPLEX® (IPLEX) Expanded Access Program (EAP) in Italy for the treatment of Amyotrophic Lateral Sclerosis (ALS). Historically, this revenue was recognized when the drugs were provided to program patients and collectability was assured. We no longer manufacture IPLEX and the cost recovery revenues from our IPLEX EAP in Europe ceased in December 2011, when our IPLEX inventory was fully depleted.

Revenue from collaborations is recognized as license fees when milestones are achieved and payments are due. The Company analyzes each element of an agreement to determine if it shall be accounted for as a separate element or single unit of accounting. If an element shall be treated separately for revenue recognition purposes, the revenue recognition principles most appropriate for that element are applied to determine when revenue shall be recognized. If an element shall not be treated separately for revenue recognition purposes, the revenue recognition principles most appropriate for the bundled group of elements are applied to determine when revenue shall be recognized. Payments

received in excess of revenues recognized are recorded as deferred revenue until such time as the revenue recognition criteria have been met.

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## Research and Development

Research and development costs are expensed as incurred, except for purchased in-process research and development (see Identified Intangible Assets policy above and Note 4). Research and development expenses consist primarily of salaries and related expenses, cost to develop and manufacture drug candidates, patent protection costs, amounts paid to contract research organizations, hospitals and laboratories for the provision of services and materials for drug development and clinical trials. Our expenses related to clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with third-party organizations that conduct and manage clinical trials on our behalf. These contracts set forth the scope of work to be completed at a fixed fee or amount per patient enrolled. Payments under these contracts primarily depend on performance criteria such as the successful enrollment of patients or the completion of clinical trial milestones as well as time-based fees. Expenses are accrued based on contracted amounts applied to the level of patient enrollment and to activity according to the clinical trial protocol.

## Stock-Based Compensation

Stock-based compensation transactions are accounted for using a fair-value-based method to recognize non-cash compensation expense; this expense is recognized ratably over the requisite service period, which generally equals the vesting period of options, and is adjusted for expected forfeitures.

## Beneficial Conversion Charge

When issuing debt or equity securities that are convertible into common stock at a discount from the fair value of the common stock at the date the debt or equity financing is committed, we are required to record a beneficial conversion charge (“BCC”) at the time of issuance in accordance with Accounting Standards Codification (“ASC”) 470-20. This BCC is measured as the difference between the fair value of the securities on the issue date and the fair value of the common stock at the commitment date. The BCC is recorded as a non-cash charge to earnings for the period in which the securities are issued. See Note 5 for further information about the beneficial conversion feature.

## Net (Loss) Income Per Share

Basic net (loss) per common share is calculated by dividing net loss by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. For the periods presented, basic and diluted net loss per common share are identical. Potentially dilutive securities from stock options and warrants would be antidilutive as the Company incurred a net loss.

The following potentially dilutive securities have been excluded from the computations of diluted weighted-average shares outstanding as of September 30, 2012 and 2011, because they would be anti-dilutive (in thousands):

|   | September 30, |      |
|---|---------------|------|
|   | 2012          | 2011 |
| Shares underlying warrants to purchase outstanding common stock | 330           | 158  |
| Shares underlying options to purchase outstanding common stock  | 1,690         | 377  |
| Shares underlying restricted stock units                        | 496           | 487  |

## Recent Accounting Pronouncements

In May 2011, the FASB issued Accounting Standards Update (ASU) 2011-04, Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS. The new guidance limits the highest-and-best-use measure to nonfinancial assets, permits certain financial assets and liabilities with offsetting

positions in market or counterparty credit risks to be measured at a net basis, and provides guidance on the applicability of premiums and discounts. Additionally, the new guidance expands the disclosures on Level 3 inputs by requiring quantitative disclosure of the unobservable inputs and assumptions, as well as description of the valuation processes and the sensitivity of the fair value to changes in unobservable inputs. We adopted ASU 2011-04 effective January 1, 2012, and it did not have a material impact on our consolidated financial statements.

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In June 2011, the FASB issued ASU 2011-05, Presentation of Comprehensive Income, which requires an entity to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income, or in two separate but consecutive statements. ASU 2011-05 eliminates the option to present components of other comprehensive income as part of the statement of equity. In December 2011, the FASB issued ASU 2011-12, Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in ASU 2011-05. ASU 2011-12 defers the effective date of the requirement in ASU 2011-05 to disclose on the face of the financial statements the effects of reclassifications out of accumulated other comprehensive income on the components of net income and other comprehensive income. All other requirements of ASU 2011-05 are not affected by ASU 2011-12. ASU 2011-05 and 2011-12 are effective for years beginning after December 15, 2011. We adopted ASU 2011-05 and ASU 2011-12 effective January 1, 2012 and it did not have a material impact on our consolidated financial statements.

In July 2012, the FASB issued ASU No. 2012-02, Testing Indefinite-Lived Intangible Assets for Impairment (the revised standard). The revised standard reduces cost and complexity of testing indefinite-lived intangible assets other than goodwill for impairment. It allows companies to perform a “qualitative” assessment to determine whether further impairment testing of indefinite-lived intangible assets is necessary. Under the revised standard, an entity would first assess qualitatively whether it is more likely than not (that is, a likelihood of more than 50 percent) that an indefinite-lived intangible asset is impaired, thus necessitating that it perform the quantitative impairment test. An entity would not be required to calculate the fair value of an indefinite-lived intangible asset and perform the quantitative impairment test unless the entity determines that it is more likely than not that the asset is impaired. The effective date for annual and interim impairment tests performed is for fiscal years beginning after September 15, 2012. We are evaluating the impact of this standard but do not expect its adoption to have a material impact on our consolidated financial statements.

### 3. Risks and Uncertainties

For the period from inception to September 30, 2012, the Company has incurred recurring operating losses and has accumulated a deficit of \$320.1 million. During the nine months ended September 30, 2012, the Company recognized a net loss of \$25.9 million. Our net cash used in operations for the nine months ended September 30, 2012 was \$22.1 million.

We believe we have sufficient funds to meet our financial needs for at least the next twelve months. In June 2012, we entered into a loan and security agreement (the “Loan and Security Agreement”) with Hercules Technology Growth Capital, Inc. (“HTGC”) for borrowings of up to \$20 million under a term loan to further underpin our ARIKACE development program. The first \$10 million of the term loan was funded at closing. The remaining \$10 million of the Loan and Security Agreement is available at Insmed’s option throughout the availability period, which ends on December 31, 2012. In September 2012, we completed a registered direct offering of 6,304,102 shares of our common stock, at a price of \$4.07 per share resulting in net proceeds of \$25.7 million. In the future, we may require additional funds for the continued development of our potential product candidates or to pursue the license of complementary technologies. There can be no assurance that adequate funds will be available when we need them or on favorable terms. If at any time we are unable to obtain sufficient additional funds, we will be required to delay, restrict or eliminate some or all of our development programs, dispose of assets or technology or cease operations.

### 4. Identified Intangible Assets

In the third quarter of 2011, the FDA placed a clinical hold on our phase 3 U.S. clinical trials for ARIKACE in CF patients with Pseudomonas lung infections and for patients with NTM lung infections.



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In January 2012, the FDA lifted the clinical hold on ARIKACE in patients with NTM lung infections. In February 2012, we announced that we would be initiating the ARIKACE NTM trial as a phase 2 trial, as well as the previously planned phase 3 trial for ARIKACE in the CF indication in Europe. In April 2012, the Company announced the first patient dosed in the European phase 3 clinical study, which is called CLEAR-108 and is proceeding with an optional longer term open-label safety study called CLEAR-110. The Company also is conducting CLEAR-108 in Canada. We also initiated a nine-month dog inhalation toxicity study in April 2012. In May 2012, the FDA lifted the clinical hold on ARIKACE in the U.S. for the treatment of CF patients with Pseudomonas lung infections. In June 2012, we announced that the first patient was dosed in the Company's U.S. phase 2 clinical study of ARIKACE in patients with NTM lung disease, which is called TARGET-NTM.

As a result of these events, the Company believes there are no indicators of impairment of in-process research and development intangible assets as of September 30, 2012.

## 5. Stockholders' Equity

### Common and Preferred Stock

On December 1, 2010, we entered into an Agreement and Plan of Merger, or the merger agreement, with Transave. Under the terms of the merger agreement, the Transave stockholders received an aggregate of 2.6 million newly issued shares of the Company's common stock and 9.2 million shares of the Company's newly created convertible Series B Preferred Stock. They also received an aggregate of approximately \$0.6 million in cash. Collectively, the shares of the Company's common stock and the Company's Series B Preferred Stock (on an as converted basis) issued in connection with the merger represented approximately 47% of the capital stock of the Company on a fully diluted basis.

On March 1, 2011, we held a special meeting of our shareholders to consider proposals relating to the conversion of our Series B Preferred Stock and a one-for-ten reverse stock split of the common stock. At the special meeting of shareholders, the shareholders approved all of those proposals.

As a result of the approval of the conversion of the Series B Preferred Stock, all 91.7 million shares of the Series B Preferred Stock outstanding (on a pre-reverse stock-split basis) were automatically and immediately converted into 91.7 million shares of our common stock. In addition, we filed Articles of Amendment to our Articles of Incorporation, as amended, to affect a one-for-ten reverse stock split of our common stock. The Amendment became effective on March 2, 2011. As a result of the Amendment, each holder of ten shares of common stock immediately prior to the effectiveness of the reverse stock split became the holder of one share of our common stock. Shareholders received a cash payment in lieu of any fractional shares of common stock they were entitled to receive. The following table (in thousands) summarizes the conversion of the shares of the Series B Preferred Stock and the reverse stock split.

|   |         |
|---|---------|
| Common stock shares outstanding February 28, 2011                     | 156,537 |
| Series B Preferred Stock converted into common stock on March 1, 2011 | 91,746  |
| Total shares outstanding prior to reverse stock split                 | 248,283 |
| 1 for 10 reverse stock split  | 1:10    |
| Approximate number of common shares outstanding March 2, 2011         | 24,828  |

As a result of the conversion of the Series B Preferred Stock, we recorded a non-cash charge for the beneficial conversion feature of the Series B Preferred Stock in the amount of \$9.2 million, which reduced net income available

to holders of our common shares and, in turn, reduced our earnings per common share on a basic and diluted basis by \$0.48. The charge represents the \$1.00 difference between the conversion price of the Series B Preferred Stock of \$7.10 per share and its carrying value of \$6.10 per share. The carrying value of the Series B Preferred Stock was based on its fair value at issuance, which was estimated using the common stock price reduced for a lack of marketability between the acquisition date (or issuance date) and the anticipated date of conversion. In June 2012, the Company amended its Articles of Incorporation to delete all provisions regarding the issuance of the Series B Preferred Stock.

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On September 28, 2012, we completed a registered direct offering of 6,304,102 shares of our common stock, at a price of \$4.07 per share resulting in net proceeds of \$25.7 million.

## Stock Warrants

Stock warrant activity for the nine months ended September 30, 2012 consisted of issuance of 0.3 million warrants with a weighted average price of \$2.94 and an expiration date of June 29, 2017 and the expiration of 0.2 million warrants outstanding with a weighted average price of \$11.00. As of September 30, 2011, we had 0.2 million warrants outstanding with a weighted average price of \$11.00 and an expiration date of May 4, 2012. See Note 7 for further information about the outstanding warrants. The Company recognized no stock-based compensation expense related to warrants for the three and nine month periods ended September 30, 2012 and 2011, respectively.

## 6. Stock Based Compensation

## Stock Options

As of September 30, 2012, we had two equity compensation plans under which we were granting stock options and shares of non-vested stock. We may grant stock-based awards from our Amended and Restated 2000 Stock Incentive Plan (the “2000 Plan”) and our Amended and Restated 2000 Employee Stock Purchase Plan (the “2000 ESPP”). Both the 2000 Plan and the 2000 ESPP are administered by the Compensation Committee of the Board of Directors and the Board of Directors (the “Board”).

The 2000 Plan was originally adopted by the Board and approved by our shareholders in 2000. Its original ten-year term was extended to March 30, 2015, when the 2000 Plan was amended in May 2005 after approval by our shareholders. At the 2011 annual meeting of shareholders, the Company’s shareholders approved an amendment to the 2000 Plan to reserve an additional 3 million shares of common stock. As of September 30, 2012, the 2000 Plan provides for the issuance of a maximum of 3.9 million shares of common stock. These shares are reserved for awards to all participants in the 2000 Plan, including non-employee directors.

The 2000 ESPP was adopted by the Board on April 5, 2000 and approved by our shareholders on the same date. The 2000 ESPP which, following the appropriate shareholder approval was subsequently amended in 2005 and 2006, provides for the issuance of a maximum of 150,000 shares of our common stock to participating employees. The Company did not offer employees the right to purchase common stock under the ESPP during the first nine months of 2012.

The following table summarizes stock option activity for the nine months ended September 30, 2012:

|   | Number of<br>Shares | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Life in<br>Years | Aggregate<br>Intrinsic<br>Value |
|---|---------------------|--|---|---------------------------------|
| Options outstanding at December 31, 2011  | 891,751             | \$5.15                                   |   |                                 |
| Granted                                   | 932,384             | 3.63                                     |   |                                 |
| Exercised                                 | -                   | -  |   |                                 |
| Forfeited                                 | (78,525 )           | 3.03                                     |   |                                 |
| Cancelled                                 | (55,251 )           | 18.93                                    |   |                                 |
| Options outstanding at September 30, 2012 | 1,690,359           | 3.96                                     | 8.11  | \$1,600,309                     |

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|   |           |      |      |             |
|---|-----------|------|------|-------------|
| Vested and expected to vest at September 30, 2012 | 1,558,961 | 4.00 | 7.97 | \$1,464,563 |
| Exercisable at September 30, 2012                 | 310,000   | 5.72 | 1.51 | \$156,712   |
| Non vested  | 1,380,359 |      |      |             |
| Wgt. Avg remaining recognition period             | 3.65      |      |      |             |

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The Company calculates the fair value of stock options based upon the Black-Scholes-Merton valuation model. The following table summarizes the fair value and assumptions used in determining the fair value of stock options issued during the nine months ended September 30, 2012.

|                                 |       |   |
|---------------------------------|-------|---|
| Volatility                      | 100.2 | % |
| Risk-free interest rate         | 0.6   | % |
| Dividend yield                  | 0.0   | % |
| Expected option term (in years) | 6.25  |   |

The volatility factor was estimated based on the Company's historical volatility. The expected life was determined using the simplified method as described in ASC Topic 718, Accounting for Stock Compensation, which is the midpoint between the vesting date and the end of the contractual term. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant. Forfeitures are based on a historical percentage of actual option forfeitures since the business combination on December 1, 2010.

The Company recognized stock-based compensation expense related to stock options of approximately \$0.4 million and \$0.1 million for the three months ended September 30, 2012 and 2011, respectively. General and administrative expenses include \$0.3 million and less than \$0.1 million and research and development expenses include \$0.1 million and less than \$0.1 million of stock-based compensation expense in the consolidated statement of operations for the three months ended September 30, 2012 and 2011, respectively.

The Company recognized stock-based compensation expense related to stock options of approximately \$0.7 million and \$0.2 million for the nine months ended September 30, 2012 and 2011, respectively. General and administrative expenses include \$0.5 million and \$0.1 million and research and development expenses include \$0.2 million and \$0.04 million of stock-based compensation expense in the consolidated statement of operations for the nine months ended September 30, 2012 and 2011, respectively. As of September 30, 2012, there was \$3.3 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 3.65 years.

#### Restricted Stock and Restricted Stock Units

In May 2008, under the 2000 Plan, we began granting Restricted Stock ("RS") and Restricted Stock Units ("RSUs") to eligible employees, including our executives. RS shares vest upon the completion of a specific period of continued service or our achievement of certain performance metrics. Each RSU represents a right to receive one share of our common stock upon the completion of a specific period of continued service or our achievement of certain performance metrics. Shares of RS are valued at the market price of our common stock on the date of grant and RSUs are valued based on the market price on the date of settlement. We recognize noncash compensation expense for the fair values of these RS and RSUs on a straight-line basis over the requisite service period of these awards, which is generally three years.

No RS was issued or outstanding during the nine months ended September 30, 2012. A summary of RSU activity for the nine months ended September 30, 2012 is as follows:

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|                                   | Number of<br>RSU's | Weighted<br>Average<br>Grant Price |
|-----------------------------------|--------------------|------------------------------------|
| Outstanding at December 31, 2011  | 487,025            | \$6.37                             |
| Granted                           | 61,011             | 3.44                               |
| Released                          | (43,819 )          | 5.98                               |
| Forfeited                         | (8,559 )           | 5.78                               |
| Outstanding at September 30, 2012 | 495,658            | \$5.11                             |
| Expected to Vest                  | 351,013            | \$5.68                             |

The Company recognized stock-based compensation expense related to RSUs of approximately \$0.1 million and \$0.4 million for the three months ended September 30, 2012 and 2011, respectively. General and administrative expenses include less than \$0.1 million and \$0.3 million and research and development expenses include less than \$0.1 million and \$0.1 million of stock-based compensation expense in the consolidated statement of operations for the three months ended September 30, 2012 and 2011, respectively.

The Company recognized stock-based compensation expense related to RSUs of approximately \$0.8 million and \$0.9 million for the nine months ended September 30, 2012 and 2011, respectively. General and administrative expenses include \$0.5 million and \$0.6 million and research and development expenses include \$0.3 million and \$0.3 million of stock-based compensation expense in the consolidated statement of operations for the nine months ended September 30, 2012 and 2011, respectively. As of September 30, 2012, there was \$1.2 million of unrecognized compensation expense related to unvested RSUs, which is expected to be recognized over a weighted average period of 1.05 years.

A total of approximately 1.0 million shares of common stock were reserved for issuance at September 30, 2012 in connection with RSUs, stock options, stock warrants and the employee stock purchase plan.

## 7. Debt

On June 29, 2012, the Company and its domestic subsidiaries, as co-borrowers, entered into loan and security agreement (the "Loan and Security Agreement") with Hercules Technology Growth Capital, Inc ("HTGC") for borrowings of up to \$20 million under a term loan. The Loan and Security Agreement bears interest at a rate per annum equal to the greater of (i) 9.25% or (ii) 9.25% plus the sum of the prevailing prime rate minus 4.50%. The first \$10 million of the Loan and Security Agreement was funded at closing, with net proceeds to the Company of \$9.7 million received, net of \$0.3 million issuance costs. The Company also incurred an end of term charge of \$0.2 million on the initial \$10 million advance. As of September 30, 2012 debt issuance and deferred financing costs, net of accumulated amortization are \$0.2 million and \$0.1 million, respectively. The Company had no debt issued or deferred financing costs as of December 31, 2011. The issuance costs of \$0.2 million are being amortized to interest expense using the effective interest rate over the term of the agreement. The end of term charge of \$0.2 million is being accrued to interest expense and debt using the effective interest rate over the term of the agreement. The Loan and Security Agreement is repayable in installments over forty-two months including an initial interest-only period of twelve months after closing. The maturity date of this loan is January 1, 2016. The interest only period is extendable to December 31, 2013, contingent upon completion of certain ARIKACE-related development milestones. The remaining \$10 million of the Loan and Security Agreement is available at the Company's option throughout the availability period, which ends on December 31, 2012. In connection with this Loan and Security Agreement, the Company granted the lender a first position lien on all of the Company's assets, excluding intellectual property.

Pursuant to the Loan and Security Agreement, the Company issued a warrant to HTGC to purchase 329,932 shares of the Company's common stock at an exercise price of \$2.94 per share. The warrant is exercisable for five years from the date of issuance. The fair value of the warrants at the date of issuance was \$0.8 million, which amount has been

recorded as a discount to debt and is being amortized ratably over the term of the Loan and Security Agreement.

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The following table presents the components of the Company's debt balances as of September 30, 2012. The Company had no debt as of December 31, 2011.

|                                   | September<br>30,<br>2012 |
|-----------------------------------|--------------------------|
| Debt:                             |                          |
| Loan and Security Agreement       | \$ 10,000                |
| Add:                              |                          |
| End of term charge                | 21                       |
| Less:                             |                          |
| Unamortized issuance costs        | (220 )                   |
| Unamortized discount from warrant | (706 )                   |
| Current portion                   | (592 )                   |
| Long-term debt                    | \$8,503                  |

#### 8. Investments and Fair Value Measurements

We categorize 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 U.S. treasuries and mutual funds listed in active markets. Financial instruments in Level 2 generally include municipal bonds listed in secondary markets.

The following table presents assets and liabilities measured at fair value as of September 30, 2012 and December 31, 2011.

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|                           | Fair Value Measurements at Reporting Date Using |  |  |  |
|---------------------------|---|--|--|--|
|                           | Total   | Quoted Prices in<br>Active Markets<br>for<br>Identical Assets<br>(Level 1) | Quoted Prices in<br>Inactive Markets<br>for<br>Identical Assets<br>(Level 2) | Significant<br>Unobservable<br>Inputs<br>(Level 3) |
| As of September 30, 2012: |   |  |  |  |
| Assets:                   |   |  |  |  |
| Cash and cash equivalents | \$44,989  | \$ 44,989  | \$ -   | \$ -   |
| Mutual funds              | 44,759  | 44,759   | -  | -  |
| Certificate of deposit    | 2,132   | 2,132  | -  | -  |
|                           | \$91,880  | \$ 91,880  | \$ -   | \$ -   |
| As of December 31, 2011:  |   |  |  |  |
| Assets:                   |   |  |  |  |
| Cash and cash equivalents | \$14,848  | \$ 14,848  | \$ -   | \$ -   |
| Mutual funds              | 56,163  | 56,163   | -  | -  |
| Government agency bonds   | 5,261   | -  | 5,261  | -  |
| Certificate of deposit    | 2,085   | 2,085  | -  | -  |
|                           | \$78,357  | \$ 73,096  | \$ 5,261   | \$ -   |

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. Short-term investments such as U.S. treasury securities, mutual funds and government agency bonds are held to their maturities and are carried at cost, which approximates fair value. The cash equivalents consist of liquid investments with a maturity of three months or less and the short-term investments consist of instruments with maturities greater than three months and less than one year. The certificate of deposit matures in July 2013.

We recognize transfers between levels within the fair value hierarchy, if any, at the end of each quarter. There were no significant transfers into/out of level 1, level 2 or level 3 during the nine months ended September 30, 2012 and 2011.

As of September 30, 2012, we held one security which was in an unrealized loss position with a total estimated fair value of \$5.0 million and gross unrealized losses of less than \$0.1 million. We also recorded \$0.9 million of gross unrealized gains. The net unrealized gain of \$0.8 million is reported in accumulated other comprehensive income in the stockholder's equity section of our balance sheet. This security had not been in a continuous unrealized loss position for greater than one year. The following table summarizes unrealized gains and losses for the nine months ended September 30, 2012.

|              | September 30, 2012 |                              |                               | Estimated<br>Fair<br>Value |
|--------------|--------------------|------------------------------|-------------------------------|----------------------------|
|              | Amortized<br>Cost  | Gross<br>Unrealized<br>Gains | Gross<br>Unrealized<br>Losses |                            |
| Mutual funds | \$43,924           | \$857                        | \$(22 )                       | \$44,759                   |

As of December 31, 2011, we held two securities which were in an unrealized loss position with a total estimated fair value of \$12.6 million and gross unrealized loss of approximately \$0.2 million. These securities have not been in a continuous unrealized loss position for greater than one year. The net unrealized gain of \$0.5 million is reported in

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accumulated other comprehensive income in the stockholder's equity section of our balance sheet. The following table summarizes unrealized gains and losses for the year ended December 31, 2011.

|                         |           | December 31, 2011 |            |           |
|-------------------------|-----------|-------------------|------------|-----------|
|                         | Amortized | Gross             | Gross      | Estimated |
|                         | Cost      | Unrealized        | Unrealized | Fair      |
|                         |           | Gains             | Losses     | Value     |
| Mutual funds            | \$55,718  | \$652             | \$(207 )   | \$56,163  |
| Government agency bonds | 5,256     | 5                 | -          | 5,261     |
|                         | \$60,974  | \$657             | \$(207 )   | \$61,424  |

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We review the status of each security quarterly to determine whether an other-than-temporary impairment has occurred. In making our determination, we consider 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) our ability and intent to retain the investment for a sufficient period of time for it to recover.

### 9. License and Collaborative Agreements

On May 25, 2012, the Company entered into an agreement with Premacure Holdings AB and Premacure AB of Sweden (collectively, "Premacure") pursuant to which the Company agreed to grant to Premacure an exclusive, worldwide license to develop manufacture and commercialize IGF-1, with its natural binding protein, IGFBP-3, for the prevention and treatment of complications of preterm birth. (the "Premacure License Agreement"). Premacure is currently focusing on retinopathy of prematurity. IGF- and IGFBP-3 were previously developed by the Company at higher concentrations as IPLEX®. The license is subject to the Company's receipt of a consent and waiver from Tercica, Inc., now known as the Ipsen Group ("Tercica"), and from Genentech, Inc., now owned by Roche ("Genentech"), of certain rights granted by the Company to Tercica and Genentech under the Settlement, License and Development Agreement dated March 5, 2007. The Premacure License Agreement includes diligence milestones and royalty payments on prospective product sales. In September 2012, we entered into an amended and restated license agreement with Premacure (the "Amended and Restated Premacure License Agreement") and received the waiver from Genentech. The license remains subject to the Company's receipt of the waiver from Tercica.

### 10. Commitments and Contingencies

#### Commitments

In January 2012, we entered into a contract with our drug supply manufacturer for drug required for our dog toxicology study at a total cost of \$1.4 million. Additionally, in the quarter ended June 30, 2012, we entered into contracts totaling \$3.0 million for the manufacturing of clinical drug supplies.

#### Legal Proceedings

##### Cacchillo v. Insmmed

On October 6, 2010, a complaint was filed against us by Angeline Cacchillo ("Plaintiff") in the U.S. District Court for the Northern District of New York (the "Court"), captioned Cacchillo v. Insmmed, Inc., No. 1:10-cv-0199, seeking monetary damages and a court order requiring Insmmed to support Plaintiff's compassionate use application to the FDA and if approved, to provide Plaintiff with IPLEX. Plaintiff was a participant in the phase II clinical trial of IPLEX sponsored by us evaluating the effectiveness of the investigational drug in patients with type 1 myotonic muscular dystrophy ("MMD"). In the complaint, Plaintiff alleged (i) violation of constitutional due process and equal protection by depriving Plaintiff of continued access to IPLEX, (ii) fraudulent inducement to enter the phase II clinical trial with the false promise to support Plaintiff's compassionate use application to the FDA, (iii) negligent representation that we would support Plaintiff's compassionate use application, (iv) breach of contract, seeking monetary and non-monetary damages, (v) intentional infliction of emotional distress by refusing to support Plaintiff's compassionate use application after providing IPLEX, (vi) violation of an assumed duty of care to Plaintiff, (vii) breach of fiduciary duty to Plaintiff, (viii) negligence and (ix) unjust enrichment. Plaintiff seeks compensatory and punitive monetary damages and sought injunction relief as noted above.

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On October 7, 2010, Plaintiff filed a motion for a preliminary injunction that would require us to provide a written statement supporting the “compassionate use” of IPLEX for Plaintiff and directing us to provide IPLEX to Plaintiff at cost in the event that the compassionate use application were granted by the FDA. On October 22, 2010, the Court denied Plaintiff’s motion for the preliminary injunction concluding that the Court lacked subject matter jurisdiction with respect to her claim for a preliminary injunction. Plaintiff appealed the Court’s denial of her motion for a preliminary injunction to the U.S. Court of Appeals for the Second Circuit, which affirmed the trial court’s order denying the Plaintiff’s motion for a preliminary injunction.

We filed a motion with the Court to dismiss all of the outstanding claims, and on June 29, 2011, the Court dismissed six of Plaintiff’s claims, leaving outstanding the claims for (i) fraudulent inducement, (ii) negligent misrepresentation, and (iii) breach of contract. We filed an answer and affirmative defenses with the Court on July 12, 2011. Plaintiff’s claim for monetary damages with respect to these claims remains outstanding. The parties completed discovery on or about June 1, 2012. We filed a Motion for Summary Judgment on August 1, 2012 seeking judgment in our favor on the three claims remaining in the case and the motion was fully submitted on October 9, 2012. We expect a decision from the Court sometime later this year. If the Court denies our motion with respect to any of Plaintiff’s claims, trial is currently scheduled to begin in January 2013.

We believe that the allegations contained in the complaint are without merit and we intend to continue to vigorously defend this action. It is not possible at this time to estimate the amount of loss or range of possible loss, if any, that might result from an adverse resolution of this action.

Pilkiewicz v. Transave LLC

On March 28, 2011, Frank G. Pilkiewicz and other former stockholders of Transave (collectively, the “Petitioners”) filed an appraisal action against our subsidiary Transave, LLC in the Delaware Court of Chancery captioned Frank G. Pilkiewicz, et al. v. Transave, LLC, C.A. No. 6319-CS. On December 13, 2011, following the mailing of the revised notice of appraisal rights in accordance with the settlement terms of Mackinson et al. v. Insmmed, an Amended Petition for Appraisal of Stock was filed by the Petitioners.

The Petitioners seek appraisal under Delaware law of their total combined common stock holdings representing total dissenting shares of approximately 7.77 million shares of Transave, Inc. common stock (the “Transave Stock”). The Petitioners are challenging the value of the consideration that they would be entitled to receive for their Transave Stock under the terms of the merger.

Under the terms of the merger agreement, certain of the former stockholders of Transave (the “Transave Stockholders”) are obligated to indemnify us for certain liabilities in connection with the appraisal action. We notified the Transave Stockholders in May 2012 that we are seeking indemnification in accordance with the merger agreement and that we will continue to retain the aggregate amount of the holdback shares totaling 1.76 million shares, as security for any indemnification payments due under the merger agreement. Discovery is ongoing and we anticipate that trial will be scheduled in the second half of 2013. We believe that the allegations contained in the amended petition are without merit and we intend to continue to vigorously defend this action. It is not possible at this time to estimate the amount of loss or range of possible loss, if any, that might result from an adverse resolution of this action.

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



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11. Subsequent Events

On September 28, 2012, we completed a registered direct financing with three investors pursuant to which we issued 6,304,102 shares of our common stock. The price at which the common stock was sold in the financing was \$4.07 per share, equal to the consolidated closing bid price for our common shares on the day prior to the issuance. On October 5, 2012, we received telephonic notice from our outside counsel on the transaction that the Staff of The NASDAQ Stock Market LLC had informed such counsel of the Staff's belief that the sale of the shares did not comply with Nasdaq Listing Rule 5365(d). The Staff's concern was based on the fact that the shares were sold at a price that was below our book value per share as reflected in our Form 10-Q for the quarter ended June 30, 2012. As a result, it was the Staff's belief that, pursuant to the Nasdaq Listing Rules, we were not permitted to issue 20% or more of our outstanding common shares, even though the sales price per share was equal to the market value per share on the date immediately preceding the issuance. Following communications by us with the Staff, on October 12, 2012, we received a Letter of Reprimand from the Staff pursuant to Listing Rule 5810(c)(4), based on our noncompliance with Listing Rule 5635(d). The Staff has informed us that it now considers the matter closed. The determination to issue a Letter of Reprimand was based on a number of factors, including that the noncompliance does not appear to have been the result of a deliberate intent to avoid compliance, that we have not demonstrated a pattern of non-compliance, that we relied on the advice of our outside counsel in structuring the financing, our decision to implement additional controls to prevent similar occurrences in the future and the fact that we will not be offering additional securities in the financing.

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

Cautionary Note Regarding Forward Looking Statements

Certain statements in this report, including “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” contain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this report and not clearly historical in nature are forward-looking, and the words “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “predicts,” “i” and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) generally are intended to identify forward-looking statements.

Forward-looking statements in this report, in press releases, written statements or other documents filed with the SEC or in our communications with investors and analysts in the normal course of business include, but are not limited to: our ability to develop ARIKACE; our estimates of expenses and future revenues and profitability; our plans to develop and market new products and the timing of these development programs; the status, results and timing of results of preclinical studies and clinical trials and preclinical and clinical data; the timing of responses to information and data requests from the U.S. Food and Drug Administration (the “FDA”) and other regulatory authorities; our clinical development of product candidates; our ability to obtain and maintain regulatory approval for our product candidates; our expectation as to the timing of regulatory review and approval; our estimates regarding our capital requirements and our needs for additional financing; our estimates of the size of the potential markets for our product candidates; our selection and licensing of product candidates; our ability to attract collaborators with development, regulatory and commercialization expertise; the benefits to be derived from corporate collaborations, license agreements and other collaborative efforts, including those relating to the development and commercialization of our product candidates; sources of revenues and anticipated revenues, including contributions from corporate collaborations, license agreements and other collaborative efforts for the development and commercialization of products; our ability to create an effective direct sales and marketing infrastructure for products we elect to market and sell directly; the rate and degree of market acceptance of our product candidates; the timing and amount of reimbursement for our product candidates; the success of other competing therapies that may become available; and the manufacturing capacity for our product candidates.

Forward-looking statements are based upon our current expectations and beliefs are subject to known and unknown risks, uncertainties and contingencies. Such risks, uncertainties and contingencies, many of which are beyond our control, may cause actual results and events to differ materially from the results and events discussed, projected, anticipated or indicated in any forward-looking statements. Any forward-looking statement should be considered in light of factors discussed in Part II, Item 1A “Risk Factors” in this report, Part I, Item 1A “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2011, as well as those discussed elsewhere in this report and in our Annual Report on Form 10-K for the year ended December 31, 2011. We caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the Securities and Exchange Commission, 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 or events 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, 2011.



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### OVERVIEW

Insmed is a biopharmaceutical company focused on developing and commercializing novel, targeted inhaled therapies for patients with high unmet need battling serious orphan lung diseases. Our lead product candidate, ARIKACE (liposomal amikacin for inhalation), is a differentiated, once-a-day inhaled antibiotic treatment engineered to deliver a proven and potent anti-infective directly to the site of serious lung infections to improve the efficacy, safety and convenience of treatment for patients. Currently, we are continuing late-stage clinical trials for two initial orphan indications for this product: lung infections caused by *Pseudomonas* in CF patients and lung infections caused by NTM. Our sole development focus is to obtain regulatory approval for, and to prepare for commercialization of ARIKACE in the U.S. and Europe.

ARIKACE is considered a New Chemical Entity by the United States Food and Drug Administration, or FDA, primarily due to its proprietary liposomal technology. The key active ingredient, amikacin, is an FDA-approved antibiotic with proven efficacy in the treatment of gram-negative infections, including *Pseudomonas*. ARIKACE is in the aminoglycoside class of antibiotics.

ARIKACE is differentiated by our proprietary advanced liposomal technology, which is designed specifically for targeted delivery of pharmaceuticals to the lung. We believe ARIKACE provides for potential improvements to the conventional inhalation methods of anti-infective delivery of drugs to the pulmonary system for these indications.

Our ongoing ARIKACE clinical development program includes a European and Canadian registration phase 3 clinical study of ARIKACE in CF patients with *Pseudomonas* lung infections (CLEAR-108) and an optional longer term open label safety study (CLEAR-110), as well as a phase 2 clinical study of ARIKACE in patients with NTM lung disease (TARGET-NTM). We expect to report clinical results from both the CLEAR-108 and TARGET-NTM studies in 2013.

### Recent Developments

In late July, we announced the departure of the Company's Executive Vice President & Chief Financial Officer, Kevin Tully, when his current contract expires on December 1, 2012 due to family reasons. On November 7, 2012, we publicly announced that we hired Andrew Drechsler as our new Chief Financial Officer. He will assume the duties of the Principal Accounting and Financial Officer of the Company as of November 8, 2012.

In early August 2012, the U.S. Patent and Trademark Office issued a new composition of matter patent for ARIKACE, U.S. Patent No. 8,226,975. Amikacin is one of the aminoglycosides covered by the patent. The patent describes a system for treating or providing prophylaxis against pulmonary infections, and includes both of the compound's lead indications, CF patients who have *Pseudomonas* lung infections and patients who have NTM lung infections. The new patent provides exclusivity through mid-August 2028.

In August 2012, Al Altomari was appointed to our Board of Directors. Mr. Altomari has nearly 30 years of pharmaceutical industry experience including commercializing specialty pharmaceuticals. He is President and Chief Executive Officer of Agile Therapeutics, a specialty pharmaceutical company in the final stages of development and commercialization of contraceptive products, and was formerly with Barrier Therapeutics, Johnson & Johnson and Ortho-McNeil Pharmaceuticals. In July 2007, he was recognized by PharmaVoice Magazine as one of the Top 100 Most Inspirational and Influential leaders in the Life Sciences Industry.

On September 10, 2012, we named Will Lewis as President and Chief Executive Officer and appointed him to the Board of Directors. Mr. Lewis has more than 20 years of experience in the pharmaceutical and finance industries both in the U.S. and internationally. He is the former Co-Founder, President and Chief Financial Officer of Aegerion

Pharmaceuticals, Inc. During his tenure at Aegerion, Mr. Lewis played a pivotal role in re-orienting the company's strategy to focus on orphan disease indications enabling Aegerion to go public in 2010. Prior to Aegerion, Mr. Lewis spent more than 10 years working in the U.S. and Europe in investment banking for JP Morgan, Robertson Stephens and Wells Fargo. During his time in banking, he was involved in a broad range of domestic and international capital raising and advisory work. On September 10, 2012, Mr. Lewis replaced Tim Whitten, who resigned as President and Chief Executive Officer and as a member of the Board of Directors after six years of service. In addition, Donald J. Hayden, Jr., who was appointed Executive Chairman in May 2012, returned to his role as non-executive Chairman on September 10, 2012.

In late September 2012, we completed a registered direct public offering of approximately 6.3 million shares of our Common Stock to certain affiliates of Ayer Capital, RA Capital and Quaker Partners, at a price of \$4.07 per share, which was the consolidated closing bid price on the NASDAQ Capital Market on September 27, 2012, resulting in gross proceeds to Insmmed of \$25.7 million.

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### Corporate History

We were incorporated in the Commonwealth of Virginia on November 29, 1999. We completed a business combination with Transave, Inc., or Transave, a privately held, New Jersey-based pharmaceutical company focused on the development of differentiated and innovative inhaled pharmaceuticals for the site-specific treatment of serious lung infections, on December 1, 2010. Our integration with Transave was completed in 2011. Our principal executive offices are located at 9 Deer Park Drive, Suite C, Monmouth Junction, New Jersey 08852 and our phone number is (732) 997-4600. Our Internet address is [www.insmed.com](http://www.insmed.com). On March 2, 2011, we completed a one-for-ten reverse stock split of our common stock. Unless otherwise noted, the per share amounts in this Quarterly Report on Form 10-Q give retroactive effect to the reverse stock split for all periods presented.

Pursuant to the merger agreement with Transave, we retained approximately 1.76 million shares of common stock (after giving effect to the conversion of the Series B Conditional Convertible Preferred Stock, or Series B Preferred Stock, and the one-for-ten reverse stock split of our common stock) to be delivered on June 1, 2012 to certain former Transave stockholders subject to reduction for any claims and indemnification payments that are pending in accordance with the terms of the merger agreement. We notified the former Transave stockholders in May 2012 that we are seeking indemnification in accordance with the terms of the merger agreement and that we intend to retain all 1.76 million holdback shares as security for any indemnification payments due under the merger agreement.

### KEY COMPONENTS OF OUR STATEMENT OF OPERATIONS

#### Revenues

Our revenue in 2011 consisted of secondary revenue streams for IPLEX<sup>®</sup> Expanded Access Program (EAP) in Europe for the treatment of Amyotrophic Lateral Sclerosis (ALS), and royalty revenue for the licensing of patent technology for CISPLATIN Lipid Complex. We no longer manufacture IPLEX and the cost recovery revenues from our IPLEX EAP in Europe ceased in December 2011, when our IPLEX inventory was fully depleted.

#### Research and Development Expenses

Research and development expenses consist primarily of salaries and related expenses, cost to develop and manufacture drug candidates, patent protection costs, amounts paid to contract research organizations, hospitals and laboratories for the provision of services and materials for drug development and clinical trials. Our expenses related to clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with third-party organizations that conduct and manage clinical trials on our behalf. These contracts set forth the scope of work to be completed at a fixed fee or amount per patient enrolled. Payments under these contracts primarily depend mainly on performance criteria such as the successful enrollment of patients or the completion of clinical trial milestones as well as time-based fees. Expenses are accrued based on contracted amounts applied to the level of patient enrollment and to activity according to the clinical trial protocol.

At present, we expect ARIKACE in the CF and NTM indications to represent our main development effort for the remainder of 2012 and for 2013.

Since we began operations in late 1999, we have devoted substantially all of our resources to the research and development of a number of product candidates. Until the sale of our Follow on Biologics (FOB) platform to Merck & Co., Inc., or Merck, on March 31, 2009, our research and development efforts were principally focused on pursuing a dual path strategy involving entry into the FOB arena and advancing our proprietary protein platform into niche markets with unmet needs. Following the Transave merger, our focus is now principally on our proprietary, advanced liposomal technology designed specifically for inhalation lung delivery. Our initial priority is to conduct phase 3

studies for ARIKACE in treating CF patients with Pseudomonas lung infections and a phase 2 study in patients with NTM lung infections.

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Historically, prior to the merger with Transave, all of our research and development expenditures related to our proprietary protein platform were interrelated because they are all associated with drugs that modulate IGF-1 activity in the human body. All of these products also share a substantial amount of our common fixed costs such as salaries, facility costs, utilities and maintenance. Given the small portion of research and development expenses that are historically related to products other than IPLEX, we have determined that very limited benefits would be obtained from implementing cost tracking systems that would be necessary to allow for cost information on a product-by-product basis.

Our clinical trials with our product candidates are subject to numerous risks and uncertainties that are outside of our control, including those necessary regulatory approvals may not be obtained. In addition, the duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during the clinical trial, including, among others, the following:

- the number of patients that ultimately participate in the trial;
- the duration of patient follow-up that is determined to be appropriate in view of results;
  - the number of clinical sites included in the trials;
- the length of time required to enroll suitable patient subjects; and
- the efficacy and safety profile of the product candidate.

Our clinical trials may also be subject to delays or rejections based on our inability to enroll patients at the rate that we expect or our inability to produce clinical trial material in sufficient quantities and of sufficient quality to meet the schedule for our proposed clinical trials.

Moreover, all of our product candidates and particularly those that are in the preclinical or early clinical trial stage must overcome significant regulatory, technological, manufacturing, reimbursement and marketing challenges before they can be successfully commercialized. Some of these product candidates may never reach the clinical trial stage of research and development.

As preclinical studies and clinical trials progress, we may determine that collaborative relationships will be necessary to help us further develop or to commercialize our product candidates, but such relationships may be difficult or impossible to arrange. Our projects or intended projects may also be subject to change from time to time as we evaluate our research and development priorities and available resources.

Any significant delays that occur or additional expenses that we incur may have a material adverse effect on our financial position and may require us to raise additional capital sooner or in larger amounts than is presently expected. In addition, as a result of the risks and uncertainties related to the development and approval of our product candidates and the additional uncertainties related to our ability to market and sell these products once approved for commercial sale, we are unable to provide a meaningful prediction regarding the period in which material net cash inflows from any of these projects is expected to become available, if at all.

## General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits and other related costs, including stock-based compensation, for personnel serving in our executive, finance, accounting, legal, market research and human resource functions, and professional fees for legal, including patent-related expenses, consulting, tax and

accounting services. Our general and administrative expenses also include facility and related costs not included in research and development expenses, insurance, depreciation and general corporate expenses. We expect that our general and administrative expenses will increase with the continued development and commercialization of our product candidates.

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## Investment Income and Interest Expense

Investment income consists of interest and dividend income earned on our cash, cash equivalents and short-term investments. Short-term investments are available for sale and consist primarily of short-term municipal bonds, U.S. treasuries and mutual funds. Interest expense consists primarily of interest costs related to interest on the debt and capital leases.

## RESULTS OF OPERATIONS

Three months ended September 30, 2012 compared to three months ended September 30, 2011

Net loss attributable to common stockholders for the three months ended September 30, 2012 was \$9.4 million (or \$0.38 per common share – basic and diluted), compared to net loss of \$34.6 million (or \$1.39 per common share – basic and diluted), for the three months ended September 30, 2011. The \$25.2 million improvement in the net loss was primarily due to the \$26.0 million non-cash impairment charge recorded in the third quarter of 2011 reflecting the decline in the fair value of in-process research and development intangible and goodwill assets due to the material impact of a clinical hold on our ARIKACE development program. This reduction in expense was partially offset by a \$0.4 million decline in IPLEX revenue from 2011 to 2012.

## Revenue

Revenues for the three months ended September 30, 2012 were zero, as compared to \$0.4 million for the three months ended September 30, 2011. The \$0.4 million decrease was due to the elimination of IPLEX EAP revenues following the depletion of IPLEX inventory in December 2011.

## Research and Development Expenses

Research and development expenses for the three months ended September 30, 2012 and 2011 were comprised of the following:

|                                  | Three Months Ended    |                       | Increase (Decrease) |      |   |
|----------------------------------|-----------------------|-----------------------|---------------------|------|---|
|                                  | September 30,<br>2012 | September 30,<br>2011 | \$                  | %    |   |
|                                  | (in thousands)        |                       |                     |      |   |
| Clinical development             | \$2,116               | \$4,391               | \$(2,275)           | (52) | % |
| Clinical manufacturing           | 1,179                 | 809                   | 370                 | 46   | % |
| Regulatory and quality assurance | 632                   | 229                   | 403                 | 176  | % |
| Compensation and related         | 1,612                 | 1,504                 | 108                 | 7    | % |
|                                  | \$5,539               | \$6,933               | \$(1,394)           | (20) | % |

Research and development expenses decreased to \$5.5 million in the three months ended September 30, 2012 from \$6.9 million for the three months ended September 30, 2011. The \$1.4 million decrease from 2011 to 2012 is primarily attributable to a reduction of \$2.3 million in clinical development costs as an additional trial was underway in 2011 targeting ARIKACE in a U.S. CF patient population. This decrease was partially offset by a combined increase of \$0.8 million in manufacturing costs and regulatory and quality assurance costs primarily for the building of clinical supply and comparator costs for the ongoing ARIKACE studies in CF and NTM and a \$0.1 million increase in compensation related expenses as headcount was added to support the ongoing clinical trials.

## General and Administrative Expenses

General and administrative expenses increased \$1.3 million to \$3.8 million in the three months ended September 30, 2012 from \$2.5 million for the three months ended September 30, 2011 due mainly to employee separation costs recorded in September, 2012.

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## Investment Income and Interest Expense

Investment income decreased by \$0.2 million to \$0.2 million in the three months ended September 30, 2012 from \$0.4 million in the three months ended September 30, 2011 due to the reduction in the amount of cash available for investment from September 30, 2011 to September 30, 2012.

Interest expense increased by \$0.2 million to \$0.2 million in the three months ended September 30, 2012 from less than \$0.1 million in the three months ended September 30, 2011 due to the interest payments made on the debt issued to HTGC in June 2012.

Nine months ended September 30, 2012 compared to nine months ended September 30, 2011

Net loss attributable to common stockholders for the nine months ended September 30, 2012 was \$25.9 million, (or \$1.04 per common share – basic and diluted), compared to net loss of \$60.7 million, (or \$2.66 per common share – basic and diluted), for the nine months ended September 30, 2011. The \$34.8 million reduction in the net loss from 2011 to 2012 was primarily due to the \$26.0 million non-cash impairment charge recorded in the third quarter of 2011 reflecting the decline in the fair value of in-process research and development intangible and goodwill assets, and a \$9.2 million non-cash charge recorded in the first quarter of 2011 for the beneficial conversion feature of the Series B Preferred Stock. Additionally, a reduction in operating expenses of \$3.3 million was partially offset by revenue reduction of \$3.0 million and a decline in investment income of \$0.5 million. Interest expense increased by \$0.2 million due to the interest payments made on the HTGC debt incurred in June 2012.

## Revenue

Revenues for the nine months ended September 30, 2012 were zero, as compared to \$3.0 million for the nine months ended September 30, 2011. The \$3.0 million decrease was due to the elimination of \$2.7 million of IPLEX EAP revenues following the depletion of IPLEX inventory in December 2011 and the receipt of \$0.3 million in license fees for our CISPLATIN lipid complex in 2011, as compared to zero in the current year.

## Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2012 and 2011 were comprised of the following:

|                                  | Nine Months Ended     |                       | Increase (Decrease) |      |   |
|----------------------------------|-----------------------|-----------------------|---------------------|------|---|
|                                  | September 30,<br>2012 | September 30,<br>2011 | \$                  | %    |   |
|                                  | (in thousands)        |                       |                     |      |   |
| Clinical development             | \$6,075               | \$10,580              | \$(4,505)           | (43) | % |
| Clinical manufacturing           | 5,242                 | 3,771                 | 1,471               | 39   | % |
| Regulatory and quality assurance | 1,550                 | 2,402                 | (852)               | (35) | % |
| Compensation and related         | 4,686                 | 4,646                 | 40                  | 1    | % |
|                                  | \$17,553              | \$21,399              | \$(3,846)           | (18) | % |

Research and development expenses decreased to \$17.6 million in the nine months ended September 30, 2012 from \$21.4 million for the nine months ended September 30, 2011. The decrease of \$3.8 million in 2012 is primarily attributable to a reduction of \$5.4 million in clinical development costs and regulatory and quality assurance costs as an additional trial was underway in 2011 targeting ARIKACE in a U.S. CF patient population. This decrease was partially offset by an increase of \$1.5 million in manufacturing costs associated with initiating the nine-month dog

inhalation toxicity study and building clinical supply for our ongoing CF and NTM trials. The Company has initiated two clinical trials consisting of a European and Canadian phase 3 CF trials and a U.S. phase 2 NTM trial.

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### General and Administrative Expenses

General and administrative expenses increased to \$9.0 million in the nine months ended September 30, 2012 from \$8.5 million for the nine months ended September 30, 2011. The \$0.5 million increase was primarily attributable to separation expenses recorded in conjunction with the resignation of certain executives partially offset by lower finance, legal and consulting fees related to post Transave merger matters, and the reverse stock split transaction on March 2, 2011.

### Investment Income and Interest Expense

Investment income decreased by \$0.5 million to \$0.9 million in the nine months ended September 30, 2012 from \$1.4 million in the nine months ended September 30, 2011. The decrease is a result of the reduction in the amount of cash available for investment from September 30, 2011 to September 30, 2012.

Interest expense increased by \$0.2 million to \$0.2 million in the three months ended September 30, 2012 from less than \$0.1 million in the three months ended September 30, 2011 due to the interest payments made on the debt issued in June 2012.

## LIQUIDITY AND CAPITAL RESOURCES

### Overview

There is considerable time and cost associated with developing a potential drug or pharmaceutical product to the point where regulatory approval for marketing and selling is received. We have generally sought to raise the funds necessary for such development primarily through the issuance of equity securities in private and public placement transactions. However, we may pursue additional financing options, including entering into agreements with collaborative partners in order to provide milestone payments, license fees and equity investments.

We have funded our operations to date through public and private placements of debt and equity securities and the proceeds from the sale of our FOB platform to Merck. We will continue to incur losses to the extent we expand our research and development and we do not expect material revenues for at least the next several years. Furthermore, revenues from our EAP in Italy associated with cost recovery ceased at the end of the fourth quarter of 2011, when our current IPLEX inventory was depleted. As of September 30, 2012, we had total cash, cash equivalents, short-term investments, and certificate of deposits on hand of \$91.9 million, consisting of \$89.7 million in cash and short-term investments, and \$2.1 million in a certificate of deposit, as compared to \$78.4 million of cash, cash equivalents, short-term investments, and certificate of deposits on hand as of December 31, 2011. The \$13.5 million increase in cash, cash equivalents, short-term investments, and certificate of deposits on hand was due primarily to the \$25.7 million of proceeds received from our registered direct public offering in September 2012 and the net \$9.7 million borrowing from HTGC in June 2012 offset by \$22.1 million used for funding of operations, which consisted mainly of research and development activities.

Even though we believe we currently have sufficient funds to meet our financial needs for at least the next 12 months, our business strategy in the future may require us, or we may otherwise determine, to raise additional capital through licensing, debt or equity sales, other means or any combination of these options.

In the future, we may require additional funds for the continued development of our potential product candidates or to pursue the license of complementary technologies. There can be no assurance that adequate funds will be available when we need them or on favorable terms. If at any time we are unable to obtain sufficient additional funds, we may be required to delay, restrict or eliminate some or all of our research or development programs, dispose of assets or

technology, cease operations or take other measures.

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Cash Flows

Net cash used in operations for the nine months ended September 30, 2012 was \$22.1 million. This was comprised of the net loss for the nine months ended September 30, 2012 of \$25.9 million, reduced by depreciation and non-cash stock expense totaling \$1.9 million and the change in other operating assets and liabilities of \$1.8 million, which primarily consisted of the change in accounts receivable, accounts payable and accrued expenses. Net cash used in operations for the nine months ended September 30, 2011 was \$24.1 million due to the net loss of \$51.5 million reduced by depreciation and non-cash stock compensation expense totaling \$1.3 million and the non-cash impairment loss charge of \$26.0 million.

Net cash provided by investing activities was \$17.0 million for the nine months ended September 30, 2012 compared with \$23.9 million provided by investing activities for the nine months ended September 30, 2011. Net cash provided by investing activities in 2012 and 2011 is primarily a result of the sale of short-term marketable security investments.

Net cash provided by financing activities was \$35.3 million for the nine months ended September 30, 2012 resulting in net proceeds of \$25.6 million from our registered direct public offering in September 2012 and \$9.7 million from the HTGC borrowing in June 2012. Less than \$0.1 million cash was used in financing activities for the nine months ended September 30, 2011.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

On June 29, 2012, the Company and its domestic subsidiaries, as co-borrowers, entered into a loan and security agreement (the "Loan and Security Agreement") with Hercules Technology Growth Capital, Inc ("HTGC"). The Loan and Security Agreement bears interest at a rate per annum equal to the greater of (i) 9.25% or (ii) 9.25% plus the sum of the prevailing prime rate minus 4.50%. The first \$10 million of the Loan and Security Agreement was funded at closing, with net proceeds to the Company of \$9.7 million received, net of \$0.3 million issuance costs. The Company also incurred an end of term charge of \$0.2 million on the initial \$10 million advance. As of September 30, 2012, debt issuance and deferred financing costs, net of accumulated amortization are \$0.2 million and \$0.1 million, respectively. The Company had no debt issued or deferred financing costs as of December 31, 2011. The issuance costs of \$0.2 million are being amortized to interest expense using the effective interest rate over the term of the agreement. The end of term charge of \$0.2 million is being accrued to interest expense and debt using the effective interest rate over the term of the agreement. The Loan and Security Agreement is repayable in installments over forty-two months including an initial interest-only period of twelve months after closing. The interest only period is extendable to December 31, 2013, contingent upon completion of certain ARIKACE-related development milestones. The remaining \$10 million of the Loan and Security Agreement is available at Insméd's option throughout the availability period, which ends on December 31, 2012. In connection with this Loan and Security Agreement, the Company granted the lender a first position lien on all of the Company's assets, excluding intellectual property.

Pursuant to the Loan and Security Agreement, the Company issued a warrant to HTGC to purchase 329,932 shares of the Company's common stock at an exercise price of \$2.94 per share. The warrant is immediately exercisable for five years from the date of issuance. The fair value of the warrants at the date of issuance is \$0.8 million, which amount has been recorded as a discount to debt and is being amortized ratably over the term of the Loan and Security Agreement.

During the nine months ended September 30, 2012, there were no other material changes outside the ordinary course of our business to our contractual obligations and commitments disclosures as set forth in our Annual Report on Form 10-K for the year ended December 31, 2011, "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Contractual Obligations."

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 effect on our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that we believe is material to investors. In particular, we do not have any interest in entities referred to as variable interest entities, which include special purpose entities and structured finance entities.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We invest excess cash in investment grade, interest-bearing securities and, at September 30, 2012, had approximately \$46.9 million invested in money market instruments, municipal bonds, mutual funds and a certificate of deposit account. Such investments are subject to interest rate and credit risk and are not insured by the federal government. We believe our policy of investing in highly rated securities, whose liquidities are, at September 30, 2012, all less than two years minimizes such risks. In addition, while a hypothetical one percent per annum decrease in market interest rates would have reduced our interest income for the period, it would not have resulted in a loss of the principal and the decline in interest income would have been immaterial to us. Our purpose in making these investments is to generate investment income.

We currently do not transact any significant portion of our business in functional currencies other than the U.S. dollar. To the extent that we continue to transact our business using the U.S. dollar as our functional currency, we do not believe that the fluctuations in foreign currency exchange rates will have a material adverse effect on our results of operations.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of certain members of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of September 30, 2012 our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the applicable rules and forms, and that it is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure. In addition, there were no changes in internal control over financial reporting during our last fiscal quarter 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

Cacchillo v. Insmmed

On October 6, 2010, a complaint was filed against us by Angeline Cacchillo (“Plaintiff”) in the U.S. District Court for the Northern District of New York (the “Court”), captioned Cacchillo v. Insmmed, Inc. , No. 1:10-cv-0199, seeking monetary damages and a court order requiring Insmmed to support the plaintiff’s compassionate use application to the FDA and if approved, to provide the plaintiff with IPLEX. Plaintiff was a participant in the phase II clinical trial of IPLEX sponsored by us evaluating the effectiveness of the investigational drug in patients with type 1 myotonic muscular dystrophy (“MMD”). In the complaint, Plaintiff alleged (i) violation of constitutional due process and equal protection by depriving Plaintiff of continued access to IPLEX, (ii) fraudulent inducement to enter the phase II clinical trial with the false promise to support Plaintiff’s compassionate use application to the FDA, (iii) negligent representation that we would support Plaintiff’s compassionate use application, (iv) breach of contract, seeking monetary and non-monetary damages, (v) intentional infliction of emotional distress by refusing to support Plaintiff’s

compassionate use application after providing IPLEX, (vi) violation of an assumed duty of care to Plaintiff, (vii) breach of fiduciary duty to Plaintiff, (viii) negligence and (ix) unjust enrichment. Plaintiff seeks compensatory and punitive monetary damages and sought injunction relief as noted above.

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On October 7, 2010, Plaintiff filed a motion for a preliminary injunction that would require us to provide a written statement supporting the “compassionate use” of IPLEX for Plaintiff and directing us to provide IPLEX to Plaintiff at cost in the event that the compassionate use application were granted by the FDA. On October 22, 2010, the Court denied Plaintiff’s motion for the preliminary injunction concluding that the Court lacked subject matter jurisdiction with respect to her claim for a preliminary injunction. Plaintiff appealed the Court’s denial of her motion for a preliminary injunction to the U.S. Court of Appeals for the Second Circuit, which affirmed the trial court’s order denying the Plaintiff’s motion for a preliminary injunction.

We filed a motion with the Court to dismiss all of the outstanding claims, and on June 29, 2011, the Court dismissed six of Plaintiff’s claims, leaving outstanding the claims for (i) fraudulent inducement, (ii) negligent misrepresentation, and (iii) breach of contract. We filed an answer and affirmative defenses with the Court on July 12, 2011. Plaintiff’s claim for monetary damages with respect to these claims remains outstanding. The parties completed discovery on or about June 1, 2012. We filed a Motion for Summary Judgment on August 1, 2012 seeking judgment in our favor on the three claims remaining in the case and the motion was fully submitted on October 9, 2012. We expect a decision from the Court sometime later this year. If the Court denies our motion with respect to any of Plaintiff’s claims, trial is currently scheduled to begin in January 2013.

We believe that the allegations contained in the complaint are without merit and we intend to continue to vigorously defend this action. It is not possible at this time to estimate the amount of loss or range of possible loss, if any, that might result from an adverse resolution of this action.

Pilkiewicz v. Transave LLC

On March 28, 2011, Frank G. Pilkiewicz and other former stockholders of Transave (collectively, the “Petitioners”) filed an appraisal action against our subsidiary Transave, LLC in the Delaware Court of Chancery captioned Frank G. Pilkiewicz, et al. v. Transave, LLC , C.A. No. 6319-CS. On December 13, 2011, following the mailing of the revised notice of appraisal rights in accordance with the settlement terms of Mackinson et al. v. Insmmed, an Amended Petition for Appraisal of Stock was filed by the Petitioners.

The Petitioners seek appraisal under Delaware law of their total combined common stock holdings representing total dissenting shares of approximately 7.77 million shares of Transave, Inc. common stock (the “Transave Stock”). The Petitioners are challenging the value of the consideration that they would be entitled to receive for their Transave Stock under the terms of the merger.

Under the terms of the merger agreement, certain of the former stockholders of Transave (the “Transave Stockholders”) are obligated to indemnify us for certain liabilities in connection with the appraisal action. We notified the Transave Stockholders in May 2012 that we are seeking indemnification in accordance with the merger agreement and that we will continue to retain the aggregate amount of the holdback shares totaling 1.76 million shares, as security for any indemnification payments due under the merger agreement. Discovery is ongoing and we anticipate that trial will be scheduled in the second half of 2013. We believe that the allegations contained in the amended petition are without merit and we intend to continue to vigorously defend this action. It is not possible at this time to estimate the amount of loss or range of possible loss, if any, that might result from an adverse resolution of this action.

From time to time, we are a party to various other 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.

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

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You should consider carefully the risk factors, together with all of the other information included in our Annual Report on Form 10-K for the year ended December 31, 2011. Each of these risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock. There have been no material changes to our risk factors as previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2011.

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

There were no unregistered sales of the Company's equity securities during the quarter ended September 30, 2012 other than as previously disclosed in the Company's Current Report on Form 8-K filed with the SEC on July 2, 2012.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

3.1 Articles of Incorporation of Insmmed Incorporated, as amended (previously filed as Annex H to the Joint Proxy Statement/Prospectus contained in Part I of Insmmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).

3.2 Amended and Restated Bylaws of Insmmed Incorporated (previously filed as Annex I to the Joint Proxy Statement/Prospectus contained in Part I of Insmmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).

3.3 Form of Articles of Amendment to Insmmed Incorporated's Articles of Incorporation, as amended, creating a new series of Preferred Stock designated as Series A Junior Participating Preferred Stock (previously filed as Exhibit A to the Rights Agreement, dated as of May 16, 2001, between Insmmed Incorporated and First Union National Bank, as Rights Agent, filed as Exhibit 4.4 to Insmmed Incorporated's Registration Statement on Form 8-A filed on May, 17, 2001, and incorporated herein by reference).

3.4 Articles of Amendment to Insmmed Incorporated's Articles of Incorporation, as amended, for Reverse Split (previously filed as Exhibit 3.4 to Insmmed Incorporated's Annual Report on Form 10-K for the year ended December 31, 2002, and incorporated herein by reference).

3.5 Articles of Amendment to Insmmed Incorporated's Articles of Incorporation, as amended, to create a new series of Preferred Stock designated as Series B Conditional Convertible Preferred Stock (previously filed as Exhibit 3.1 to Insmmed Incorporated's Current Report on Form 8-K filed on December 2, 2010, and incorporated herein by reference).



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- 3.6 Articles of Amendment to Insmmed Incorporated's Articles of Incorporation, as amended, for one for ten reverse stock split (previously filed as Exhibit 3.1 to Insmmed Incorporated's Current Report on Form 8-K filed on March 2, 2011, and incorporated herein by reference).
- 3.7 Amendment to Amended and Restated Bylaws of Insmmed Incorporated (previously filed as Exhibit 3.2 to Insmmed Incorporated's Current Report on Form 8-K filed on December 2, 2010, and incorporated herein by reference).
- 3.8 Amended and Restated Bylaws of Insmmed Incorporated (previously filed as Exhibit 3.1 to Insmmed Incorporated's Current Report on Form 8-K filed on March 9, 2012, and incorporated herein by reference).
- 3.9 Articles of Amendment to Insmmed Incorporated's Articles of Incorporation, as amended, to delete the series of preferred stock designated as Series B Conditional Convertible Preferred Stock (previously filed as Exhibit 3.1 to Insmmed Incorporated's Current Report on Form 8-K filed on June 14, 2012, and incorporated herein by reference).
- 4.1 Warrant Agreement to purchase shares of common stock issued to Hercules Technology Growth Capital, Inc., dated as of June 29, 2012 (previously filed as Exhibit 4.1 to Insmmed Incorporated's Current Report on Form 8-K filed on July 2, 2012, and incorporated herein by reference).
- 10.1 Loan and Security Agreement, dated as of June 29, 2012, by and between Insmmed Incorporated and its domestic subsidiaries and Hercules Technology Growth Capital, Inc. (previously filed as Exhibit 10.1 to Insmmed Incorporated's Current Report on Form 8-K filed on July 2, 2012, and incorporated herein by reference).
- 10.2 Separation Agreement, dated as of July 25, 2012, by and between Insmmed Incorporated and Kevin P. Tully (previously filed as Exhibit 10.1 to Insmmed Incorporated's Current Report on Form 8-K filed on July 30, 2012).
- 10.3 Employment Agreement, dated September 10, 2012, between Insmmed Incorporated and William H. Lewis, Insmmed's new Chief Executive Officer (previously filed as exhibit 10.1 to Insmmed Incorporated's Current Report on Form 8-K filed on September 11, 2012).
- 10.4 Severance Agreement, dated as of September 10, 2012, between Insmmed Incorporated and Timothy Whitten (previously filed as exhibit 10.2 to Insmmed Incorporated's Current Report on Form 8-K filed on September 11, 2012).
- 10.5 Letter Agreement, dated September 10, 2012, between Insmmed Incorporated and Donald Hayden, Jr. (previously filed as exhibit 10.3 to Insmmed Incorporated's Current Report on Form 8-K filed on September 11, 2012).
- 10.6 Letter Agreement, dated October 5, 2012, between Insmmed Incorporated and Nicholas A. LaBella, Jr. (previously filed as exhibit 10.1 to Insmmed Incorporated's Current Report on Form 8-K filed on October 5, 2012).
- 10.7 Form Subscription Agreement, dated as of September 28, 2012, by and between Insmmed Incorporated and its certain investors (previously filed as Exhibit 10.1 to Insmmed Incorporated's Current Report on Form 8-K filed on September 28, 2012, and incorporated herein by reference).

31.1 Certification of William Lewis, Chief Executive Officer (Principal Executive Officer) of Insmmed 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 2003.

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- 31.2 Certification of Kevin P. Tully, Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer) of Insmmed 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 2003.
- 32.1 Certification of William Lewis, Chief Executive Officer (Principal Executive Officer) of Insmmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2003.
- 32.2 Certification of Kevin P. Tully, Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer) of Insmmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2003.

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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  
(Registrant)

Date: November 7, 2012

By /s/ Kevin P. Tully  
Name: Kevin P. Tully, C.G.A.,  
Title: Executive Vice President and Chief Financial  
Officer (Principal Financial Officer and Principal  
Accounting Officer)

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EXHIBIT INDEX

Exhibit No. Description of Exhibit

|      |  |
|------|--|
| 3.1  | Articles of Incorporation of Insmmed Incorporated, as amended (previously filed as Annex H to the Joint Proxy Statement/Prospectus contained in Part I of Insmmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).  |
| 3.2  | Amended and Restated Bylaws of Insmmed Incorporated (previously filed as Annex I to the Joint Proxy Statement/Prospectus contained in Part I of Insmmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).  |
| 3.3  | Form of Articles of Amendment to Insmmed Incorporated's Articles of Incorporation, as amended, creating a new series of Preferred Stock designated as Series A Junior Participating Preferred Stock (previously filed as Exhibit A to the Rights Agreement, dated as of May 16, 2001, between Insmmed Incorporated and First Union National Bank, as Rights Agent, filed as Exhibit 4.4 to Insmmed Incorporated's Registration Statement on Form 8-A filed on May, 17, 2001 and incorporated herein by reference). |
| 3.4  | Articles of Amendment to Insmmed Incorporated's Articles of Incorporation, as amended, for Reverse Split (previously filed as Exhibit 3.4 to Insmmed Incorporated's Annual Report on Form 10-K for the year ended December 31, 2002 and incorporated herein by reference).   |
| 3.5  | Articles of Amendment to Insmmed Incorporated's Articles of Incorporation, as amended, to create a new series of Preferred Stock designated as Series B Conditional Convertible Preferred Stock (previously filed as Exhibit 3.1 to Insmmed Incorporated's Current Report on Form 8-K filed on December 2, 2010, and incorporated herein by reference).  |
| 3.6  | Articles of Amendment to Insmmed Incorporated's Articles of Incorporation, as amended, for one-for-ten reverse stock split (previously filed as Exhibit 3.1 to Insmmed Incorporated's Current Report on Form 8-K filed on March 2, 2011, and incorporated herein by reference).  |
| 3.7  | Amendment to Amended and Restated Bylaws of Insmmed Incorporated (previously filed as Exhibit 3.2 to Insmmed Incorporated's Current Report on Form 8-K filed on December 2, 2010, and incorporated herein by reference).   |
| 3.8  | Amended and Restated Bylaws of Insmmed Incorporated (previously filed as Exhibit 3.1 to Insmmed Incorporated's Current Report on Form 8-K filed on March 9, 2012, and incorporated herein by reference).   |
| 3.9  | Articles of Amendment to Insmmed Incorporated's Articles of Incorporation, as amended, to delete the series of preferred stock designated as Series B Conditional Convertible Preferred Stock (previously filed as Exhibit 3.1 to Insmmed Incorporated's Current Report on Form 8-K filed on June 14, 2012, and incorporated herein by reference).   |
| 4.1  | Warrant to purchase shares of common stock issued to Hercules Technology Growth Capital, Inc., dated as of June 29, 2012 (previously filed as Exhibit 4.1 to Insmmed Incorporated's Current Report on Form 8-K filed on July 2, 2012, and incorporated herein by reference).   |
| 10.1 | Loan and Security Agreement, dated as of June 29, 2012, by and between Insmmed Incorporated and its domestic subsidiaries and Hercules Technology Growth Capital, Inc. (previously filed as Exhibit 10.1 to  |

Inmed Incorporated's Current Report on Form 8-K filed on July 2, 2012, and incorporated herein by reference).

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- 10.2 Separation Agreement, dated as of July 25, 2012, by and between Insmmed Incorporated and Kevin P. Tully (previously filed as Exhibit 10.1 to Insmmed Incorporated's Current Report on Form 8-K filed on July 30, 2012).
- 10.3 Employment Agreement, dated September 10, 2012, between Insmmed Incorporated and William H. Lewis, Insmmed's new Chief Executive Officer (previously filed as exhibit 10.1 to Insmmed Incorporated's Current Report on Form 8-K filed on September 11, 2012).
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- 32.2 Certification of Kevin P. Tully, Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer) of Insmmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2003.

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\* This certification accompanies this Quarterly Report on Form 10-Q pursuant to Section 906 of the Sarbanes-Oxley Act of 2003 and shall not be deemed filed by the Company for purposes of the Securities Exchange Act of 1934.