

INSMED INC  
Form 10-Q  
November 09, 2011

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, 2011

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

54-1972729

(State or other jurisdiction of  
incorporation or organization)

(I.R.S. employer identification no.)

11 Deer Park Drive, Suite 117  
Monmouth Junction, NJ

08852

(Address of principal executive offices)

(Zip Code)

(732) 438-9434

(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

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

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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 8, 2011, there were 24,833,301 shares of the registrant's common stock, \$.01 par value, outstanding.

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INSMED INCORPORATED

INDEX

PART I. FINANCIAL INFORMATION

|               |   |   |
|---------------|---|---|
| <u>ITEM 1</u> | <u>Financial Statements (unaudited)</u> | <u>Consolidated Balance Sheets at September 30, 2011 and December 31, 2010</u><br><u>Consolidated Statements of Operations for the three and nine month periods ended September 30, 2011 and 2010</u><br><u>Consolidated Statements of Cash Flows for the nine month periods ended September 30, 2011 and 2010</u><br><u>Notes to Consolidated Financial Statements</u> |
| <u>ITEM 2</u> | -                                       | <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>  |
| <u>ITEM 3</u> | -                                       | <u>Quantitative and Qualitative Disclosures about Market Risk</u>   |
| <u>ITEM 4</u> | -                                       | <u>Controls and Procedures</u>  |

PART II. OTHER INFORMATION

|                |   |  |
|----------------|---|--|
| <u>ITEM 1</u>  | - | <u>Legal Proceedings</u>   |
| <u>ITEM 1A</u> | - | <u>Risk Factors</u>  |
| <u>ITEM 2</u>  | - | <u>Unregistered Sales of Equity Securities and Use of Proceeds</u> |
| <u>ITEM 3</u>  | - | <u>Defaults Upon Senior Securities</u>                             |
| <u>ITEM 4</u>  | - | <u>(Removed and Reserved)</u>                                      |
| <u>ITEM 5</u>  | - | <u>Other Information</u>   |
| <u>ITEM 6</u>  | - | <u>Exhibits</u>  |

SIGNATURE

CERTIFICATIONS

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.

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>2011 | December<br>31,<br>2010 |
|---|--------------------------|-------------------------|
| Assets  |                          |                         |
| Current assets:   |                          |                         |
| Cash and cash equivalents   | \$ 10,449                | \$ 10,743               |
| Short-term investments  | 72,751                   | 97,306                  |
| Accounts receivable, net  | 440                      | 471                     |
| Prepaid expenses  | 343                      | 277                     |
| Total current assets  | 83,983                   | 108,797                 |
| Certificate of deposit  | 2,085                    | 2,176                   |
| In-process research and development   | 58,200                   | 77,900                  |
| Goodwill  | -                        | 6,290                   |
| Deposits  | 377                      | -                       |
| Fixed assets, net   | 1,424                    | 1,102                   |
| Total assets  | \$ 146,069               | \$ 196,265              |
| Liabilities and stockholders' equity  |                          |                         |
| Current liabilities:  |                          |                         |
| Accounts payable  | \$ 1,504                 | \$ 1,450                |
| Accrued expenses  | 1,548                    | 1,256                   |
| Deferred rent   | 154                      | 150                     |
| Capital lease obligations, current  | 55                       | 81                      |
| Deferred revenue  | 421                      | 402                     |
| Total current liabilities   | 3,682                    | 3,339                   |
| Capital lease obligations, long-term  | 45                       | 83                      |
| Total liabilities   | 3,727                    | 3,422                   |
| Stockholders' equity:   |                          |                         |
| Common stock; \$.01 par value; authorized shares<br>500,000,000; issued and outstanding shares, 24,833,301 in 2011 and 15,653,734 in 2010 | 248                      | 1,565                   |
| Preferred stock; \$.01 par value; authorized shares<br>200,000,000; issued and outstanding shares, zero in 2011 and 9,174,589 in 2010     | -                        | 918                     |
| Additional paid-in capital  | 427,234                  | 423,877                 |
| Accumulated deficit   | (286,011 )               | (234,510 )              |
| Accumulated other comprehensive income:   |                          |                         |
| Unrealized gain on investments  | 871                      | 993                     |
| Total stockholders' equity  | 142,342                  | 192,843                 |
| Total liabilities and stockholders' equity  | \$ 146,069               | \$ 196,265              |

See accompanying notes to unaudited consolidated financial statements



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

|   | Three Months Ended<br>September 30, |           | Nine Months Ended<br>September 30, |           |
|---|-------------------------------------|-----------|------------------------------------|-----------|
|   | 2011                                | 2010      | 2011                               | 2010      |
| License fees  | \$1                                 | \$1       | \$252                              | \$3       |
| Other expanded access program income, net                                       | 434                                 | 1,806     | 2,762                              | 5,597     |
| Total revenues  | 435                                 | 1,807     | 3,014                              | 5,600     |
| Operating expenses:   |                                     |           |                                    |           |
| Research and development  | 6,933                               | 769       | 21,399                             | 2,304     |
| General and administrative  | 2,472                               | 1,636     | 8,474                              | 5,058     |
| Impairment Loss   | 25,990                              | -         | 25,990                             | -         |
| Total operating expenses  | 35,395                              | 2,405     | 55,863                             | 7,362     |
| Operating loss  | (34,960 )                           | (598 )    | (52,849 )                          | (1,762 )  |
| Investment income   | 371                                 | 345       | 1,358                              | 1,280     |
| Interest expense  | (2 )                                | -         | (9 )                               | (28 )     |
| Loss before income taxes  | (34,591 )                           | (253 )    | (51,500 )                          | (510 )    |
| Income tax expense  | -                                   | 77        | 2                                  | 80        |
| Net loss  | (34,591 )                           | (330 )    | (51,502 )                          | (590 )    |
| Less: accretion of beneficial conversion feature                                | -                                   | -         | (9,175 )                           | -         |
| Net loss attributable to common stockholders                                    | \$(34,591 )                         | \$(330 )  | \$(60,677 )                        | \$(590 )  |
| Basic and diluted net loss attributable to common stockholders per common share | \$(1.39 )                           | \$(0.03 ) | \$(2.66 )                          | \$(0.05 ) |
| Weighted average basic and diluted common shares outstanding                    | 24,833                              | 13,030    | 22,848                             | 13,025    |

See accompanying notes to unaudited consolidated financial statements

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

|   | Nine Months Ended<br>September 30, |           |
|---|------------------------------------|-----------|
|   | 2011                               | 2010      |
| Operating activities  |                                    |           |
| Net loss  | \$(51,502 )                        | \$(590 )  |
| Adjustments to reconcile net loss to net cash (used in) provided by operating activities: |                                    |           |
| Depreciation and amortization   | 233                                | 25        |
| Stock based compensation expense  | 1,091                              | 215       |
| Impairment Loss   | 25,990                             | -         |
| Changes in operating assets and liabilities:  |                                    |           |
| Accounts receivable   | 31                                 | 67        |
| Income tax receivable   | -                                  | 1,964     |
| Prepaid expenses and other assets   | (352 )                             | (205 )    |
| Accounts payable  | 54                                 | 119       |
| Accrued expenses  | 296                                | (100 )    |
| Deferred revenue  | 19                                 | (300 )    |
| Net cash (used in) provided by operating activities                                       | (24,140 )                          | 1,195     |
| Investing activities  |                                    |           |
| Purchase of fixed assets  | (555 )                             | -         |
| Sales of short-term investments   | 26,018                             | 90,739    |
| Purchases of short-term investments   | (1,585 )                           | (94,757 ) |
| Net cash provided by (used in) investing activities                                       | 23,878                             | (4,018 )  |
| Financing activities  |                                    |           |
| Payments on capital lease obligations   | (64 )                              | -         |
| Repayment of convertible notes  | -                                  | (230 )    |
| Proceeds from issuance of common stock  | 32                                 | -         |
| Net cash used in financing activities   | (32 )                              | (230 )    |
| Decrease in cash and cash equivalents   | (294 )                             | (3,053 )  |
| Cash and cash equivalents at beginning of period  | 10,743                             | 12,740    |
| Cash and cash equivalents at end of period  | \$10,449                           | \$9,687   |
| Supplemental disclosures of cash flow information   |                                    |           |
| Cash paid for interest  | \$9                                | \$-       |
| Cash paid for taxes, net  | \$2                                | \$139     |
| Supplemental disclosures of non-cash investing and financing activities                   |                                    |           |
| Unrealized (loss) gain on investments   | \$(122 )                           | \$1,146   |
| Accretion of beneficial conversion feature  | \$(9,175 )                         | \$-       |

See accompanying notes to unaudited consolidated financial statements





INSMED INCORPORATED

NOTES TO UNAUDITED

CONSOLIDATED FINANCIAL STATEMENTS

1. Description of the Business and Background

On December 1, 2010, we completed a business combination (the “Business Combination”) with Transave, Inc. (“Transave”), a privately-held, New Jersey-based pharmaceutical company focused on the development of differentiated, innovative inhaled pharmaceuticals for the site-specific treatment of serious lung infections. Under the terms of the merger agreement, Insmmed paid off Transave’s \$7.8 million in outstanding indebtedness, and the Transave stockholders received an aggregate of 2.6 million newly issued shares of our common stock, par value \$0.01 per share, and 9.2 million shares of newly created Series B Conditional Convertible Preferred Stock, par value \$0.01 per share, of the Company (the “Series B Preferred Stock”). The Transave stockholders also received an aggregate of \$0.6 million in cash. On March 1, 2011, at a special meeting of our shareholders, all of our shares of Series B Preferred Stock were converted into shares of our common stock, on a one for one basis. Also at this meeting, our shareholders approved a one for ten reverse stock split of our common stock, which became effective on March 2, 2011 (see Note 5). The reverse stock split is reflected in the shares outstanding and earnings per share calculations throughout this Form 10-Q.

We are a pharmaceutical company and following the Business Combination, have expertise in proprietary, advanced liposomal technology designed specifically for inhalation lung delivery. Our proprietary liposomal technology is designed specifically for delivery of pharmaceuticals to the lung and provides for potential improvements to the conventional inhalation methods of delivering drugs to the pulmonary system. These potential advantages include improvements in efficacy, safety and patient convenience. Our primary focus is orphan markets with high unmet medical needs which we believe present a significant opportunity, as their challenges and complexity best fit our knowledge, know-how and expertise.

Our strategy is to utilize our patented advanced liposomal technology to develop safe and effective medicines that improve upon standards of care for those orphan respiratory diseases in which patient needs are currently unmet. Our initial primary target indications are Pseudomonas lung infections in cystic fibrosis (“CF”) patients and non-tuberculous mycobacteria (“NTM”) lung infection patients. Both indications are being studied using our lead product candidate ARIKACE®.

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 nine months ended September 30, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011. The consolidated balance sheet at December 31, 2010 has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by generally accepted accounting principles 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, 2010 filed with the Securities and Exchange Commission on March 16, 2011.

## Principles of Consolidation

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

## 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. Actual results could differ from those estimates.

## Revenue Recognition

Revenue from our Expanded Access Program in Italy is recognized when the drugs have been provided to program patients and collectability is assured. License fees are recognized as revenue when the milestones are achieved and payments are due.

## 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") in accordance with Accounting Standards Codification ("ASC") 470-20. This BCC is measured as the difference between the fair values of the securities at the time of issue, \$6.10 in this case, and the fair value of the common stock at the commitment date, which was \$7.10. The carrying value of the 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 issuance date and the anticipated date of conversion. The BCC is recorded as a non-cash charge to earnings. A BCC of \$9.2 million was recognized at the time of the Series B Preferred Stock conversions and represents a \$1.00 discount on the fair value of our common stock purchased by the note holders. See Note 4 for further information about the beneficial conversion feature.

## Net Loss Per Share

Basic net loss per share is computed based upon the weighted average number of common shares outstanding during the year. The weighted average number of common shares used to compute basic net loss per common share equaled the same number of shares used to compute diluted net loss per common share for the three and nine months ended September 30, 2011 and 2010.

The following potentially dilutive securities have been excluded from the computations of diluted weighted-average shares outstanding as of September 30, 2011 and 2010, as they would be anti-dilutive (in thousands):

|   | Nine Months Ended<br>September 30, |      |
|---|------------------------------------|------|
|   | 2011                               | 2010 |
| Shares underlying warrants to purchase outstanding common stock | 158                                | 158  |
| Shares underlying options to purchase outstanding common stock  | 377                                | 214  |
| Shares underlying restricted stock units                        | 487                                | 25   |

## Comprehensive (Loss) Income

Comprehensive (loss) income consists of net loss plus unrealized (losses) gains on short-term investments. Comprehensive (loss) income for the three and nine months ended September 30, 2011 and 2010 consists of the following (in thousands):

|  | Three Months Ended<br>September 30, |          | Nine Months Ended<br>September 30, |          |
|--|-------------------------------------|----------|------------------------------------|----------|
|  | 2011                                | 2010     | 2011                               | 2010     |
| Net loss   | \$(34,591 )                         | \$(330 ) | \$(51,502 )                        | \$(590 ) |
| Unrealized (loss) gain on short-term investments | (246 )                              | 544      | (122 )                             | 1,146    |
| Total comprehensive (loss) income                | \$(34,837 )                         | \$214    | \$(51,624 )                        | \$556    |

## Goodwill and Identified Intangible Assets

As part of the Business Combination, we recorded in-process research and development 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 the 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 by the U.S. Food and Drug Administration (FDA) material delays in our development program, or a sustained decline in market capitalization.

Goodwill and other indefinite-lived intangible assets are not subject to periodic amortization. Rather goodwill and other 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 related to the in-process research and development intangible assets. The potential impairment of goodwill is assessed by comparing the fair value (using income or market approaches) of the reporting unit with its carrying amount, including goodwill. If the carrying value of the reporting unit exceeds its fair value, an impairment charge would be recorded in the amount that the carrying amount of goodwill exceeds its implied fair value. The Company has elected to perform its annual impairment test as of October 1 of each year.

In quarter ended September 30, 2011 the FDA placed a clinical hold on our phase 3 clinical trials for ARIKACE®. Our management determined the clinical hold was an indicator of possible intangible asset impairment due to the associated additional costs and, therefore, interim impairment testing was performed as of September 30, 2011. The interim impairment review resulted in a non-cash charge of \$26.0 million in the three and nine months ended September 30, 2011 to reflect the decline in the fair value of goodwill and in-process research and development intangible assets as of September 30, 2011 due to the material impact of the clinical hold on our ARIKACE development program. (Note 4).

## Recent Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2009-13, Multiple-Deliverable Revenue Arrangements. The new standard changes the requirements for establishing separate units of accounting in a multiple element arrangement and requires the allocation of arrangement consideration to each deliverable based on the relative selling price. The selling price for each deliverable is based on vendor-specific objective evidence (“VSOE”) if available, third-party evidence (“TPE”) if VSOE is not available, or

estimated selling price if neither VSOE or TPE is available. ASU No. 2009-13 is effective for revenue arrangements entered into in fiscal years beginning on or after June 15, 2010. We adopted ASU No. 2009-13 effective January 1, 2011 and it did not have a material impact on our consolidated financial statements.

In January 2010, the FASB issued ASU No. 2010-06, Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements (ASU 2010-06), which amends the existing fair value measurement and disclosure guidance currently included in Accounting Standards Codification (ASC) Topic 820, Fair Value Measurements and Disclosures, to require additional disclosures regarding fair value measurements. Specifically, ASU No. 2010-06 requires entities to disclose the amounts of significant transfers between Level 1 and Level 2 of the fair value hierarchy and the reasons for these transfers, the reasons for any transfer in or out of Level 3 and information in the reconciliation of recurring Level 3 measurements about purchases, sales, issuances and settlements on a gross basis. In addition, ASU No. 2010-06 also clarifies the requirement for entities to disclose information about both the valuation techniques and inputs used in estimating Level 2 and Level 3 fair value measurements. The adoption of ASU No. 2010-06 did not impact our consolidated financial statements.

In April 2010, the FASB issued ASU No. 2010-17, Revenue Recognition—Milestone Method (Topic 605): Milestone Method of Revenue Recognition, a consensus of the FASB Emerging Issues Task Force, which provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. ASU No. 2010-17 is effective for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. We adopted ASU No. 2010-17 effective January 1, 2011 and it did not have a material impact on our consolidated financial statements.

In June 2011, the FASB issued ASU No. 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. ASU 2011-05 will be effective for years beginning after December 15, 2011. The adoption of ASU 2011-05 is related to presentation in the financial statements only and is not expected to have a material impact on our consolidated financial statements.

In September 2011, the FASB issued ASU No. 2011-08, Intangibles — Goodwill and Other, which amends current guidance to allow a company to first assess qualitative factors to determine whether it is necessary to perform the two-step quantitative goodwill impairment test. The amendment also revises previous guidance by expanding upon the examples of events and circumstances that an entity should consider between annual impairment tests in determining whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. ASU 2011-08 is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. The adoption of ASU 2011-08 is not expected to have a material impact on our consolidated financial statements.

### 3. Risks and Uncertainties

For the period from inception to September 30, 2011, the Company has incurred recurring operating losses and has accumulated a deficit of \$286.0 million. During the nine months ended September 30, 2011, the Company recognized a net loss of \$51.5 million. Our net cash used in operations for the nine months ended September 30, 2011 was \$24.1 million.

Even though we believe we currently have sufficient funds to meet our financial needs for fiscal year 2011, our business strategy in the future may require us to raise additional capital either through licensing, or sales of debt or equity. 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 research or development programs, dispose of assets or technology or cease operations.

#### 4. Identified Intangible Assets and Goodwill

In the quarter ended September 30, 2011 the FDA placed a clinical hold on our phase 3 clinical trials for ARIKACE (liposomal amikacin for inhalation) in Cystic Fibrosis (CF) patients with Pseudomonas lung infections and patients with non-tuberculous mycobacterial (NTM) lung disease as a result of an initial review by the FDA of the interim results of a long-term rat inhalation carcinogenicity study, with ARIKACE. A clinical hold is a notification issued by the FDA to the sponsor to delay a proposed clinical trial or suspend an ongoing clinical trial. The FDA requested additional information on ARIKACE and data from the rat study. The Company complied and in October 2011 the FDA notified the Company that the agency is continuing the clinical hold on the Company's clinical trials in CF and NTM due to the agency having insufficient information to assess the risks of ARIKACE in CF and NTM patients. As a result of the clinical hold, we have suspended initiation of the ARIKACE phase 3 clinical trial programs, including the recruitment and enrollment of patients.

Our management determined the clinical hold was an indicator of possible impairment of in-process research and development and goodwill assets due to the associated additional costs, and, therefore, interim impairment testing was performed as of September 30, 2011. Using a discounted cash flow analysis the impairment analysis compared the fair value of the in-process research and development intangible assets with their respective carrying amounts. Additionally, based on the discounted cash flow analysis, the carrying value of the business exceeded its fair value, and accordingly we performed the second step of the goodwill impairment test by comparing the carrying value of goodwill to its implied fair value. The impairment review resulted in impairment losses for both assets. Non-cash charges of \$19.7 million and \$6.3 million were recognized for the decline in the fair value of in-process research and development and goodwill assets, respectively, as of September 30, 2011. \$26.0 million was recorded as an impairment loss in the three and nine months ended September 30, 2011 and classified as an operating expense in the Consolidated Statements of Operations.

#### 5. Convertible Debt and Stockholders' Equity

##### Convertible Debt

On March 15, 2005, we entered into several purchase agreements with a group of institutional investors, pursuant to which we issued and sold to such investors certain 5.5% convertible notes in the aggregate principal amount of \$35.0 million, which convert into a certain number of shares of our common stock (the "2005 Notes") as well as warrants to purchase our common stock (the "2005 Warrants"). On March 1, 2010 our final payments to the holders of the remaining 2005 Notes were paid. The 2005 Warrants expired on March 15, 2010.

##### Common and Preferred Stock

On December 1, 2010, we entered into an Agreement and Plan of Merger (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 common stock, par value \$0.01 per share, of the Company and 9.2 million shares of newly created Series B Preferred Stock, par value \$0.01 per share, of the Company. The Transave stockholders also received an aggregate of \$0.6 million in cash. Collectively, the shares of the Company's common stock and the Company's preferred stock (on an as converted basis) issued in connection with the merger represent approximately 47% of the capital stock of the Company on a fully diluted basis at the time of issuance.

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 the proposals.

As a result of the approval of the conversion of the Series B Preferred Stock, the 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 (the “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 10 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 are entitled to receive. Below is a table detailing the conversion of the preferred shares and the reverse stock split.

|   |             |
|---|-------------|
| Common stock shares outstanding February 28, 2011                     | 156,537,341 |
| Series B Preferred Stock converted into common stock on March 1, 2011 | 91,745,892  |
| Total shares outstanding prior to reverse stock split                 | 248,283,233 |
| 1 for 10 reverse stock split  | 1:10        |
| Approximate number of common shares outstanding March 2, 2011         | 24,828,323  |

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 \$0.40 for the nine months ended September 30, 2011. 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 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.

## 6. Stock Based Compensation

### Stock Warrants

There was no stock warrant activity for the nine months ended September 30, 2011. As of September 30, 2011 we had 0.2 million warrants outstanding with a weighted average price of \$11 and an expiration date of May 2012.

### Stock Options

As of September 30, 2011, we had two equity compensation plans under which we were granting stock options and shares of non-vested stock. We are currently granting 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 15, 2015 when the 2000 Plan was last amended. Under the terms of the 2000 Plan, we are authorized to grant a variety of incentive awards based on our common stock, including stock options (both incentive options and non-qualified options), performance shares and other stock awards. At the 2011 annual meeting of shareholders held on May 18, 2011, the Company’s shareholders approved three million additional shares to be set aside for current and future use under the 2000 Plan. As of September 30, 2011, 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. It was amended by the Board to increase the number of shares available for issuance, and such amendment was approved by our shareholders on May 11, 2005. The 2000 ESPP was subsequently amended and restated by action of the Board on October 4, 2006 and the amendment and restatement was approved by our shareholders on December 14, 2006. Under the terms of the 2000 ESPP, eligible employees have the opportunity to purchase our common stock at a discount. An option gives its holder the right to purchase shares of our common stock, up to a maximum value of \$0.02 million per year. The 2000 ESPP provides for the issuance of a maximum of 150,000 shares of our common stock to participating employees.

A summary of stock option activity for the nine months ended September 30, 2011 is as follows:

|   | 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, 2010          | 214,275             | \$ 18.43                                 |   |                                 |
| Granted   | 198,400             | 5.90                                     |   |                                 |
| Exercised   | (5,200 )            | 6.16                                     |   |                                 |
| Cancelled   | (30,474 )           | 48.91                                    |   |                                 |
| Options outstanding at September 30, 2011         | 377,001             | 9.54                                     | 5.30  | \$272                           |
| Vested and expected to vest at September 30, 2011 | 361,208             | 9.72                                     | 5.13  | \$272                           |
| Exercisable at September 30, 2011                 | 178,601             | 13.58                                    | 0.82  | \$272                           |

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, 2011.

Assumptions Used:

|  |     |   |
|--|-----|---|
| Volatility factors of expected market price of stock | 129 | % |
| Risk-free interest rate                              | 2   | % |
| Dividend yield                                       | N/A |   |
| Expected option term (in years)                      | 6   |   |

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 an estimated percentage of option forfeitures since the closing of the Business Combination on December 1, 2010.

The Company recognized stock-based compensation expense related to stock options of approximately \$0.17 million and \$0.04 million for the nine months ended September 30, 2011 and 2010, respectively. For the nine months ended September 30, 2011 and 2010, respectively, "General and administrative" expenses include \$0.13 million and \$0.03 million and "Research and development" expenses include \$0.04 million and \$0.1 million of stock-based compensation expense. As of September 30, 2011, there was \$0.8 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 3.34 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. Each RS and 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 and RSUs are generally valued at the market price of our common stock on the date of grant. RSUs granted in the first quarter of 2011 were accounted for as liability awards, since they would have been cash settled until additional shares were authorized for issuance under the 2000 plan. On the date these additional shares were authorized, the RSUs were converted to equity awards and were valued at the market price of our common stock. 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 during the nine months ended September 30, 2011. A summary of RSU activity for the nine months ended September 30, 2011 is as follows:

|                                   | Number of Awards<br>Restricted Stock<br>Units | Weighted-Average<br>Grant Price |
|-----------------------------------|---|---------------------------------|
| Outstanding at December 31, 2010  | -   |                                 |
| Granted                           | 491,255                                       | \$ 6.36                         |
| Vested                            | -   | -                               |
| Cancelled                         | (3,780  | ) 4.96                          |
| Outstanding at September 30, 2011 | 487,475                                       | \$ 6.37                         |

The Company recognized stock-based compensation expense related to RSUs of approximately \$0.9 million and \$0.17 million for the nine months ended September 30, 2011 and 2010, respectively. For the nine months ended September 30, 2011 and 2010, respectively, “General and administrative” expenses include \$0.6 million and \$0.12 million and “Research and development” expenses include \$0.3 million and \$0.05 million of stock-based compensation expense respectively in the consolidated statement of operations. As of September 30, 2011, there was \$3.0 million of unrecognized compensation expense related to unvested RSUs, which is expected to be recognized over a weighted average period of 2.26 years.

A total of approximately 2.6 million shares of common stock were reserved for issuance at September 30, 2011 in connection with restricted stock, restricted stock units, stock options, stock warrants, and the 2000 employee stock purchase plan.

## 7. 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.

Assets and liabilities measured at fair value as of September 30, 2011 and December 31, 2010 are as follows (in thousands):

|                            | Fair Value Measurements at Reporting Date Using |  |  |  |
|----------------------------|---|--|--|--|
|                            | Total   | Quoted<br>Prices in<br>Active<br>Markets for<br>Identical<br>Assets<br>(Level 1) | Quoted<br>Prices in<br>Inactive<br>Markets for<br>Identical<br>Assets<br>(Level 2) | Significant<br>Unobservable<br>Inputs<br>(Level 3) |
| As of September 30, 2011:  |   |  |  |  |
| Assets:                    |   |  |  |  |
| Cash and Cash Equivalents  | \$ 10,449                                       | \$ 10,449  | \$ -   | \$ -   |
| U.S. Treasury securities   | 303   | 303  | -  | -  |
| Mutual Funds               | 56,019  | 56,019   | -  | -  |
| Government agency bonds    | 16,429  | -  | 16,429   | -  |
| Certificate of deposit (a) | 2,085   | 2,085  | -  | -  |
|                            | \$ 85,285                                       | \$ 68,856  | \$ 16,429  | \$ -   |
| As of December 31, 2010:   |   |  |  |  |
| Assets:                    |   |  |  |  |
| Cash and Cash Equivalents  | \$ 10,743                                       | \$ 10,743  | \$ -   | \$ -   |
| Corporate bonds            | 10,228  | 10,228   | -  | -  |
| U.S. Treasury securities   | 505   | 505  | -  | -  |
| Mutual Funds               | 54,311  | 54,311   | -  | -  |
| Government agency bonds    | 32,262  | -  | 32,262   | -  |
| Certificate of deposit (a) | 2,176   | 2,176  | -  | -  |
|                            | \$ 110,225                                      | \$ 77,963  | \$ 32,262  | \$ -   |

(a) - 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 in or out of Level 1, Level 2 or Level 3 during the nine months ended September 30, 2011 and 2010.

As of September 30, 2011, we held one security which was in an unrealized loss position with a total estimated fair value of \$6.3 million and gross unrealized loss of approximately \$0.2 million. This security has not been in a

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continuous unrealized loss position for greater than one year. The net unrealized gain of \$0.9 million is reported in accumulated other comprehensive income in the stockholder's equity section of our balance sheet. Unrealized gains and losses for the nine months ended September 30, 2011 are as follows (in thousands):

|                          | Amortized<br>Cost | September 30, 2011           |                               | Estimated<br>Fair Value |
|--------------------------|-------------------|------------------------------|-------------------------------|-------------------------|
|                          |                   | Gross<br>Unrealized<br>Gains | Gross<br>Unrealized<br>Losses |                         |
| U.S. Treasury securities | \$298             | \$5                          | \$-                           | \$303                   |
| Mutual Funds             | 55,278            | 900                          | (159 )                        | 56,019                  |
| Government agency bonds  | 16,304            | 125                          | -                             | 16,429                  |
|                          | \$71,880          | \$1,030                      | \$(159 )                      | \$72,751                |

At December 31, 2010, we held 9 securities which were in an unrealized loss position with a total estimated fair value of \$14.7 million and gross unrealized losses of approximately \$0.1 million. We also recorded \$1.1 million of gross unrealized gains. The net unrealized gain of \$1.0 is reported in accumulated other comprehensive income in the stockholder's equity section of our Balance Sheet. Of the 9 securities, none had been in a continuous unrealized loss position for greater than one year. Below is a table which summarizes unrealized gains and losses for 2010.

|                          | Amortized<br>Cost | December 31, 2010            |                               | Estimated<br>Fair Value |
|--------------------------|-------------------|------------------------------|-------------------------------|-------------------------|
|                          |                   | Gross<br>Unrealized<br>Gains | Gross<br>Unrealized<br>Losses |                         |
| U.S. Treasury securities | \$494             | \$11                         | \$-                           | \$505                   |
| Corporate bonds          | 10,105            | 123                          | -                             | 10,228                  |
| Mutual Funds             | 53,468            | 843                          | -                             | 54,311                  |
| Government agency bonds  | 32,246            | 123                          | (107 )                        | 32,262                  |
|                          | \$96,313          | \$1,100                      | \$(107 )                      | \$97,306                |

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.

## 8. Commitments and Contingencies

### Commitments

In June 2011, we entered into a short-term sublease and a three year lease for a larger facility totaling 27,035 square feet of lab and office space at 9 Deer Park Drive as our current lease at 11 Deer Park Drive is due to expire on November 30, 2011. The sublease for the new facility expires in December 2011 and is with the existing lessor, a large pharmaceutical company that has vacated the facility. Following expiration of the sublease the lease for the same building will commence with our current landlord, Princeton Corporate Plaza LLC, beginning in January 2012 and expiring in December 2014. We began full occupancy of the new facility which is adjacent to our prior lab and offices in October 2011. We have vacated the majority of the space at 11 Deer Park Drive and are currently in discussions with the landlord regarding our potential interest in retaining approximately 4,000 square feet, following expiration of that lease at the end of November 2011. If leased, the additional space at 11 Deer Park Drive may be utilized for the manufacture of non-clinical product for the 9 month dog inhalation toxicity study depending on the resolution of the current FDA clinical hold on our phase 3 program. Total financial obligations through the term of the

new facility lease are approximately \$1.7 million. We determined that the larger facility was required to upgrade the lab space to meet regulatory requirements as ARIKACE progressed in the clinical and for our growing clinical, regulatory and development efforts in support of our ARIKACE programs in CF and NTM.

## Legal Proceedings

### Cacchillo vs. Insmmed

On October 6, 2010, a complaint was filed against us by Angeline Cacchillo (“Plaintiff”) in the United States District Court for the Northern District of New York (“Court”), captioned *Cacchillo v. Insmmed, Inc.*, No. 1:10-cv-0199, seeking monetary damages and a court order requiring Insmmed to support her compassionate use application to the U.S. Food and Drug Administration (the “FDA”) and if approved, to provide her 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”). The data from this trial did not provide sufficient evidence that IPLEX was effective to treat MMD. As a result, Insmmed decided not to proceed to a phase III trial.

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.

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 United States 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 are currently engaged in discovery in connection with the remaining claims.

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.

### Mackinson et al. v. Insmmed

On February 24, 2011, an action was filed in the Court of Chancery of the State of Delaware against us, our subsidiary Transave, LLC, Transave, our directors and the former directors of Transave, captioned *Mackinson et al. v. Insmmed Incorporated et al.*, C.A. No. 6216, as a purported class action seeking a quasi-appraisal remedy for alleged violations of Delaware’s appraisal statute and the fiduciary duty of disclosure in connection with the merger consummated pursuant to that certain Agreement and Plan of Merger, dated as of December 1, 2010, by and among Insmmed Incorporated, River Acquisition Co., Transave, LLC, Transave and TVM V Life Science Ventures GmbH & Co. KG,

in its capacity as stockholders' agent. The parties to this action agreed to a settlement, which was approved by the Court on October 6, 2011. As part of the settlement, we mailed a revised notice of appraisal rights to the former Transave stockholders who did not consent to the Business Combination. In addition, pursuant to the terms of the settlement, we agreed to pay plaintiff's legal fees and expenses.

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

## 9. Subsequent Events

On August 1, 2011, we announced that the U.S. Food and Drug Administration (the "FDA") had notified us that the FDA had placed a clinical hold on our phase 3 clinical trials for ARIKACE® (liposomal amikacin for inhalation) in Cystic Fibrosis (CF) patients with Pseudomonas lung infections and patients with non-tuberculous mycobacterial (NTM) lung disease. A clinical hold is a notification issued by the FDA to the sponsor to delay a proposed clinical trial or suspend an ongoing clinical trial. The FDA delivered written confirmation of the clinical holds to us on August 3, 2011 and requested additional information on ARIKACE and data from the rat study. We have been informed by the FDA that their decision was based on an initial review of the interim results of a long-term rat inhalation carcinogenicity study with ARIKACE. The relevant findings of the rat carcinogenicity study have been peer reviewed and are confirmed. In the study, rats received daily doses of ARIKACE by inhalation for up to two years. The rat carcinogenicity study was initiated in 2009 so that the results could be included in a potential future NDA submission if the phase 3 trials were successful for CF and NTM. Following notification from the FDA of the clinical holds, we suspended initiation of the CF and NTM phase 3 clinical trial programs, including the recruitment and enrollment of patients. To date, no patients have been dosed in the phase 3 clinical trials for CF and NTM.

We provided our complete response to the FDA's request for information before the end of August 2011. On October 10, 2011, we announced that the FDA notified us that it is continuing the clinical hold previously placed on our phase 3 clinical trial for ARIKACE in CF patients with Pseudomonas lung infections and on October 14, 2011, we announced that the FDA notified us that it is continuing the clinical hold previously placed on our phase 3 clinical trial for ARIKACE in NTM patients. We have been informed by the FDA that, based on its review of the information provided to date, including the rat inhalation carcinogenicity study results, the FDA has insufficient information to assess the risks for ARIKACE in CF and NTM patients. For CF, the FDA has requested additional information from us including that we conduct a 9-month dog inhalation toxicity study of ARIKACE to determine if the findings of the rat inhalation carcinogenicity study are also demonstrated in a non-rodent model, and to propose a CF patient population/disease state where the risk-benefit profile of ARIKACE may be more favorable. For NTM, the FDA is requiring that we conduct a phase 2 clinical trial in adult NTM patients intended to provide proof-of-concept efficacy and safety data for ARIKACE in this patient population before we can proceed with the phase 3 clinical trial previously approved for initiation by the agency. In addition, among other things, we also will need to further revise the description and assessment of the rat carcinogenicity study findings in the investigator brochure for CF and NTM patients.

We are seeking further input and clarification from the FDA in order to gain a better understanding of its requests regarding CF and NTM. Insmed was informed during further dialogue with the Agency that, if the Company chooses to proceed, the required nine month dog inhalation toxicity study can be conducted concurrently with the phase 3 CF clinical trial. We are continuing to evaluate all of our options and timelines for our potential NTM and CF clinical programs including the pending phase 3 trials in Europe which are not on clinical hold.

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



shares of Series B Preferred Stock, 1.76 million shares were retained by us as security for any indemnification payments required pursuant to the merger agreement. On March 1, 2011, at a special meeting of our shareholders, all of our shares of Series B Preferred Stock were converted into shares of our common stock on a one for one basis. At this meeting, our shareholders also approved a one for ten reverse stock split of our common stock, which became effective on March 2, 2011. The reverse stock split is reflected in the shares outstanding and earnings per share calculations throughout this Quarterly Report on Form 10-Q.

After giving effect to the business combination and following conversion of the preferred stock into common stock, former Transave stockholders had approximately a 47% equity interest in the combined Company, and legacy Insmmed Incorporated shareholders had a 53% interest on a fully diluted, as exercised, basis. The shares retained by us pursuant to the merger agreement (approximately 1.76 million shares of common stock) will be delivered on June 12, 2012, subject to reduction for any indemnification payments made under the merger agreement.

We are a pharmaceutical company and following the business combination on December 1, 2010, have expertise in proprietary, advanced liposomal technology designed specifically for inhalation lung delivery. Our proprietary liposomal technology is designed specifically for delivery of pharmaceuticals to the lung and provides for potential improvements to the conventional inhalation methods of delivering drug to the pulmonary system. These potential advantages include improvements in efficacy, safety and patient convenience. Our primary focus is orphan markets with high unmet medical needs, which we believe present a significant opportunity, as their challenges and complexity best fit our knowledge, know-how and expertise.

Our strategy is to utilize our patented advanced liposomal technology to develop safe and effective medicines that improve upon standards of care for those orphan respiratory diseases in which patient needs are currently unmet. Our initial primary target indications are Pseudomonas lung infections in cystic fibrosis (“CF”) patients and non-tuberculous mycobacteria (“NTM”) lung infections.

#### Key Components of Our Statement of Operations

##### Revenues

Our revenue consists of secondary revenue streams for IPLEXTM 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 manufacturer IPLEX and the cost recovery revenues from our IPLEX EAP in Europe will cease in the fourth quarter of 2011, when our current IPLEX inventory is expected to be 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 depend on performance criteria such as the successful enrollment of patients or the completion of clinical trial milestones. Expenses are accrued based on contracted amounts applied to the level of patient enrollment and to activity according to the clinical trial protocol.

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 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 business combination with Transave, our focus is now principally on our proprietary, advanced liposomal technology designed specifically for inhalation lung delivery. Our initial priority has been to conduct phase 3 studies for ARIKACE® in treating CF patients with Pseudomonas lung infections and patients with NTM lung infections. The FDA has placed a clinical hold on our phase 3 clinical trials for ARIKACE in CF patients and NTM patients due to the results of a long-term rat carcinogenicity study.

Historically, all of our research and development expenditures related to our proprietary protein platform were interrelated as 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. Prospectively, all of our currently planned research and development activities are expected to be incurred in the development of ARIKACE.

At present, we expect research of ARIKACE in the CF and NTM indications to represent our main development effort for the remainder of 2011.

Our clinical trials with our product candidates are subject to numerous risks and uncertainties that are outside of our control, including the possibility that the FDA's clinical holds on our phase 3 clinical trials for ARIKACE in the US for CF patients and NTM patients will remain in place or necessary regulatory approvals may not be obtained. For example, 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 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. Our phase 3 clinical trials for ARIKACE in the CF and NTM indications have been placed on clinical hold by the FDA due to the results of a long-term rat carcinogenicity study. 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.

#### Impairment Loss

Impairment loss consists of the write-down of the carrying amounts of in-process research and development intangible and goodwill assets.

#### 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 convertible notes that were fully repaid in March 2010.

#### Results of Operations

Three months ended September 30, 2011 compared to three months ended September 30, 2010

Net loss attributable to common stockholders for the three months ended September 30, 2011 was \$34.6 million, (or \$1.39 per common share – basic and diluted), compared to net loss of \$0.3 million, (or \$0.03 per common share – basic and diluted), for the three months ended September 30, 2010.

#### Revenue

Revenues for the three months ended September 30, 2011 totaled \$0.4 million, as compared to \$1.8 million for the three months ended September 30, 2010. The \$1.4 million decrease was due to a year-over-year decrease in cost recovery from our IPLEX EAP in Europe.

#### Research and Development Expenses

Research and development expenses for the three months ended September 30, 2011 and 2010 were comprised of the following:

|                                  | Three Months Ended    |                       | Increase (Decrease) |        |
|----------------------------------|-----------------------|-----------------------|---------------------|--------|
|                                  | September 30,<br>2011 | September 30,<br>2010 |                     |        |
|                                  | (in thousands)        |                       |                     |        |
| Clinical development             | \$4,343               | \$193                 | \$4,150             | 2150 % |
| Clinical manufacturing           | 809                   | -                     | 809                 | N/A    |
| Preclinical development          | 48                    | -                     | 48                  | N/A    |
| Regulatory and quality assurance | 229                   | 74                    | 155                 | 209 %  |



|                          |         |       |         |     |   |
|--------------------------|---------|-------|---------|-----|---|
| Compensation and related | 1,504   | 502   | 1,002   | 200 | % |
|                          | \$6,933 | \$769 | \$6,164 | 802 | % |

Research and development expenses increased to \$6.9 million in the three months ended September 30, 2011 from \$0.8 million for the three months ended September 30, 2010. The increase of \$6.1 million in 2011 is attributable to research and development of ARIKACE including preparation for the phase 3 clinical studies for CF and NTM which have been placed on clinical hold in the US by the FDA due to the results of a rat carcinogenicity study., and the manufacturing of supply to support the studies. Clinical development expenses increased \$4.1 million for the three months ended September 30, 2011 compared to the same period in 2010, as a result of the planning efforts for the two phase 3 CF studies and one phase 3 NTM study noted above. The \$0.8 million increase in clinical manufacturing expenses from 2011 to 2010 is attributable to the manufacturing of ARIKACE for proposed use in the on hold phase 3 studies. The regulatory and quality assurance expense increase of \$0.2 million in the third quarter of 2011 compared to the same period 2010 is attributable to the planning for the on hold phase 3 studies, during the quarter. The increase in compensation and related expenses of \$1.0 million was attributable to increased headcount and average per salary headcount associated with the development of ARIKACE. Overall research and development headcount increased from approximately 8 as of September 30, 2010 to 28 as of September 30, 2011.

#### General and Administrative Expenses

General and administrative expenses increased to \$2.5 million in the three months ended September 30, 2011 from \$1.6 million for the three months ended September 30, 2010. The \$0.9 million increase was mainly attributable to the increased headcount and average per salary headcount associated with the administrative support for the development of ARIKACE. Overall general and administrative headcount increased from approximately 6 as of September 30, 2010 to 14 as of September 30, 2011.

#### Impairment Loss

Impairment loss was \$26.0 million in the three months ended September 30, 2011 and zero in the three months ended September 30, 2010. The \$26.0 million non-cash charge was 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 ARIKFACE development program.

#### Investment Income and Interest Expense

Investment income increased \$0.1 million to \$0.4 million in the three months ended September 30, 2011 from \$0.3 million in the three months ended September 30, 2010. The increase is a result of improved returns on our short-term investments totaling \$72.8 million as of September 30, 2011, despite a decrease in overall short-term investment balances year over year.

Nine months ended September 30, 2011 compared to nine months ended September 30, 2010

Net loss attributable to common stockholders for the nine months ended September 30, 2011 was \$60.7 million, (or \$2.66 per common share – basic and diluted), compared to a net loss of \$0.6 million, (or \$0.05 per common share – basic and diluted), for the nine months ended September 30, 2010. The net loss attributable to common stockholders in 2011 includes the conversion of the Series B Preferred Stock, and a non-cash charge for the beneficial conversion feature of the Series B Preferred Stock in the amount of \$9.2 million, which increased net loss available to holders of our common shares and, in turn, increased our loss per common share on a basic and diluted basis by \$0.40 for the nine months ended September 30, 2011. 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 issuance date and the anticipated date of conversion.

## Revenue

Revenues for the nine months ended September 30, 2011 totaled \$3.0 million, as compared to \$5.6 million for the nine months ended September 30, 2010. The \$2.6 million decrease was primarily due to a year-over-year decrease of \$2.8 million in cost recovery from our IPLEX EAP in Europe, offset by \$0.2 million in license fees received in 2011 for the licensing of patent technology for CISPLATIN Lipid Complex.

## Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2011 and 2010 were comprised of the following:

|                                  | Nine Months Ended<br>September 30, |         | Increase (Decrease) |      |   |
|----------------------------------|------------------------------------|---------|---------------------|------|---|
|                                  | 2011                               | 2010    |                     |      |   |
|                                  | (in thousands)                     |         |                     |      |   |
| Clinical development             | \$9,509                            | \$529   | \$8,980             | 1698 | % |
| Clinical manufacturing           | 3,771                              | -       | 3,771               | N/A  |   |
| Preclinical development          | 1,071                              | -       | 1,071               | N/A  |   |
| Regulatory and quality assurance | 2,402                              | 525     | 1,877               | 358  | % |
| Compensation and related         | 4,646                              | 1,250   | 3,396               | 272  | % |
|                                  | \$21,399                           | \$2,304 | \$19,095            | 829  | % |

Research and development expenses increased to \$21.4 million in the nine months ended September 30, 2011 from \$2.3 million for the nine months ended September 30, 2010. The increase of \$19.1 million in 2011 is attributable to research and development of ARIKACE including the preparation for initiation of the phase 3 studies which are now on clinical hold and the manufacturing of supply to support the studies. Clinical development expenses increased \$9.0 million for the first nine months of 2011 compared to 2010, as a result of the planning efforts for the studies while the \$3.8 million increase in clinical manufacturing expenses from 2011 to 2010 is attributable to the manufacturing of ARIKACE for use in these studies. The preclinical development expense increase of \$1.1 million in 2011 compared to 2010 is attributable to the final major milestone payment in the first quarter of 2011 for a carcinogenicity study associated with the ARIKACE development program. The regulatory and quality assurance increase of \$1.9 million in the first nine months of 2011 compared to 2010 is attributable to the planning associated with the phase 3 studies, detailed above. Higher compensation and related expenses of \$3.4 million are attributable to increased headcount and average per salary headcount associated with the development of ARIKACE. Overall research and development headcount increased from approximately 8 as of September 30, 2010 to 28 as of September 30, 2011.

## General and Administrative Expenses

General and administrative expenses increased to \$8.5 million in the nine months ended September 30, 2011 from \$5.1 million for the nine months ended September 30, 2010. The \$3.4 million increase was due largely to the increased finance, legal and consulting fees related to the business combination with Transave on December 1, 2010 as well as the reverse stock split transaction on March 2, 2011. In addition headcount and average per salary headcount increased due to the increase in the administrative support for the development of ARIKACE. Overall general and administrative headcount increased from approximately 6 as of September 30, 2010 to 14 as of September 30, 2011.

## Impairment Loss

Impairment loss was \$26.0 million in the nine months ended September 30, 2011 and zero in the nine months ended September 30, 2010. The \$26.0 million non-cash charge was 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 ARIKFACE development program.

## Investment Income and Interest Expense

Investment income increased by \$0.1 million to \$1.4 million in the nine months ended September 30, 2011 from \$1.3 million in the nine months ended September 30, 2010. The increase is a result of improved returns on our short-term investments totaling \$72.8 million as of September 30, 2011, despite a decrease in overall short-term investment balances year over year. The reduction in interest expense for the nine month period ended September 30, 2011 as compared to the same period in 2010 was entirely due to the elimination of convertible notes, which were fully repaid in March 2010.

## Liquidity and Capital Resources

### Overview

There is considerable time and cost associated with developing a potential drug or pharmaceutical product to the point where the U.S. Food and Drug Administration ("FDA") approval for sales is received. 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 & Co., Inc. We will continue to incur losses to the extent we expand our research and development and do not expect material revenues for at least the next several years. Furthermore, revenues from our EAP in Italy associated with cost recovery will be eliminated in the fourth quarter of 2011, when our current IPLEX™ inventory, which has fully been expensed, is expected to be depleted. As of September 30, 2011, we had total cash, cash equivalents, short-term investments, and certificate of deposits on hand of \$85.3 million, consisting of \$83.2 million in cash and short-term investments and \$2.1 million in a certificate of deposit, as compared to \$110.2 million of cash, cash equivalents, short term investments and certificate of deposit on hand as of December 31, 2010. The \$24.9 million decrease in total cash and investments was due to the funding of operations, primarily research and development activities. Our working capital was \$80.3 million as of September 30, 2011.

Even though we believe we currently have sufficient funds to meet our financial needs for the remainder of 2011, our business strategy in the future may require us to raise additional capital either through licensing, debt or equity sales. 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 research or development programs, dispose of assets or technology or cease operations.

We could, but presently have no plans to, enter into agreement with collaborative partners in order to fund operations through milestone payments, license fees and equity investments.

## Cash Flows

Net cash used in operating activities was \$24.1 million for the nine months ended September 30, 2011 compared with \$1.2 million provided by operating activities in the nine months ended September 30, 2010. Net cash used in

operating activities in 2011 related primarily to a net loss of \$51.5 million from higher operating expenses and decreased revenues, which included a \$19.1 million increase in research and development expenses, a \$3.4 million increase in general and administrative expenses, an interim impairment review non-cash charge of \$26.0 million, and a \$2.6 million decrease in revenues attributable to the reduction of cost recovery from IPLEX EAP in Europe.

Net cash provided by investing activities was \$23.9 million for the nine months ended September 30, 2011 compared with \$4.0 million used in investing activities for the nine months ended September 30, 2010. The net cash provided by investing activities in 2011 is primarily a result of the sale of short-term investments, and the use of cash during the nine months ended September 30, 2010 is primarily the result of net purchases of short-term investments.

\$0.03 million cash was used in or provided by financing activities for the nine months ended September 30, 2011 compared with \$0.2 million used in financing activities for the nine months ended September 30, 2010 due to the final payment of the 2005 convertible notes in 2010.

### Contractual Obligations and Commitments

In June 2011, we entered into a short-term sublease and a three year lease for a larger facility totaling 27,035 square feet of lab and office space at 9 Deer Park Drive as our current lease at 11 Deer Park Drive is due to expire on November 30, 2011. The sublease for the new facility expires in December 2011 and is with the existing lessor, a large pharmaceutical company that has vacated the facility. Following expiration of the sublease the lease for the same building will commence with our current landlord, Princeton Corporate Plaza LLC, beginning in January 2012 and expiring in December 2014. We began full occupancy of the new facility which is adjacent to our prior lab and offices in October 2011. We have vacated the majority of the space at 11 Deer Park Drive and are currently in discussions with the landlord regarding our potential interest in retaining approximately 4000 square feet, following expiration of that lease at the end of November 2011. If leased, the additional space at 11 Deer Park Drive may be utilized for the manufacture of non-clinical product for the 9 month dog inhalation toxicity study depending on the resolution of the current FDA clinical hold on our phase 3 program. Total financial obligations through the term of the new facility lease are approximately \$1.7 million. We determined that the larger facility was required to upgrade the lab space to meet regulatory requirements as ARIKACE progressed in the clinical and for our growing clinical, regulatory and development efforts in support of our ARIKACE programs in CF and NTM.

We had no other material changes, during the nine months ended September 30, 2011, 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, 2010, "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.

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We invest excess cash in investment grade, interest-bearing securities and, at September 30, 2011, had approximately \$85.3 million invested in money market instruments, treasuries, 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. Our policy of investing in highly rated securities, whose liquidities are, at September 30, 2011, 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. Our purpose in making these investments is to generate investment income while preserving capital.

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 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). Based on that evaluation, as of September 30, 2011, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective at the reasonable assurance level.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II  
OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Cacchillo vs. Insmmed

On October 6, 2010, a complaint was filed against us by Angeline Cacchillo (“Plaintiff”) in the United States 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 her compassionate use application to the FDA and if approved, to provide her 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”). The data from this trial did not provide sufficient evidence that IPLEX was effective to treat MMD. As a result, Insmmed decided not to proceed to a phase III trial.

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.

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 United States 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 are currently engaged in discovery in connection with the remaining claims.

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.

Mackinson et al. v. Insmmed

On February 24, 2011, an action was filed in the Court of Chancery of the State of Delaware against us, our subsidiary Transave, LLC, Transave, our directors and the former directors of Transave, captioned *Mackinson et al. v. Insmmed Incorporated et al.*, C.A. No. 6216, as a purported class action seeking a quasi-appraisal remedy for alleged violations of Delaware’s appraisal statute and the fiduciary duty of disclosure in connection with the merger consummated pursuant to that certain Agreement and Plan of Merger, dated as of December 1, 2010, by and among Insmmed

Incorporated, River Acquisition Co., Transave, LLC, Transave and TVM V Life Science Ventures GmbH & Co. KG, in its capacity as stockholders' agent. The parties to this action agreed to a settlement, which was approved by the Court on October 6, 2011. As part of the settlement, we mailed a revised notice of appraisal rights to the former Transave stockholders who did not consent to the Business Combination. In addition, pursuant to the terms of the settlement, we agreed to pay plaintiff's legal fees and expenses.

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

## ITEM 1A. RISK FACTORS

Our operating results and financial condition have varied in the past and may in the future vary significantly depending on a number of factors. Except for the historical information in this report, the matters contained in this report include forward-looking statements that involve risks and uncertainties. The 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, among others, may have a material adverse effect upon our business, results of operations and financial condition.

You should consider carefully the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2010, including the amended risk factors below, together with all of the other information included therein and in this Quarterly Report on Form 10-Q. Each of such 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.

We depend heavily on the success of our most advanced product candidate, ARIKACE®. US clinical trials of ARIKACE have been placed on clinical hold by the FDA and may not be successful. If we are unable to commercialize ARIKACE, or experience significant delays in doing so, our business will be materially harmed.

We are investing a significant portion of our efforts and financial resources in the development of ARIKACE. Our ability to generate product revenue, which we do not expect will occur for at least the next several years, if ever, will depend heavily on the successful development and commercialization of ARIKACE. The FDA placed a clinical hold on our phase 3 clinical trials for ARIKACE in CF patients and NTM patients due to the results of a long-term rat carcinogenicity study. As a result of the clinical hold, we have, among other things, suspended the recruitment and enrollment of patients. If we are not able to continue development of ARIKACE or if our progress in development of ARIKACE is delayed significantly, our business, results of operations and financial condition will be adversely affected.

Positive results from clinical trials or in preclinical studies of a drug candidate may not be predictive of similar results in human clinical trials, and promising results from earlier clinical trials of a drug candidate may not be replicated in later clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in earlier stages of development. Accordingly, the results of the completed clinical trials for ARIKACE may not be predictive of the results we may obtain in later stage trials. We do not expect any of our drug candidates to be commercially available for at least several years, if at all.

If our preclinical studies do not produce positive results, if our clinical trials are delayed or if serious side effects are identified during drug development, we may experience delays, incur additional costs and ultimately be unable to

commercialize our product candidates.

Before obtaining regulatory approval for the sale of our product candidates, we must conduct, at our own expense, extensive preclinical tests to demonstrate the safety of our product candidates in animals, and clinical trials to demonstrate the safety and efficacy of our product candidates in humans. For example, the FDA has requested that we conduct a 9-month dog inhalation toxicity study to determine if the findings of the rat inhalation carcinogenicity study are also demonstrated in a non-rodent model. Preclinical and clinical testing is expensive, difficult to design and implement and can take many years to complete. A failure of one or more of our preclinical studies or clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent our ability to obtain regulatory approval or commercialize our product candidates, including:

- our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials or we may abandon projects that we expect to be promising;
- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- conditions imposed on us by the FDA or any non-U.S. regulatory authority regarding the scope or design of our clinical trials may require us submit information to regulatory authorities, Ethics Committees, Institutional Review Boards or others for review and approval;
- the number of patients required for our clinical trials may be larger than we anticipate or participants may drop out of our clinical trials at a higher rate than we anticipate;
- our third party contractors or clinical investigators may fail to comply with regulatory requirements or fail to meet their contractual obligations to us in a timely manner;
- we might have to suspend or terminate one or more of our clinical trials if we, the regulators or the institutional review boards determine that the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
  - the cost of our clinical trials may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct our clinical trials may be insufficient or inadequate or we may not be able to reach agreements on acceptable terms with prospective clinical research organizations; and
- the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

The FDA has placed a clinical hold on our phase 3 clinical trials for ARIKACE in CF patients and NTM patients in the US. We have been informed by FDA that this decision was based on the results of a rat carcinogenicity study. There can be no assurance that the FDA will allow us to further develop ARIKACE.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete our clinical trials or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:



- be delayed in obtaining, or may not be able to obtain, marketing approval for one or more of our product candidates;
- obtain approval for indications that are not as broad as intended or entirely different than those indications for which we sought approval; or
  - have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or approvals. We do not know what impact the current clinical hold will have on our phase 3 clinical programs for ARIKACE. In addition, we do not know whether any preclinical tests or clinical trials will be initiated as planned, will need to be restructured or will be completed on schedule, if at all. Significant preclinical or clinical trial delays also could shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates. Such delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products or product candidates.

ARIKACE must be administered via an Investigational e-Flow® electronic nebulizer system, manufactured by a private German company, PARI. This nebulizer system has not received regulatory approval in the U.S. or elsewhere throughout the world. For ARIKACE to be successfully developed and commercialized, the nebulizer must pass its own set of regulatory requirements.

We are not device experts. For ARIKACE clinical trials to be conducted, we must have adequate supply of the Investigational e-Flow electronic nebulizer system and PARI must be able to supply the system. We are dependent upon PARI being able to provide a continuous supply of the nebulizers both for the clinical trials and also supply the nebulizer in the event ARIKACE receives marketing approval. In addition these nebulizers must be in good working order and meet specific performance characteristics.

Both the drug (ARIKACE) and the device, Investigational e-Flow electronic nebulizer system must receive regulatory approval before we can market the drug and device.

We cannot be certain that we will obtain regulatory approvals in the United States, European Union or other countries. The failure to obtain such approvals may materially adversely affect our business, financial condition and results of operations.

We are required to obtain various regulatory approvals prior to studying our products in humans and then again before we market and distribute our products. The regulatory review and approval process required to perform a clinical study in both the United States and European Union includes evaluation of preclinical studies and clinical studies, as well as the evaluation of our manufacturing process. This process is complex, lengthy, expensive, resource intensive and uncertain. Securing regulatory approval to market our products also requires the submission of extensive preclinical and clinical data, manufacturing information regarding the process and facility, scientific data characterizing our product and other supporting data to the regulatory authorities in order to establish its safety and effectiveness. This process is also complex, lengthy, expensive, resource intensive and uncertain. We have limited experience in filing and pursuing applications necessary to gain these regulatory approvals.

Data submitted to the regulators is subject to varying interpretations that could delay, limit or prevent regulatory agency approval. The FDA has placed a clinical hold on phase 3 clinical trial for ARIKACE, our leading drug candidate, and we do not know whether or when the FDA will allow us to continue the US phase 3 clinical trials. We may also encounter delays or rejections based on changes in regulatory agency policies during the period in which we develop a product and the period required for review of any application for regulatory agency approval of a particular

product. Delays in obtaining regulatory agency approvals could adversely affect the development and marketing of any drugs that we or our collaborative partners develop. Such delays could impose costly procedures on our collaborative partners' or our activities, diminish any competitive advantages that our collaborative partners or we may attain and adversely affect our ability to receive royalties, any of which could materially adversely affect our business, financial condition and results of operations.

In order to market our products outside of the United States and European Union, our collaborative partners and we must comply with numerous and varying regulatory requirements of other countries. The approval procedures vary among countries and can involve additional product testing and administrative review periods. The time required to obtain approval in these other territories might differ from that required to obtain FDA or European Agency for the Evaluation of Medicinal Products, or EMA, approval. The regulatory approval process in these other territories includes at least all of the risks associated with obtaining FDA and EMA approval detailed above. Approval by the FDA or the EMA does not ensure approval by the regulatory authorities of other countries. The failure to obtain such approvals may materially adversely affect our business, financial condition and results of operations.

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

Not applicable.

## ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

## ITEM 4. (Removed and Reserved)

## 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 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).
- 3.3 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).
- 3.4

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Articles of Amendment to Insmmed Incorporated's Articles of Incorporation, as amended, to create a new series of Preferred Stock designated as Series B 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).

- 3.5 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).
- 3.6 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).
- 3.7 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).
  
- 31.1 Certification of Timothy Whitten, Chief 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 2002.
- 31.2 Certification of Kevin P. Tully, Executive Vice President and Chief Financial 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 2002.
- 32.1 Certification of Timothy Whitten, Chief 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 2002.
- 32.2 Certification of Kevin P. Tully, Executive Vice President and Chief Financial Officer of Insmmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.

\* This certification accompanies this Quarterly Report on Form 10-Q pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed filed by the Company for purposes of the Securities Exchange Act of 1934.

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SIGNATURES

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 9, 2011

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

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- 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)
- 31.1 Certification of Timothy Whitten, Chief 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 2002.
- 31.2 Certification of Kevin P. Tully, Executive vice President and Chief Financial 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 2002.
- 32.1 Certification of Timothy Whitten, Chief 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 2002.
- 32.2 Certification of Kevin P. Tully, Executive Vice President and Chief Financial Officer of Insmmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted

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pursuant to Section 906 of the Sarbanes Oxley Act of 2002.\*

\* This certification accompanies this Quarterly Report on Form 10-Q pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed filed by the Company for purposes of the Securities Exchange Act of 1934.