INSMED INC
Form 10-K
March 13, 2012

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 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.)
9 Deer Park Drive, Suite C Monmouth Junction, NJ 08852	732-997-4600
(Address of principal executive offices)	(Registrant's telephone number including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, par value $0.01 per share	NASDAQ Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No þ

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No þ

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 þ No o

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part 2I of this Form 10-K or any amendment to this Form 10-K. þ

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant on [date], was [$] (based on the closing price for shares of the registrant's Common Stock as reported on the NASDAQ Capital Market on that date). In determining this figure, the registrant has assumed that all of its directors, officers and persons owning 10% or more of the outstanding Common Stock are affiliates. This assumption shall not be deemed conclusive for any other purpose.

On March 9, 2012, there were 24,863,771 shares of the registrant's common stock, $.01 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2012 Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission no later than 120 days, or April 30, 2012, after the registrant's fiscal year ended December 31, 2011, and to be delivered to shareholders in connection with the 2012 Annual Meeting of Shareholders, are herein incorporated by reference in Part III of this Form 10-K.

INSMED INCORPORATED

INDEX

REPORT:	FORM 10-K		PAGE
CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS			
PART I			
	ITEM 1	BUSINESS	5
	ITEM 1A	RISK FACTORS	30
	ITEM 1B	UNRESOLVED STAFF COMMENTS	49
	ITEM 2	PROPERTIES	49
	ITEM 3	LEGAL PROCEEDINGS	50
	ITEM 4	(REMOVED AND RESERVED)	51
PART II			
	ITEM 5	MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES	52
	ITEM 6	SELECTED FINANCIAL DATA	53
	ITEM 7	MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	55
	ITEM 7A	QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	63
	ITEM 8	FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	63
	ITEM 9	CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	63
	ITEM 9A	CONTROLS AND PROCEDURES	63
	ITEM 9B	OTHER INFORMATION	64
PART III			
	ITEM 10	DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE	65
	ITEM 11	EXECUTIVE COMPENSATION	65
	ITEM 12	SECURITIES OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	65
	ITEM 13	CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE	65
	ITEM 14	PRINCIPAL ACCOUNTING FEES AND SERVICES	65
PART IV			
	ITEM 15	EXHIBITS AND FINANCIAL STATEMENT SCHEDULES	66
SIGNATURES			67
REPORTS OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM			68
CONSOLIDATED FINANCIAL STATEMENTS			70
EXHIBIT INDEX			95

In this Form 10-K, we use the words the “Company,” “Insmed,” “Insmed Incorporated,” “we,” “us” and “our” to refer to Insme
Incorporated, a Virginia corporation. [Insmed], ARIKACE and IPLEX are registered trademarks of Insmed Incorporated. This Form 10-K also contains trademarks of third parties. Each trademark of another Company appearing in this Form 10-K is the property of its owner.

Index

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements contained herein, including without limitation, “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” contain certain projections, estimates and other forward-looking statements. “Forward-looking statements,” as that term is defined in the Private Securities Litigation Reform Act of 1995, are not historical facts and involve a number of risks and uncertainties. Words herein such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “predicts,” “intends,” “potential,” “con similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.

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

Forward-looking statements are based upon our current expectations and beliefs. Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated or indicated in any forward-looking statements. Any forward-looking statement should be considered in light of factors discussed in Item 1A “Risk Factors” as well as those discussed in Item 7 under the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere throughout this Annual Report on Form 10-K and in any other documents incorporated by reference. We caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the Securities and Exchange Commission, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Index

PART I

ITEM 1. BUSINESS

BUSINESS OVERVIEW

Insmed Incorporated is a development-stage biopharmaceutical company with expertise in proprietary, advanced liposomal technology designed specifically for inhalation lung delivery. We develop innovative inhaled treatments for serious lung infections. Our proprietary liposomal technology is designed specifically for delivery of pharmaceuticals to the lung, and we believe it 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 on orphan markets with high unmet medical needs, which we believe presents a significant opportunity, as their challenge 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 aeruginosa, which we refer to as Pseudomonas, lung infections in cystic fibrosis (CF) patients and patients with non-tuberculous mycobacteria (NTM) lung infections.

We completed a business combination with Transave, Inc., or Transave, on December 1, 2010, which we refer to as the "Merger," a privately-held, NJ-based pharmaceutical company focused on the development of differentiated and innovative inhaled pharmaceuticals for the site-specific treatment of serious lung infections. Our integration with Transave was completed in 2011 including the relocation of corporate headquarters to Monmouth Junction, New Jersey, and cessation of operations at the Richmond, Virginia, location as of December 31, 2011. On March 2, 2011, we completed a one-for-ten reverse stock split of our common stock. Unless otherwise noted, the per share amounts in this 10-K give retroactive effect to the reverse stock split for all periods presented.

Immediately after giving effect to the Merger, former Transave stockholders owned approximately a 46.7% equity interest in the combined company (on an as-converted, fully diluted basis), and legacy Insmed shareholders had a 53.3% equity interest. The shares retained by us pursuant to the merger agreement with Transave (approximately 1.76 million shares of common stock after giving effect to the conversion of the Series B Conditional Convertible Preferred Stock, or Series B Preferred Stock, and the one-for-ten reverse stock split of our common stock) will be delivered on June 12, 2012 to certain former Transave stockholders, subject to reduction for any claims and indemnification payments that are pending.

Development Program

Our lead product candidate, ARIKACE® (liposomal amikacin for inhalation), is a differentiated, inhaled antibiotic supported by positive Phase 2 results for treating serious lung infections due to susceptible bacteria. ARIKACE is considered a New Chemical Entity (NCE) by the United States (U.S.) Food and Drug Administration, or FDA, primarily due to its patented liposomal technology. However, the key active ingredient, amikacin, is already an FDA-approved antibiotic with proven efficacy in the treatment of gram-negative infections including Pseudomonas. ARIKACE is in the aminoglycoside class of antibiotics.

We believe that ARIKACE has potential usage in at least two orphan indications with high unmet need: CF patients who have Pseudomonas lung infections and patients who have NTM lung infections. We estimate the global market potential for these two orphan indications combined to be up to $1 billion.

5

Index

For CF patients, we believe ARIKACE has the potential to be differentiated from other marketed drugs for the treatment of chronic Pseudomonas lung infections due to its ability to deliver high, sustained levels of amikacin directly to the lung, potentially providing sustained improvement in lung function and improvement in patient symptoms with only a once-a-day dosing regimen. In Phase 2 clinical studies, ARIKACE was shown to improve lung function both during and between treatment periods in patients with CF. If approved for CF, ARIKACE could potentially be the first inhaled antibiotic to be approved for once-daily administration. For NTM patients, we believe that ARIKACE has the potential to fulfill a growing, significant unmet medical need.

We have been granted orphan drug designation for CF patients who have Pseudomonas lung infections in both the United States (U.S.) and the EU. We applied for orphan drug designation for NTM infections in the U.S. in 2011. In response to this application, the FDA has requested either in vivo or clinical data in support of our application for orphan drug designation. We plan to file for orphan drug designation for NTM lung infections in the EU after obtaining additional pre-clinical data, which is expected by the end of 2012.

In August 2011, we announced that the FDA had placed a clinical hold on our Phase 3 clinical trials for ARIKACE in CF patients with Pseudomonas lung infections and for patients with NTM lung infections. Since the clinical programs were being conducted under separate INDs, we received separate notifications for CF and NTM. 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 informed us that this decision was based on an initial review of the results of a long-term rat inhalation carcinogenicity study with ARIKACE. As part of the study, rats were given ARIKACE daily by inhalation for almost two years. Two of the 120 rats receiving the highest dose had a single lung tumor. These rats received ARIKACE doses that are much greater than the doses to be administered to humans. The relevance of the observed rat tumors to the use of ARIKACE in humans is unknown. ARIKACE was not associated with changes that may lead to tumors in shorter-term studies that we conducted in other animals. Additionally, in a standard series of tests that we performed, ARIKACE was not shown to be genotoxic. The FDA requested additional information on ARIKACE and data from the rat study. As a result of the clinical hold, we suspended initiation of the ARIKACE Phase 3 clinical trial programs, including the recruitment and enrollment of patients.

We provided the requested information to the FDA in August and was informed by the FDA that, based on its review of the information provided to date, including the rat inhalation carcinogenicity study results, the FDA had insufficient information to assess the risks for ARIKACE in CF patients. In October 2011, the FDA notified us that the FDA was continuing the clinical hold previously placed on our Phase 3 clinical trial for ARIKACE in CF patients with Pseudomonas lung infections and in patients with NTM lung infections. Regarding the clinical hold for CF patients with Pseudomonas lung infections, the FDA requested additional information from us, including that we conduct a nine-month dog inhalation toxicity study of ARIKACE to determine if the findings of the rat inhalation carcinogenicity study are also observed in a non-rodent model and to propose a CF patient population/disease state in which the risk-benefit profile of ARIKACE may be more favorable. We were informed during further dialogue with the FDA that if we chose to proceed, the required nine-month dog inhalation toxicity study of ARIKACE could be conducted in parallel with the CF Phase 3 clinical trials in human subjects. Regarding the clinical hold for patients with NTM lung infections, the FDA requested we conduct a Phase 2 clinical trial in adult (age 18 and older) NTM patients to provide proof-of-concept efficacy and safety data for ARIKACE in NTM patients.

In January 2012, the FDA lifted the clinical hold on ARIKACE in patients with NTM lung infections. We intend to conduct, as requested by the FDA, a Phase 2 clinical trial in adult NTM patients to provide proof-of-concept efficacy and safety data for ARIKACE in NTM patients. We expect to begin enrolling patients in the Phase 2 clinical trial in mid-2012. We have also begun the work required to allow the Company to initiate the nine-month dog inhalation toxicity study in the second quarter of 2012.

In February 2012, we filed our complete response to the FDA clinical hold on the U.S. study of ARIKACE in CF patients with Pseudomonas infection. We will continue discussions with the FDA to pursue removal of the clinical hold on ARIKACE in U.S. for the treatment of CF patients with Pseudomonas lung infections.

Index

We are moving forward with the ARIKACE clinical development program in CF in Europe. The European study in CF patients with Pseudomonas lung infections will be a randomized, phase 3 trial comparing ARIKACE 560 mg, delivered once daily via an optimized, investigational eFlow® Nebulizer System (PARI Pharma GmbH, Munich, Germany), to TOBI®(1) (inhaled tobramycin solution), which is a marketed inhaled antibiotic that is delivered twice daily. The Company anticipates that the study will be conducted in approximately 300 patients. The primary endpoint will be change in pulmonary function (FEV-1) measured after three 28 day on-treatment and three 28 day off-treatment cycles (about six months). A key secondary endpoint will be time to pulmonary exacerbation. The study design was previously agreed upon by Insmed and the European Medicines Agency. Eligible patients will have the option to participate in a longer term open-label safety study. The Company expects to begin enrolling patients in the phase 3 European clinical study in the second quarter of 2012.

Our current priorities are as follows.

- Initiate a European Phase 3 pivotal clinical trial for ARIKACE in the treatment of CF patients with Pseudomonas lung infections with initial patient enrollment expected in the second quarter of 2012;

- Initiate a U.S. Phase 2 clinical trial in patients with NTM lung infections with initial patient enrollment expected in mid-2012;

- Continue discussions with FDA to attempt to remove the clinical hold on ARIKACE in U.S. for the treatment of CF patients with Pseudomonas lung infections; and

- Initiate a nine-month dog inhalation toxicity study in the second quarter of 2012.

In addition to the ARIKACE development program, we have a secondary proprietary compound, IPLEX®, which is no longer a development priority for us. We no longer have protein development capability nor the in-house capability to manufacture IPLEX. We announced in January 2012 that we intend to seek licensing partners for the IPLEX development programs. Under the proprietary IPLEX protein platform, we maintained an expanded access program until drug supplies were exhausted at the end of 2011 for amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease. We also have provided IPLEX for an early-stage research program investigating retinopathy of prematurity (ROP) through an IPLEX Material Transfer Agreement with Premacure AB, a private company located in Sweden. Sufficient quantity of IPLEX has been supplied to Premacure for its completion of an ongoing Phase 2 trial, which Premacure will conduct and analyze at its expense.

ARIKACE Overview

We believe that our lead product candidate, ARIKACE,has the potential to be differentiated from other marketed drugs for the treatment of chronic lung infections due to its ability to deliver high, sustained levels of amikacin directly to the lung and to minimize the serum levels of amikacin compared with IV administration. We believe the inhalation delivery of amikacin provided by ARIKACE may improve efficacy and may reduce the potential to cause adverse events such as ototoxicity (hearing loss, ringing in the ears and/or loss of balance) and nephrotoxicity (toxicity to the kidneys) compared with intravenous administration. In addition, ARIKACE may be more convenient to administer as it is delivered once daily compared with the currently marketed inhaled antibiotics, which require administration two to three times daily.

We believe that ARIKACE has the potential to be differentiated further because the liposomal delivery technology may allow ARIKACE to reach the site of the lung infection better than other inhaled aminoglycoside antibiotics. For treating Pseudomonas lung infections in CF patients, ARIKACE was designed with a neutrally charged liposome and has been shown, in vitro (or in laboratory studies), to penetrate the negatively charged bacterial biofilm, a protective

barrier produced by Pseudomonas. While all aminoglycoside antibiotics are positively charged and bind to the negative surface of the biofilm, only ARIKACE has been shown to penetrate the biofilm effectively. This means that ARIKACE may reach the site of the Pseudomonas infection in CF patients' lungs more efficiently than the other aminoglycoside antibiotics.

Index

For NTM lung infections, ARIKACE has been shown to be preferentially taken up by the macrophages, where NTM often grows. As NTM is an intracellular pathogen, this may allow ARIKACE to reach the site of the NTM lung infections better than other antibiotics.

Development Summary: Treatment of Pseudomonas Lung Infections in CF Patients

In Phase 2 studies in CF patients with Pseudomonas lung infections, ARIKACE has been shown to provide improvement in lung function during treatment and sustained improvement in lung function between treatment periods. If approved, ARIKACE could be the first approved inhaled antibiotic to be administered once daily.

Typically an inhaled antibiotic is given to CF patients with chronic Pseudomonas lung infections for 28 days followed by a 28-day off-treatment cycle. We completed two randomized, placebo-controlled phase 2 studies with ARIKACE in 105 CF patients who had chronic Pseudomonas lung infections. Data from the patients receiving the target Phase 3 program dose of ARIKACE, 560 mg, is summarized below. ARIKACE was delivered at a dose of 560 mg once daily via an eFlow Nebulizer System for 28 consecutive days. ARIKACE demonstrated statistically significant and clinically meaningful improvement in lung function throughout the 28-day treatment period compared with placebo. In addition, the improvement in lung function that was achieved at the end of the 28-day on-treatment period was sustained during the 28-day off-treatment period (days 29 through 56) and was statistically significantly better than placebo.

In a follow-on separate long-term, open-label, multi-cycle clinical trial conducted in Europe, ARIKACE was given at a dose of 560 mg via an eFlow Nebulizer System (to patients for six complete cycles). (Open label means that both the patient and the treating physician know that they are receiving ARIKACE and not placebo.) Each cycle consisted of a 28-day on-treatment and 56-day off-treatment period, which is double the standard 28-day off-treatment period. In this clinical study, ARIKACE produced an improvement in lung function that was sustained over the six cycles (approximately 17 months). In addition, during the off-treatment periods, approximately 50% to 70% of the benefit achieved during the 28-day on-treatment periods was sustained at the end of the 56-day off-treatment periods. In other words, ARIKACE demonstrated sustained efficacy in lung function improvement during the treatment and off-treatment periods across multiple cycles of therapy. To our knowledge, no other inhaled antibiotic has shown sustained improvement in lung function at the end of a 56-day off-treatment period. In addition, ARIKACE was well-tolerated with overall adverse events reported as consistent with those expected in a population of CF patients receiving inhaled medicines.

We currently expect to commence patient accrual in the second quarter of 2012 for a Phase 3 clinical study of ARIKACE for CF patients with Pseudomonas lung infections to support potential approval in Europe and potentially other countries outside the U.S. The study will be a randomized, Phase 3 trial comparing ARIKACE 560 mg, delivered once daily via an optimized, investigational eFlow Nebulizer System, to Tobi®(1) (inhaled tobramycin solution, Novartis Pharmaceutical Corporation), which is a marketed inhaled antibiotic that is delivered twice daily. We anticipate that the study will be conducted in approximately 300 patients. The primary endpoint will be change in pulmonary function (FEV-1) measured after three 28 day on-treatment and three 28 day off-treatment cycles (about six months). A key secondary endpoint will be time to pulmonary exacerbation. The study design was previously agreed upon by us and the European Medicines Agency (EMA).

The key elements of these study designs and regulatory paths have been agreed to with the EMA and with the regulatory agencies in the individual countries in which the trials will be conducted.

In February 2012, we filed our complete response to the FDA clinical hold on the U.S. study of ARIKACE in CF patients with Pseudomonas infection. We will continue discussions with the FDA to pursue removal of the clinical hold on ARIKACE in U.S. for the treatment of CF patients with Pseudomonas lung infections.

Development Summary: Treatment of Patients with NTM Lung Infections

In the NTM indication, we filed an IND application and gained agreement from the FDA in the first quarter of 2011 to conduct a Phase 3 clinical trial in patients with NTM lung infections. In August 2011, we announced that the FDA had placed the ARIKACE clinical trial program for patients with NTM lung infections on hold. In January 2012, the FDA lifted the clinical hold on the ARIKACE clinical trial program for NTM.

Index

On February 9, 2012, we announced that we were proceeding with initiation of patient accrual to a Phase 2, placebo-controlled trial for adult patients who have lung infections due to NTM. This NTM trial differs in two ways from the trial that was agreed to by us and the FDA before the clinical hold was put into place: (1) the current trial is considered a Phase 2 trial rather than a Phase 3 trial, and (2) the current trial will be conducted in adult patients (ages 18 and above) rather than patients who are ages 12 and above.

The Phase 2 clinical trial for ARIKACE in NTM patients will consist of a randomized, placebo-controlled study of approximately 100 adult patients with recalcitrant NTM lung infections. There are two parts to the study: a randomized portion and an open-label portion. Patients who are NTM culture positive will continue with their antibiotic treatment regimen, and receive additionally, either ARIKACE 560 mg, delivered once daily via an optimized, investigational eFlow Nebulizer System, or placebo once daily. The primary efficacy endpoint will be change in mycobacterial density from baseline to the end of 84 days of treatment. At the conclusion of the randomized portion of the study, eligible patients will receive ARIKACE 560 mg once daily for an additional 84 days in an open-label design, primarily to measure longer-term safety and efficacy. The clinical trial design was previously agreed upon by us and the FDA. We expect to begin enrolling patients in the Phase 2 clinical trial in mid-2012.

Patients enrolled in the study will include those with NTM lung infections with persistently positive mycobacterial cultures following a stable ATS/IDSA-guidelines-based treatment regimen defined as “adherent to a multi-drug regimen for at least 6 months prior to screening.” Only patients who have non-TB Mycobacterium Avium Complex (MAC) or non-TB Mycobacterium Abscessus will be permitted to enroll in the trial. These are two sub-types of NTM that are believed to account for the vast majority of NTM lung infections in the U.S.

Overall Product Profile

The overall product profile that we are working to develop for ARIKACE includes: (1) improved efficacy resulting from sustained deposition of drug in the lung and improved ability to reach the site of infection (for CF Pseudomonas infections, this means penetration of Pseudomonas biofilm and facilitated drug release by factors that are secreted by the bacteria, and for NTM, this means enhanced uptake into macrophages, where NTM often grows); (2) decreased adverse events and improved tolerability; (3) reduced dosing frequency; and (4) decreased administration time.

ARIKACE Delivery Technology

There are two separate components to the delivery technology for ARIKACE. There is the liposomal formulation of the drug and the device, a nebulizer through which ARIKACE is inhaled through the mouth into the lung.

The liposomal formulation is key to both the retention of amikacin in the lung, which allows once-a-day dosing, and the ability of ARIKACE to gain close access to bacteria (Pseudomonas aeruginosa) either within a biofilm, as in the case in CF patients, or within infected macrophages, as in the case of NTM patients. It is localization near the bacteria that allows high concentrations of drug to be delivered where it is needed most to improve efficacy.

Liposomes are microscopic spherical shells that contain water surrounded by a thin lipid membrane. ARIKACE liposomes are less than 0.3 microns in diameter and contain amikacin in the water interior in a very high concentration; they are very efficient delivery systems that have been optimized for inhalation therapy. These liposomes are formed using neutral lipids identical to those found naturally in the lung; therefore the composition is highly compatible with lung tissue.

With a neutral surface charge and small size, ARIKACE liposomes are able to effectively penetrate the thick CF mucus and the bacteria’s protective covering (biofilm), both of which we believe restrict the availability of unencapsulated aminoglycosides such as tobramycin and amikacin. ARIKACE liposomes are also readily taken up by

immune cells in the lung (alveolar macrophages) that “eat” inhaled particles. When NTM infects these immune cells, it is usually sheltered against attack from external antibiotics, but with ARIKACE, the uptake of the liposomes allows the drug to get inside these cells to attack the organisms.

Index

The second part of our technology is the state-of-the-art drug delivery nebulizer, which we believe represents a competitive advantage. ARIKACE will be administered once daily via inhalation using an investigational eFlow Nebulizer System optimized specifically for ARIKACE. We believe the optimized, investigational eFlow Nebulizer System significantly reduces treatment time, thereby easing the patient's treatment burden and potentially improving patient compliance.

The patented optimized, investigational eFlow Nebulizer System is a medical device that uses eFlow technology to enable highly efficient aerosolization, or delivery of inhaled medication, including liposomal formulations via a vibrating, perforated membrane that includes thousands of specially designed laser-drilled holes, which aids the delivery of ARIKACE to the lung. We believe that compared with current nebulizer systems, the optimized, investigational eFlow Nebulizer System is significantly more efficient because it delivers a very high density of active drug, in a precisely defined and controlled droplet size, with a high proportion of respirable droplets delivered in a relatively short period of time. Combined with its quiet mode of operation, small size, light weight and battery-powered operation, we believe the optimized, investigational eFlow Nebulizer System potentially reduces the burden of taking daily inhaled treatments.

Market Opportunity Summary

ARIKACE

Our current intention is to retain marketing rights for ARIKACE in the U.S. We will continue to evaluate our marketing options for Europe and other countries. Because of the small focused nature of the potential physician prescribing population for CF and NTM patients in the U.S., we believe ARIKACE will require limited commercial infrastructure (e.g., fewer than 50 sales representatives in the U.S.), which may enable us to achieve profitability sooner following market launch than an indication that requires a much larger internal commercial infrastructure.

Market Opportunity: CF Patients with Pseudomonas Lung Infections

CF is an inherited chronic disease that is often diagnosed before the age of two. According to the Cystic Fibrosis Foundation, CF affects roughly 30,000 children and adults in the U.S. and roughly 70,000 children and adults worldwide. Among other issues, CF causes a thick, sticky mucous to develop in and clog the lungs creating an ideal environment for various pathogens, such as Pseudomonas, to form and grow, infecting the lung and leading to inflammation and loss of lung function.

According to the Cystic Fibrosis Foundation Patient Registry (2010), despite extensive treatment with multiple antibiotics, improved nutrition, and other treatments, life expectancy of a CF patient is only about 38 years. A recent study reported in the Journal of Cystic Fibrosis (2010) found that deterioration in lung function is the main cause of death in these patients and despite best efforts, lung function declines by 1% to 3% annually with some patients experiencing an annual decline of 10% or more.

According to the Cystic Fibrosis Foundation (Cystic Fibrosis Foundation Patient Registry, 2010), more than half of all CF patients acquired Pseudomonas lung infections by age 18. Patients generally receive extensive antibiotic treatments, which can be delivered via the oral, intravenous and inhaled routes. Antibiotics delivered via inhalation have become part of standard treatments for CF patients with Pseudomonas lung infections and are generally thought to be a way to deliver more drug directly to the site of infection compared with other routes of administration. However, in part because of the thick sticky mucous these patients produce in their lungs, CF patients seldom clear the Pseudomonas permanently from their lungs and become chronically infected in spite of all currently available antibiotic treatments.

CF therapy significantly impacts patients' quality of life. Some patients with CF spend up to three hours per day taking medications and other treatments, including inhaled antibiotics. The current most commonly used inhaled antibiotic in the U.S. is inhaled tobramycin (Tobi), which was approved by the FDA and has been sold in the U.S. since January 1998. Tobi is administered twice daily over 30 to 40 minutes per day for 28 days followed by a 28-day-off period. This cycle of "on" and "off" treatment is repeated in a chronic pattern. We anticipate that ARIKACE will be administered once daily for approximately 13 minutes per day for 28 days followed by 28-day off-drug period. We believe that any inhaled treatment that reduces the treatment burden of a CF patient could represent a significant improvement in the patient's quality of life. We believe a once-daily shorter treatment could foster better compliance and potentially result in better effectiveness. We have been granted orphan drug designation for CF patients who have Pseudomonas lung infections in both the U.S. and the EU.

Index

Because current marketed inhaled antibiotics do not produce an improvement in lung function as measured by Forced Expiratory Volume in one second (FEV-1) that lasts during the 28-day-off treatment periods, CF thought leaders have begun to recommend more aggressive inhaled antibiotic treatment for CF patients by using a different class of inhaled antibiotic in the off period with the goal of better maintaining lung function. Aminoglycosides, including Tobi, are recommended as first-line inhaled antibiotic treatment in the on-month due to their established effectiveness against Pseudomonas. If the effectiveness of ARIKACE against Pseudomonas is confirmed after the evaluation of Phase 3 data and ARIKACE is approved, our goal is for ARIKACE also to be recommended as first-line inhaled antibiotic treatment in the on-month.

We believe that the global CF market for inhaled antibiotics will experience significant growth in the next five to ten years from the approximately $450 to $500 million market today. This growth is being driven by physicians' desire to maintain CF patients' lung function, which continues to decline in many patients despite extensive treatment with current therapies including the currently approved inhaled antibiotics.

Expected growth in the market is due to:

- Physicians moving to alternating regimens every month as opposed to giving patients off-treatment holidays on alternate months;

- Better patient adherence to physician prescribed regimens resulting from more convenient (less frequent and less time consuming) treatments

- Physicians initiating inhaled antibiotics earlier for patients with Pseudomonas in their lungs;

- CF patients living longer; and

- The standard of care in the rest of the world continuing to advance closer to that of the EU and the U.S.

Market Opportunity: NTM Lung Infections

NTM lung infections can cause severe pulmonary disease for which there are currently limited effective treatments. NTM are organisms common in soil and water that have been associated with lung disease in select patient groups. NTM may be considered to be a cousin of tuberculosis (TB) but not contagious. Many people have NTM in their bodies, but it does not normally cause a problem and lead to an infection, as it is believed the body's self-regulating immune system usually successfully combats the threat of NTM infection. It is not completely understood why some individuals are susceptible to NTM infections. However, the patients affected often are immune-compromised or have structural damage in their lungs at the time they become infected.

Mycobacteria are intracellular organisms that invade and multiply chiefly within macrophages. They are characteristically resistant to most antibiotics. NTM lung infections usually are chronic conditions that can lead to frequent exacerbations and lengthy hospital stays. Treatment for NTM lung infections requires lengthy multi-drug regimens that can be poorly tolerated and poorly effective, especially in patients with severe disease or in those who have failed prior treatment attempts. There have been very few clinical trials to support current treatment recommendations, and no new drugs have been assessed for this disease in many years.

According to a Company-sponsored analysis conducted by SDI Healthcare, more than 30,000 patients visited physician offices suffering with NTM lung infections in the U.S. during 2008. There were between 14,000 and 15,000 patients who had a hospital visit for a primary diagnosis of NTM. The average age of these patients was about 66. Approximately two-thirds of the NTM patients received at least one antibiotic and of those receiving an

antibiotic, they received between seven and eight courses in 2008.

Index

Although there are many species of nontuberculous mycobacteria that have been reported to cause lung infections, ARIKACE will be used to treat two of the most common, Mycobacterium Avium Complex (MAC) and Mycobacterium abscessus. MAC accounts for the vast majority of NTM lung infections with prevalence rates from 72% to over 85% in the U.S. The reported prevalence rates for M. Abscessus range from 3% to 11% in the U.S. The diagnosed prevalence of NTM species causing lung infections varies geographically with lower rates of MAC reported in Europe in the 25% to 55% range.

We believe the unmet need for new therapies in the treatment of NTM lung infections is very high. Patients are often treated with the same antibiotics that are used to treat TB. Current treatment usually consists of lengthy multi-drug antibiotic regimens that are often poorly tolerated and not very effective, especially in patients with severe disease or in those who have failed prior treatments. Treatment guidelines published in 2007 in the American Journal of Respiratory and Critical Care Medicine report that few clinical trials are under way to identify treatment recommendations, and no new antibiotics have been studied for the treatment of NTM lung infections in multi-center, randomized clinical trials for many years.

Amikacin is not approved by the FDA for NTM lung infections but is often recommended as part of the standard treatment regimen for some NTM patients. It is delivered mostly via intravenous administration but sometimes via inhalation. As the drug is delivered for months at a time, there can be considerable toxicity associated with treatment due to the high systemic (blood) levels of the drug, which can lead to ototoxicity (hearing loss, ringing in the ears and/or loss of balance) and nephrotoxicity (toxicity to the kidneys).

We believe that ARIKACE may be effective in treating patients with NTM lung infections because of the ability of the ARIKACE liposomes to be taken up inside lung macrophages that harbor invading organisms such as NTM. Macrophages are immune cells whose primary function includes removing foreign particles and bacteria from the lungs. Ironically, NTM organisms “hide” within the macrophages, making treatment difficult as drugs cannot efficiently gain access to the macrophage interior. Because ARIKACE liposomes are recognized as foreign particles, they are also internalized by the macrophages, consequently delivering very high levels of drug inside the macrophages to reach the NTM bacteria. In addition, we believe that the depot effect of ARIKACE in the lung and lower level of systemic exposure compared to intravenous amikacin may provide additional benefits to these patients and reduce the ototoxicity and nephrotoxicity.

We applied for orphan drug designation for NTM infections in the U.S. in 2011. In response to our application, the FDA has requested either in vivo (non-clinical data in animals) or clinical data in support of our application for orphan drug designation. We plan to file for orphan drug designation for NTM lung infections again the U.S. and in the EU after obtaining additional pre-clinical data.

Additional Market Opportunity: Non-CF Bronchiectasis Patients with Pseudomonas aeruginosa Lung Infections

While we are concentrating our development efforts on the areas we believe have the greatest potential, the treatment of Pseudomonas lung infections in CF patients and patients with NTM lung infections, we believe that ARIKACE has potential to be used for treating other types of conditions. We may pursue additional areas of development once we have completed clinical studies for the first two indications. We believe non-CF bronchiectasis offers another potential market opportunity and that ARIKACE has the potential to be used to treat non-CF bronchiectasis characterized by Pseudomonas lung infections, for which we also have orphan drug status in the U.S.

Non-CF bronchiectasis is a serious pulmonary condition characterized by localized, irreversible enlargement of the bronchial tubes. Accumulation of mucus in the bronchi leads to frequent infections, which causes inflammation and further reduces lung function in these patients. Patients evolve to a chronic inflammation-infection cycle. Disease burden has primarily been linked to productive cough and high levels of sputum (lung mucus) production.

It is estimated that approximately 30% of non-CF bronchiectasis patients are infected with Pseudomonas. When bronchiectasis patients become infected with Pseudomonas, they tend to have more frequent exacerbations and hospitalizations and are more frequent users of antibiotics.

While we believe there is a significant opportunity to develop ARIKACE for non-CF bronchiectasis, we do not intend to initiate further clinical studies until we have completed additional clinical studies for the first two indications, CF patients with Pseudomonas lung infections and NTM lung infections. At that time, we will evaluate whether to develop ARIKACE further for this potential indication.

Index

IPLEX

We have a proprietary protein product, IPLEX (mecaserminrinfabate, recombinant DNA origin, injection), a complex of recombinant human IGF-1 and its binding protein IGFBP-3 (rhIGF-1/rhIGFBP-3). IPLEX has been studied as a treatment for several serious medical conditions such as myotonic muscular dystrophy (MMD) and ALS. It is currently being evaluated in the treatment of retinopathy of prematurity (ROP).

IPLEX development is no longer a development priority for us. We announced in January 2012 that we intend to seek licensing partners for future development of IPLEX. In addition, we no longer have protein development capability nor the in-house capability to manufacture IPLEX.

Consistent with our out-licensing plans, IPLEX is being evaluated as treatment for ROP by Premacure.

Expanded Access Program (EAP) for Patients in the U.S. and Europe with ALS

ALS is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord. Motor neurons reach from the brain to the spinal cord and from the spinal cord to innervate muscles throughout the body. When the motor neurons die, the ability of the brain to initiate and control muscle movement is lost. The progressive degeneration of the motor neurons in ALS patients eventually leads to death. IGF-1 has been shown to be highly neurotrophic and normally circulates in the body bound with its natural chaperone, BP3.

At the request of the Italian Ministry of Health, we established an EAP in Italy to provide IPLEX to physicians for use in their patients with ALS. Through an agreement with Cephalon, Inc., which holds patent rights in the EU to IGF-1 as it relates to the treatment of ALS, we have been able to provide IPLEX to physicians in Italy and receive payment for the drug, on a cost recovery basis, from the Italian Health Authorities. In November 2009, through an agreement with Genentech, Inc. (now Hoffman-LaRoche Ltd.or Roche), and Tercica Inc. (now Ipsen Inc.), we were allowed to develop IPLEX in ALS on a royalty-free basis for the rest of the world. Although we are not actively or directly pursuing any such controlled clinical development at this time in this area, we have been gathering uncontrolled data on ALS through our EAP, which will be completed during the first half of 2012 as drug supplies were exhausted at the end of 2011.

ROP

ROP is a disease in which the small blood vessels in the back of the eye, the retina, grow abnormally. This disorder primarily affects premature infants weighing about 2.75 pounds, or 1250 grams, or less who are born before 31 weeks of gestation (a full-term pregnancy has a gestation of 38–42 weeks). The smaller a baby is at birth, the more likely that baby is to develop ROP. This disorder, which usually develops in both eyes, is one of the most common causes of vision loss in childhood and can lead to lifelong visual impairment and blindness.

There are approximately 3.9 million infants born in the U.S. each year; of those, about 28,000 weigh 2.75 pounds or less. It is estimated that 14,000 to 16,000 of these infants are affected by some degree of ROP. Of these, 1,100 to 1,500 infants annually develop ROP that is severe enough to require medical treatment and 400 to 600 infants each year in the U.S. become legally blind from ROP.

In an earlier clinical study of 84 gestational-age-matched premature infants with or without ROP, the mean serum IGF-I was significantly lower in those with ROP than without ROP, and a relationship was found with the severity of ROP. This finding that the development of ROP is associated with low levels of IGF-I after premature birth suggest the replacement of IGF-I to physiological levels found in utero might prevent the disease by allowing normal vascular development.

We have supplied IPLEX to Premacure, which has conducted a Phase 1 pharmacokinetic, pharmacodynamic and safety study that merited the ongoing Phase 2 multicenter trial for IPLEX in the ROP indication. The study is using the IPLEX previously supplied to Premacure, which it believes is sufficient to complete the Phase 2 trial. We have been informed by Premacure that eight infants have been recruited into the trial as of the end of January 28, 2012 and we understand that Premacure plans to accrue up to 95 patients to get 80 evaluable patients in the trial.

Index

Short-Stature and Other Indications

In the past, we were focused on development and commercialization of IPLEX for the treatment of growth failure in children with severe primary IGF-1 deficiency. IPLEX was approved by the FDA for treatment of severe primary IGF-1 deficiency in December 2005 and was commercially launched in the second quarter of 2006.

In December 2004, Tercica, Inc. (now The Ipsen Group) and Genentech (now Roche) filed patent infringement suits against us in the U.S. District Court for the Northern District of California and in the United Kingdom at the High Court of Justice, Chancery Division, Patents Court.

On March 5, 2007, we reached a settlement agreement ending all litigation with Tercica, Inc. and Genentech. The settlement agreement prevents us from actively pursuing worldwide development activities for the short-stature indication. Pursuant to the agreement, we agreed to cease sales and marketing of IPLEX in the U.S. and agreed to withdraw our European Marketing Authorization Application for IPLEX. The agreement also gives us the right, through a worldwide development partnership with Tercica and Genentech, to market IPLEX for conditions not related to short-stature. The development partnership includes provisions for certain royalty payment obligations to Tercica and Genentech based on product sales. The development partnership also includes provisions for a 50% share of profits and reimbursement for 50% of development costs if either Tercica or Genentech exercises opt-in rights for marketing of IPLEX in any of these new indications that we develop.

Other Programs

We have three other compounds for which we are not pursuing further development on our own, Inhaled CISPLATIN Lipid Complex, rhIGFBP-3 and INSM-18, all of which are in early stage development.

Inhaled CISPLATIN Lipid Complex is a novel sustained-release formulation of CISPLATIN in a lipid-based complex designed specifically for administration via inhalation for cancers affecting the lung. The compound was studied in three separate phase 1 clinical studies: patients who have lung metastasis due to recurrent osteosarcoma, patients who have broncho-alveolar carcinoma of the lung and patients with end-stage non-small cell lung cancer. The compound is currently in pre-clinical development, and we have out-licensed the rights to this compound to Eleison Pharmaceuticals Inc., a privately held company focused on developing compounds for orphan indications. The license agreement obligates Eleison to make payments to us upon the achievement of certain milestones.

Preclinical models demonstrate that both rhIGFBP-3 and INSM-18 interact with the IGF system to reduce tumor growth. We are not actively pursuing the development of either of these products at this time and have out licensed the rights of INSM-18 to Napo Pharmaceuticals, Inc., for diabetes and to TriAct Therapeutics Inc. for other indications. Due to the high cost of trials in the oncology area, we would need to identify a partner to co-develop rhIGFBP-3.

RESEARCH AND DEVELOPMENT

ARIKACE Development Program

We are developing ARIKACE, liposomal amikacin for inhalation for use in the treatment of gram-negative infections of the lung, and for the treatment of pulmonary mycobacterial infections.

We initiated non-clinical development of liposomal amikacin for inhalation in 2000 and continued with optimization of the formulation to develop ARIKACE with the perspective of having a differentiated commercial product with the potential for enhanced efficacy, safety and convenience for patients. The toxicology program for ARIKACE was initiated in 2006 and was the basis for the U.S. IND filing in May 2007. The early development of ARIKACE has

been partly funded under grants from the Cystic Fibrosis Foundation.

ARIKACE is a sterile aqueous liposomal dispersion for inhalation via nebulization using an optimized, investigational eFlow Nebulizer System. ARIKACE is comprised of amikacin sulfate encapsulated in liposomes composed of dipalmitoylphosphatidylcholine (DPPC) and cholesterol.

Index

The ingredients of ARIKACE were selected to maximize the potential therapeutic effects and stability of the product. Lipids are the major constituents of pulmonary surfactant. The single most prevalent compound in pulmonary surfactant is the di-saturated phospholipid, DPPC, which makes up about one-third of lung surfactant phospholipids. Another principal neutral lipid in pulmonary surfactant is cholesterol.

Penetration of Sputum and Biofilm

CF patients produce and have a buildup of mucus in their lungs. In addition, Pseudomonas organisms create a biofilm within the mucus, which acts as an added physical barrier protecting the bacteria from direct attack by antibiotics. Current scientific evidence indicates that both the patient's mucus and the bacterial biofilm have negative charges and because conventional aminoglycosides antibiotics are positively charged, it is believed that they bind to the surface of the mucus and biofilm and therefore have limited ability to penetrate them, preventing effective dose levels of the drug from getting to the bacteria. The currently approved aminoglycoside antibiotic, inhaled tobramycin, has been reported to bind to the CF patient's sputum and biofilm. This electrostatic binding accounts for an approximately 50% decrease in bioavailability of inhaled tobramycin (Hunt et al., 1995), which means that less antibiotic may reach the site of the infection in the lung.

The proprietary liposomal technology upon which ARIKACE is based, which utilizes lipids that occur naturally in the lung, may make it possible for the antibiotic to overcome the protective physical barriers presented by the CF patient's own mucus and by the bacterial biofilm. We believe that the charge-neutral surface of the liposomes used in our patented liposomal formulation allows them to penetrate the negatively charged biofilm and deliver the drug near the bacteria, which are encased inside the biofilm.

We have conducted in vitro experiments that demonstrate that ARIKACE liposomes penetrate both human CF sputum and the biofilm of Pseudomonas macro-colonies. We believe getting the amikacin near to the bacteria enhances the antimicrobial effect of ARIKACE because virulence factors secreted from the targeted bacteria have been shown to facilitate the release of amikacin from the ARIKACE liposomes once they have penetrated the biofilm, a "Trojan Horse" type of effect. In other words, by causing the liposomes to leak once ARIKACE is inside the biofilm, the drug is released where it is needed most, near the bacteria, and, thus, the Pseudomonas bacteria participate in their own potential destruction (Meers et al, Journal of Antimicrobial Chemotherapy (2008) 61, 859–868).

Cystic Fibrosis

CF is a genetic disease resulting from mutations in a 230kb gene on chromosome 7 known as the CF transmembrane conductance regulator (CFTR). There are more than 1,000 mutations known to cause CF. Study subjects with CF manifest pathological changes in a variety of organs that express CFTR. The lungs are frequently affected, the sequelae being chronic infections and airway inflammation. The principal goal of treatment of subjects with CF is to slow the chronic deterioration of lung function.

CF occurs primarily in individuals of central and western European origin. In the U.S., in 2010, the median predicted age of survival rose in 2010 to about 38 years, up from 32 years in 2000 (Cystic Fibrosis Foundation Patient Registry, 2010). The median predicted age of survival is the age by which half of the current CF Patient Registry population would be expected to survive, given the ages of the patients in the registry and the distribution of deaths. The Eurocare CF Registry has approximately 29,000 CF patients in its database, with an estimated population of 37,000 patients with CF in Europe (Data presented at NACFC, 2007).

Bronchial infections with Pseudomonas are a major cause of morbidity and mortality among patients with CF. A major factor in the respiratory health of CF subjects is acquisition of chronic Pseudomonas infections. The infection rate with Pseudomonas increases with age, and by age twenty-four almost 80% of CF subjects in the U.S. are

infected. Pseudomonas grows in macrocolonies with biofilm-like characteristics in the hypoxic (lacking oxygen) environment of the inspissated (the process of thickening due to, for example, dehydration) mucus of CF patients.

A major contributor to the significant increase in life expectancy is improved antibiotic treatment of chronic respiratory tract infections in CF subjects (Goss and Rosenfeld, 2004), as well as improved nutrition and earlier diagnosis.

Index

Therapies for CF

Pseudomonas is susceptible to several wide spectrum antibiotics, notably aminoglycosides. Some examples of aminoglycoside antibiotics include tobramycin and amikacin. Studies found that Aminoglycosides are an important class of antibiotics for the treatment of CF because of their broad antimicrobial activity and concentration dependent bactericidal activity (Lacy et al., 1998; Lortholary et al., 1995; Zembower et al., 1998). Intravenous antibiotics were originally used for treatment of chronic infections associated with CF and are still used for pulmonary exacerbations. Studies report that Ototoxicity and nephrotoxicity are common adverse events associated with the use of intravenous aminoglycosides and these effects are related to plasma drug levels (Mingeot-Leclercq and Tulkens, 1999).

The current standard of care in the U.S. for the management of chronic Pseudomonas infection in subjects with CF includes the use of suppressive therapy with inhaled tobramycin (Tobi). A study reports that Inhaled tobramycin, 300 mg, administered twice a day for cycles of 28 days followed by 28-days-off treatment was shown to reduce Pseudomonas colony counts, increase FEV1 % predicted, reduce hospitalizations and decrease additional antibiotic use (Ramsey et al., 1999). High levels of tobramycin can be attained in the lung with relatively low systemic exposure with inhaled drug compared to intravenous tobramycin. However, patients must be dosed twice a day for approximately 15 to 20 minute inhalation sessions per dose. More recent data have appeared to show that the effect of Tobi on pulmonary function has lessened since its introduction into the marketplace more than a decade ago (Konstan et al, Journal of Cystic Fibrosis, January 2011 and Assael et al, 34th European Cystic Fibrosis Society Conference, Poster 86, June 2011).

There are two main obstacles to effective and safe treatment of CF. First, high-level multi-drug resistance complicates eradication of such strains from the bronchial secretions of CF patients; and second, there is antibiotic limited penetration of animnoglycoside antibiotics into the sputum/biofilm matrix and availability of the drug at the location of the microorganism is suboptimal. Aminoglycoside antimicrobial agents, such as amikacin and tobramycin, are commonly used for treating CF patients who have Pseudomonas lung infections; however, due to this high-level resistance, large effect-site exposures of these drugs are required. Unfortunately, the intravenous doses needed to achieve such exposures can be nephro- and oto-toxic.

With ARIKACE, high lung and sputum concentrations that are sustained for prolonged periods with biofilm penetration are potential advantages over other aminoglycoside solutions for inhalation. We believe possible improvements over inhaled tobramycin would be to potentially increase the potency of antibacterial activity and efficacy of drug in the off-treatment period, decrease the frequency of administration, reduce the administration time and improve quality of life.

NTM Lung Infections

Non-tuberculous mycobacteria are ubiquitous in the environment. The pulmonary disease caused by these organisms has features that overlap with tuberculosis, but disease definition can be more complex as recovery of a single isolate from the airway secretions does not necessarily indicate disease. In contrast to tuberculosis, there is no convincing evidence of person-to-person transmission.

It appears that the prevalence of human disease attributable to NTM over the past two decades is increasing. Pulmonary disease due to NTM was traditionally reported as occurring in male smokers with emphysema. More recently, certain disease and demographic populations seem to be particularly susceptible to pulmonary disease with NTM. Elderly, Caucasian women without apparent predisposing conditions have been reported with increasing frequency to have pulmonary disease associated with MAC, and is reported as a prominent cause of chronic cough with infiltrates.

Signs and symptoms of NTM pulmonary disease are variable and nonspecific. They include chronic cough, sputum production, and fatigue. Less commonly, malaise, dyspnea, fever, hemoptysis, and weight loss can also occur, usually with advanced NTM disease. Evaluation is often complicated by the symptoms caused by co-existing lung diseases. According to a study published in the American Journal of Respiratory and Critical Care Medicine,, these conditions include chronic obstructive airway disease associated with smoking, bronchiectasis, previous mycobacterial diseases, CF, and pneumoconiosis. (Olivier et al. 2003).

Treatment guidelines for patients with MAC lung disease published in the 2007 ATS/IDSA consensus document were based primarily on small uncontrolled or non-comparative studies in patients with predominantly severe or recalcitrant MAC disease. There remains a lack of sufficiently powered prospective, randomized, clinical trials aimed at the treatment of pulmonary MAC disease. There were no sufficient clinical trials for pulmonary M. abscessus upon which to base treatment recommendations; so the guidelines list drugs that may be effective based on either in vitro susceptibility or efficacy shown in skin and soft tissue infections. Many of the drugs used in these prolonged, multi-drug regimens are poorly tolerated. It is clear from single-site studies that more effective, less-toxic therapeutic options are needed.

Index

Amikacin solution for parenteral administration is an established drug that is effective against a variety of NTM. However, its use is limited by the need to administer it intravenously and by toxicity to hearing, balance, and kidney function.

In the case of bacterial infections of the lung, the inhalation route of administration is advantageous over the intravenous route in that the aminoglycoside is delivered directly to the effect-site (in this case, the lung) with neither significant systemic absorption nor the associated systemic toxicities. Disadvantages of currently formulated aerosolized aminoglycoside solutions include rapid clearance from lung tissue, which, according to a study in 2002, necessitates frequent dosing (Geller et al., 2002) and the length of time required to inhale sufficient amounts of drug. Both factors place a high daily treatment burden on patients and may limit patient compliance. ARIKACE was developed to overcome these limitations.

ARIKACE Non-Clinical Program

In addition to the release of drug in uninfected pulmonary tissue, amikacin is released from ARIKACE by specific factors present in the infected airways of CF patients. Sputum components concentrated at the sites of infection and inflammation in the CF lung release amikacin from liposomes. In vitro studies showed that incubation of ARIKACE with sputum from CF patients led to an enhanced release of amikacin when compared to incubation with saline. This finding suggests that there are components in sputum of patients that can enhance the release of drug in vivo. Other in vitro studies showed that the supernatant obtained from a culture of Pseudomonas originating from a CF patient released approximately 50% of the amikacin from ARIKACE over four hours. It was also shown that virulence factors (rhamnolipids) derived from Pseudomonas released amikacin from ARIKACE liposomes in a concentration-dependent manner. These findings suggest that the microenvironment around bacteria may further facilitate release of amikacin near the infecting organism.

Therefore, it is proposed that the relatively high concentrations of drug that can be delivered and maintained locally to the bacterial macrocolony environment are the basis for the enhanced microbiologic activity and the predicted efficacy of ARIKACE.

Results from the nonclinical evaluation of ARIKACE demonstrate: (1) High concentrations of drug are deposited in the lung, and high levels are sustained for prolonged periods, with low serum concentrations, (2) ARIKACE penetrates CF sputum and biofilm, (3) ARIKACE exhibits antipseudomonal activity in in vitro and in vivo models, including against resistant isolates, (4) virulence factors secreted by Pseudomonas facilitate the release of amikacin from ARIKACE and (5) ARIKACE has in vitro activity that is superior to amikacin solution against different strains of NTM.

In August 2011, we announced that the FDA had placed the clinical trial programs for CF and NTM on clinical hold due to findings from a two-year rat inhalation carcinogenicity study. As part of the study, rats were given ARIKACE daily by inhalation for almost two years. Two of the 120 rats receiving the highest dose had a single lung tumor. These rats received ARIKACE doses that are much greater than the doses to be administered to humans. The relevance of the observed rat tumors to the use of ARIKACE in humans is unknown. ARIKACE was not associated with changes that may lead to tumors in shorter-term studies that we conducted in other animals. Additionally, in a standard series of tests that we performed, ARIKACE was not shown to be genotoxic. For CF, the FDA has requested that we conduct a 9-month dog toxicity study in parallel with the Phase 3 clinical program. The objective of the dog toxicity study is to determine if the findings of the rat inhalation carcinogenicity study are observed in a non-rodent model. We have begun the work required to initiate the nine-month dog inhalation toxicity study in the second quarter of 2012. FDA has indicated that this study may be conducted in parallel with a Phase 3 trial in CF patients who have Pseudomonas lung infections.

ARIKACE Clinical Program

Liposomal amikacin for inhalation has been evaluated in a series of Phase 1 clinical studies involving healthy volunteers and CF patients who have Pseudomonas lung infections (the predecessor amikacin formulation). The current formulation of ARIKACE has been evaluated in Phase 2 clinical studies in CF patients who have Pseudomonas lung infections and bronchiectasis patients who have Pseudomonas lung infections.

Index

CF Program

ARIKACE was evaluated in two double-blind, placebo-controlled Phase 2 studies in CF patients with chronic infections due to Pseudomonas. 105 subjects were enrolled. The European study (TR02-105) was completed in February 2008, and the U.S. study (TR02-106) was completed in June 2009.

Both studies were conducted in CF patients > 6 years of age who were chronically infected with Pseudomonas. Patients received via inhalation 70, 140, 280, 560 mg dose of ARIKACE or placebo daily for 28 days. Overall, all doses administered once daily were well tolerated. There were no unexpected adverse events, and there were no differences between the groups in overall rates of adverse events. The adverse events were consistent with underlying CF diseases, although there was a trend toward mild to moderate dysphonia in the 560-mg-dose group. There were no appreciable changes in acute tolerability, and there was improvement in oxygen saturation.

Patients receiving 560 mg dose of ARIKACE demonstrated superior clinical benefit as compared with patients receiving placebo. There was a statistically superior and sustained reduction in Pseudomonas density, including mucoid strains (~2.0 log reduction; p=0.021), and clinically meaningful and statistically significant evidence of clinical benefit as measured by improvement in respiratory symptoms of CFQ-R- Respiratory Scale (67% on ARIKACE improving vs. 36% on placebo). Patients receiving 560 mg of ARIKACE demonstrated improved lung function over baseline while patients on placebo declined over time. A statistically significant treatment effect of relative change in FEV-1 (lung function) of 12.3% (p=0.003) was observed at one month after discontinuing study drug. Patients receiving ARIKACE had prolonged time to exacerbation (Mean = 45.3 days), as compared to placebo (Mean = 31.5 days). There were dose proportional and high levels of amikacin achieved in the sputum with low systemic exposure.

Pharmacokinetic and pharmacodynamic analyses demonstrated statistically significant correlations between change in FEV1 and dose, and Pseudomonas aeruginosa colony forming units (CFU) and dose at days 7, 14, 21 and 28 of the trial ($p<0.05$).

In addition, protocol TR02-105 was extended as an open label multi-cycle (six cycles over approximately 18 months: 28 days on treatment and 56 days off) study to evaluate the long-term safety and efficacy of ARIKACE 560 mg dose delivered once daily. The study was completed in November 2010.

The observations from this study are summarized below:

- 49 CF patients participated in this study. Overall, ARIKACE 560 mg administered once daily for six cycles was well tolerated and demonstrated adverse effects that were consistent with those expected in a population of CF patients. No unexpected adverse events were observed with longer term dosing (72 weeks).

- The data showed statistically significant reduction in P. aeruginosa density including mucoid strains when compared with baseline (p=0.0030). This effect was sustained over 6 cycles, including the 56-day interval between dosing. There was no significant change in minimum inhibitory concentration (MIC50) over six cycles of therapy with ARIKACE.
- Inhalation of 560 mg of ARIKACE once daily for 28 days demonstrated statistically significant improvement in lung function over baseline that was sustained over a 72-week period. A mean increase in FEV-1 (%) of 11.7% from baseline was observed at the end of treatment of six cycles ($p<0.0001$). The improvement in lung function was sustained at the end of two months off ARIKACE, as shown by a mean increase in FEV-1 (%) of 5.7% (p=0.0001).

We believe the safety and efficacy data from the Phase 2 studies demonstrate that ARIKACE administered once daily is generally safe and well tolerated in CF patients who have Pseudomonas lung infections, and there is evidence of

clinical and microbiologic benefit, particularly at the 560-mg dose.

Index

We announced in August 2011 that the FDA had placed a clinical hold on our Phase 3 clinical trials for ARIKACE in patients with CF patients with Pseudomonas lung infections. FDA informed us that this decision was based on an initial review of the results of a long-term rat inhalation carcinogenicity study with ARIKACE. In this study, rats received daily doses of ARIKACE by inhalation for up to two years. The FDA requested additional information on ARIKACE and data from the rat study. As a result of the clinical hold, we suspended initiation of the ARIKACE Phase 3 clinical trial programs, including the recruitment and enrollment of patients.

We provided the requested information to the FDA in August and was informed by the FDA that, based on its review of the information provided to date, including the rat inhalation carcinogenicity study results, the FDA had insufficient information to assess the risks for ARIKACE in CF patients. In October 2011, the FDA notified the Company that the FDA was continuing the clinical hold previously placed on Insmed's Phase 3 clinical trial for ARIKACE in CF patients with Pseudomonas lung infections. The FDA requested additional information from us, including that we conduct a nine-month dog inhalation toxicity study of ARIKACE to determine if the findings of the rat inhalation carcinogenicity study are also observed in a non-rodent model and to propose a CF patient population/disease state in which the risk-benefit profile of ARIKACE may be more favorable. We were informed during further dialogue with the FDA that if we chose to proceed, the required nine-month dog inhalation toxicity study of ARIKACE could be conducted in parallel with the CF Phase 3 clinical trials in human subjects.

In February 2012, we filed our complete response to the FDA clinical hold on the U.S. study of ARIKACE in CF patients with Pseudomonas infection. We will continue discussions with the FDA to pursue removal of the clinical hold on ARIKACE in U.S. for the treatment of CF patients with Pseudomonas lung infections.

We are moving forward with the ARIKACE clinical development program in CF in Europe. The European study in CF patients with Pseudomonas lung infections will be a randomized, phase 3 trial comparing ARIKACE 560 mg, delivered once daily via an optimized, investigational eFlow Nebulizer System, to TOBI®(1) (inhaled tobramycin solution), which is a marketed inhaled antibiotic that is delivered twice daily. The Company anticipates that the study will be conducted in approximately 300 patients. The primary endpoint will be change in pulmonary function (FEV-1) measured after three 28 day on-treatment and three 28 day off-treatment cycles (about six months). A key secondary endpoint will be time to pulmonary exacerbation. The study design was previously agreed upon by Insmed and the European Medicines Agency. Eligible patients will have the option to participate in a longer term open-label safety study. The Company expects to begin enrolling patients in the phase 3 European clinical study in the second quarter of 2012.

We have been granted orphan drug designation in the U.S. and EU for ARIKACE in CF patients who have Pseudomonas lung infections.

NTM lung infections Program

Data obtained from in-vitro testing of ARIKACE vs. four different strains of Mycobacterium avium complex and M. abscessus, have demonstrated dose response with ARIKACE and superior activity to free amikacin. We received a response to our Pre-IND application for ARIKACE in the treatment of NTM lung infections and submitted an IND to launch a Phase 3 study of ARIKACE in CF and non-CF patients with non-tuberculous mycobacterial lung disease.

We announced in August 2011 that the FDA had placed a clinical hold on our Phase 3 clinical trials for ARIKACE for patients with NTM lung infections. In January 2012, the FDA lifted the clinical hold on ARIKACE in patients with NTM lung infections. We intend to conduct, as requested by the FDA, a Phase 2 clinical trial in adult NTM patients to provide proof-of-concept efficacy and safety data for ARIKACE in NTM patients. We expect to begin enrolling patients in the Phase 2 clinical trial in mid-2012.

We believe that the safety and efficacy data obtained from the Phase 2 studies of ARIKACE in CF and non-CF patients with chronic lung disease and pulmonary infections and the non-clinical data summarized to date serve as the bases for further development of ARIKACE in patients with NTM lung infections.

We applied for orphan drug designation for NTM infections in the U.S. in 2011. In response to our application, the FDA has requested either in vivo or clinical data in support of our application for orphan drug designation. We plan to file for orphan drug designation for NTM lung infections again in the U.S. and in the EU after obtaining additional pre-clinical data.

Index

Bronchiectasis Program

We believe that ARIKACE has the potential to be used to treat non-CF bronchiectasis characterized by Pseudomonas aeruginosa lung infections, for which we also have orphan drug status in the U.S. Bronchiectasis is a serious pulmonary condition characterized by localized, irreversible enlargement of the bronchial tubes that leads to accumulation of mucus in the bronchi resulting in frequent lung infections.

ARIKACE has also been studied in patients with non-CF bronchiectasis and chronic infection with Pseudomonas. This study was completed in May 2009. Sixty-four study subjects were randomized (1:1:1) to receive either ARIKACE 280 mg or 560 mg or placebo on study days 1 through 28 and completed follow-up assessments through Day 56. This Phase 2 placebo-controlled study demonstrated safety, tolerability and clinically meaningful efficacy of ARIKACE in the treatment of chronic Pseudomonas infection in non-CF patients with bronchiectasis.

ARIKACE 280 mg and 560 mg, administered once daily for 28 days, was safe and well tolerated. The adverse events were consistent with underlying chronic lung disease in bronchiectasis patients. There was no evidence of renal toxicity or ototoxicity. Patients in the 560-mg cohort appear to have a slightly higher frequency of dry cough post administration than in the 280-mg cohort. Cough was of short duration, and self-limiting. One patient discontinued due to dysphonia (hoarseness or difficulty speaking) and cough.

There was a statistically significant reduction in Pseudomonas density observed in the 560 mg ARIKACE arm vs. placebo. Patients receiving ARIKACE experienced fewer pulmonary exacerbations (4.7%) vs. those receiving placebo (10.5%). No patients in the ARIKACE group required anti-Pseudomonas rescue treatment while 15% of patients in the placebo group required treatment. Greater frequency of any cause hospitalization was noted in the placebo group (5.3%) vs. the ARIKACE group (2.3%). Patients receiving ARIKACE demonstrated sustained superior clinical benefit compared with patients receiving placebo as measured by improvement in Patient Respiratory Symptoms and Quality of Life assessment.

While we believe there is a significant opportunity to develop ARIKACE for non-CF bronchiectasis, we do not intend to decide whether to initiate further clinical studies until we have completed clinical studies for the first two indications, CF patients with Pseudomonas lung infections and patients with NTM lung infections.

MANUFACTURING

ARIKACE

ARIKACE is manufactured by a third-party contract manufacturing organization using the technology developed and optimized within our company. The contract manufacturer is familiar with complex formulations such as ARIKACE and has the facilities and equipment to support the further development of the product. We and the contract manufacturer must comply with applicable FDA regulations relating to the FDA's cGMP regulations. The cGMP regulations include requirements relating to the organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. The facilities meet cGMP requirements for the sterile manufacturing of the finished product. An active program is underway that evaluates the facility requirements for commercial production.

IPLEX

We do not intend to pursue IPLEX manufacturing and we announced in January 2012 that we plan to seek out-licensing opportunities for the compound. We previously manufactured our own supply of IPLEX and

rhIGFBP-3 at the Boulder, Colorado, manufacturing facility. The sale of our Boulder facility to Merck removed our internal IPLEX production capability. We have no plans at this time to pursue a manufacturing arrangement for IPLEX with a third party. If we were to pursue such an arrangement, the production process would likely require significant investment and could take 18 to 24 months or longer once an acceptable third party is identified.

Index

INTELLECTUAL PROPERTY

Patents and Trade Secrets

Our success depends in part on our ability to maintain proprietary protection surrounding our product candidates, technology and know-how; to operate without infringing the proprietary rights of others; and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by filing U.S. and foreign patent applications related to our proprietary technology, including both new inventions and improvements of existing technology, that are important to the development of our business, unless this proprietary position would be better protected using trade secrets.

Our patent strategy includes obtaining patent protection, where possible, on compositions of matter, methods of manufacture, methods of use, treatment, dosing and administration regimens and formulations. We also rely on trade secrets, know-how, continuing technological innovation, in-licensing and partnership opportunities to develop and maintain our proprietary position.

We monitor third parties for activities that may infringe our proprietary rights, as well as the progression of third-party patent applications that may have the potential to create blocks to our products or otherwise interfere with the development of our business. We are aware, for example, of U.S. patents, and corresponding international counterparts, owned by third parties that contain claims related to treating lung infections using inhaled antibiotics. If any of these patents were to be asserted against us, we do not believe that our proposed products would be found to infringe any valid claim of these patents. Any conclusions regarding non-infringement and invalidity are based in part on a review of publicly available databases and other information. There may be information not available to us or otherwise not reviewed by us that might change our conclusions. Moreover, the scope and validity of patent claims are determined based on many facts and circumstances, and in a litigation, a court may reach a different conclusion on any given patent claim than the conclusions that we have reached. Also there is no assurance that, if we choose or are required to seek a license, a license to any of these patents would be available to us on acceptable terms or at all.

Reflecting our commitment to safeguarding proprietary information, we require our employees and consultants to sign confidentiality agreements. Furthermore, we enter into research agreements in which we exchange proprietary materials and information with collaborators including material transfer agreements, research agreements, development agreements and clinical trial agreements. These agreements prohibit unauthorized disclosure of our proprietary information. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Even though we employ a number of safeguards to protect our proprietary information, including confidentiality agreements and implementation of physical security and electronic security of information technology systems, we cannot be assured that our proprietary information is protected. Despite our efforts to protect our proprietary information, unauthorized parties may attempt to obtain and use our proprietary information. Policing unauthorized use of our proprietary information is difficult and the steps we have taken might not prevent misappropriation, particularly in foreign countries where the laws may not protect our proprietary rights as fully as do the laws of the U.S.

In some cases, litigation or other proceedings may be necessary to enforce our patents or protect our know-how or other intellectual property rights. Any additional potential litigation is likely to result in a substantial cost to us and a diversion of our resources. We cannot be sure that any of our patents will ultimately be held valid. An adverse outcome in any litigation or proceeding could subject us to significant liability.

We focus special attention on filing patent applications for formulations and delivery regimens for our products in development to further enhance our patent exclusivity for those products. We seek to protect our proprietary technology and processes, in part, by contracting with our employees, collaborators, scientific advisors and our commercial consultants to ensure that any inventions resulting from the relationship are disclosed promptly, maintained in confidence until a patent application is filed and preferably until publication of the patent application, and assigned to us or subject to a right to obtain a license.

Index

We do not know whether any of our own patent applications or those patent applications that are licensed to us will result in the issuance of any patents. Furthermore, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that any related patent may expire prior to or shortly after commencing commercialization, thereby reducing the advantage of the patent to our business and products.

We own or license rights to more than 200 issued patents and pending patent applications in the U.S. and in foreign countries. Our patent portfolio includes patents and patent applications with claims relating to compositions and methods of treating lung infections. The patent positions for ARIKACE and IPLEX are described below:

- We own U.S. Patent No. 7,544,369 (issued June 6, 2009), U.S. Patent No. 7,718,189 (issued May 18, 2010) and pending U.S. and foreign patent applications that cover the ARIKACE composition and its use in treating lung infections, including Pseudomonas aeruginosa and non-tuberculosis mycobacteria.

- Through an agreement with PARI Pharma GmbH, we have a license to U.S. and foreign patents and applications that cover the optimized, investigational eFlow Nebulizer System medical device.

- We have rights to several U.S. patents relating to the composition, production, antibodies and methods of use for IPLEX and rhIGFBP-3. In addition, foreign counterparts to the above-referenced U.S. patents have issued or are pending issue in major pharmaceutical markets, such as the EU, Canada and Japan.

As part of our product development, we have filed or may file patent applications related to new production methods, improved formulations, new medical uses and new dosing regimens in the U.S. and in many of the major international pharmaceutical markets.

Individual patents extend for varying time periods depending on the effective date of filing the patent application or the date of patent issuance, and the legal term of the patents in the countries in which they are obtained. Generally, patents issued in the U.S. are effective for:

- The longer of 17 years from the issue date or 20 years from the earliest effective filing date, if the patent application was filed prior to June 8, 1995; or

    - 20 years from the earliest effective filing date, if the patent application was filed on or after June 8, 1995.

The term of foreign patents varies in accordance with provisions of applicable local law, but typically is 20 years from the earliest effective filing date.

The U.S. Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act, provides for an extension of one patent, known as a Hatch-Waxman statutory extension, for each new chemical entity to restore a portion of the patent term lost while awaiting premarket government approval from a regulatory agency. However, the maximum extension is five years and the extension cannot extend the patent beyond 14 years from New Drug Application approval. Similar extensions for exclusivity are available in European countries (known as supplementary protection certificate extensions), Japan and other countries. However, we will not know what, if any, extensions are available until a drug is approved.

Also in the U.S., under provisions of the Best Pharmaceuticals for Children’s Act, we may be entitled to an additional six-month period of patent protection for completing pediatric clinical studies in response to a FDA issued Pediatric Written Request before said exclusivities expire.

An additional Orphan Drug Exclusivity (which was enacted before the Hatch Waxman Act) provides an additional seven-year period of exclusivity from generic competition. The seven-year period is supposed to reflect the time it will take to recover the cost of developing an orphan drug from sales of such drug in the U.S. The exclusivity only applies to the disease or condition for which the approved drug was designated. The seven-year exclusivity period can be extended for an additional six months by pediatric study. In the EU, a product receiving EMA marketing approval which has an orphan drug designation is entitled to exclusivity for a period of ten years.

Index

License Agreements

We consider from time to time the license of intellectual property that we feel may be important to the development and commercialization of our products.

We currently have a licensing agreement with PARI Pharma GmbH for use of the optimized, investigational eFlow Nebulizer System for delivery of ARIKACE in treating patients with CF, bronchiectasis, and non-tuberculosis mycobacterial infections. Insmed has rights to several U.S. and foreign issued patents, and there are future patent applications involving improvements to the optimized, investigational eFlow Nebulizer System. In consideration of this agreement, PARI shall receive payments either in cash, qualified stock or a combination of both, at PARI's discretion, based on achievement of certain milestone events including Phase 3 trial initiation, NDA acceptance and regulatory approval of ARIKACE together with royalty payments on commercial sales of ARIKACE.

We also currently have the following licensing arrangements for IPLEX and rhIGFBP-3 development in place:

- In February 2011, we entered into an out-licensing agreement with Eleison Pharmaceuticals granting Eleison exclusive rights to patent applications covering our CISPLATIN Lipid Complex technology.

- On December 20, 2010, we entered into an agreement with TriAct Therapeutics Inc, whereby TriAct obtained an exclusive license from Insmed for INS-18 also known as Masoprocal. The license gives TriAct the right to develop, manufacture and commercialize Masoprocal products for any indications relating specifically to Oncology. The agreement provides for the issuance by TriAct of its common stock to us upon the achievement of certain milestones, which have not been met to date.

- In November 2008 we gained Royalty-Free Worldwide Rights for IPLEX from Tercica (now Ipsen) and Genentech in connection with potential expanded access ALS programs.

- In March 2007, we were granted a license or sublicense as applicable to patents held by Tercica and Genentech to develop IPLEX in certain medical indications in the U.S. and foreign territories, as discussed earlier in this section.

- On January 5, 2007, we entered into an agreement with NAPO Pharmaceuticals, whereby NAPO will license from us the technology surrounding INSM-18 also known as Masoprocal. The license gives NAPO the right to develop, manufacture and commercialize Masoprocal products for any indications relating specifically to diabetes, cardiac disease, vascular disease, metabolic disease and Syndrome X. The agreement calls for payments from NAPO to us upon the achievement of certain milestones.

- In April 2005, we were granted a non-exclusive license to certain proprietary manufacturing technology from Avecia Limited for the production of IPLEX.

- In January 2004, we were granted a non-exclusive license to patent rights pertaining to the use of IGF-1 therapy for the treatment of extreme or severe insulin resistant diabetes from Fujisawa Pharmaceutical Co., Ltd.

- In November 1998, we were granted a non-exclusive license to certain proprietary manufacturing technology from Brookhaven Science Associates, LLC.

Trademarks

In addition to our patents and trade secrets, we have filed applications to register certain trademarks in the U.S. and/or abroad, including INSMED, ARIKACE, and IPLEX. At present, we have received either registration or a notice of

allowance for these marks from the U.S. Patent and Trademark Office. We have also received foreign allowances or issued foreign registrations for certain of these marks. Our ability to obtain and maintain trademark registrations will in certain geographical locations depend on making use of the mark in commerce on or in connection with our products and approval of the trademarks for our products by regulatory authorities in each country.

Index

COMPETITION

The biotechnology and pharmaceutical industries are highly competitive. We face potential competitors from many different areas including commercial pharmaceutical, biotech and device companies, academic institutions and scientists, other smaller or earlier stage companies and non-profits organizations developing anti-infective drugs and drugs for respiratory diseases. Many of these companies have greater human and financial resources and may have product candidates in more advanced stages of development and may reach the market before our product candidates. Competitors may develop products that are more effective, safer or less expensive or that have better tolerability or convenience. We may also face generic competitors where third-party payors will encourage use of the generic products. While we believe that our formulation delivery technology, respiratory and anti-infective expertise, experience and knowledge in our specific areas of focus provide us with competitive advantages, these potential competitors could reduce our commercial opportunity.

Major Competitors

Our major competitors include pharmaceutical and biotechnology companies that have approved therapies or therapies in development for the treatment of chronic lung infections. Most of these competitors are focused on the CF market for their lead indication. Inhaled antibiotics are a standard of care in the treatment of CF to manage the chronic Pseudomonas infections due to the high concentrations of drug deposited directly into the lung, where the infection resides. We are not aware of any other companies developing an inhaled antibiotic for NTM lung infections.

Inhaled tobramycin (Tobi) was the first inhaled antibiotic to be approved by the FDA and has been sold in the U.S. since January 1998 and is currently marketed by Novartis. Tobi is administered for 15 to 20 minutes twice daily and continues to dominate the treatment landscape as the first line standard of care in most countries.

A second inhaled tobramycin (Bramitob®) has also been approved and is marketed in several European countries by Chiesi Group. Additionally, specialty pharmacies in the U.S. compound generic tobramycin originally formulated for IV use and sell it for inhalation purposes.

Tobi Podhaler® (tobramycin inhalation powder), a dry powder version of tobramycin was approved by the EU in 2011 for use by patients with CF. We also believe that Novartis filed for approval of Tobi Podhaler in the U.S. in 2011. Although it was reported that Tobi Podhaler was approved and launched in Canada and at least one country in Europe in 2011, we are not aware of the company reporting sales to date.

Forest Laboratories markets inhaled colistin (Colomycin®) in Europe. Colomycin is used in Europe primarily as an adjunct therapy and in some cases as a primary therapy. Because it is less expensive than Tobi, Colistin is used as a first line treatment in some countries that have a more restrictive reimbursement system. Colistin is not approved for inhaled treatment in the U.S., but it is frequently used off label (via pharmacist compounding) for patients that cannot use Tobi and for more severe patients in the off month alternating with Tobi in an attempt to maintain lung function in patients who are deteriorating on Tobi alone.

Gilead Sciences received approval from the FDA for Cayston® (aztreonam for inhalation) in early 2010. It was launched in the U.S. that same year with less convenient three times per day inhalation over about 10 minutes in total. Gilead received conditional approval for Cayston in Europe during September 2009. The approval is for one cycle of treatment only and limited to adult patients.

Market data on marketed competitors as reported by the individual companies is summarized below.

24

Index

Competitor	Indication	Product	Class of Product	Marketing Status	2011 Global Sales (in millions)
Novartis	CF Patients with Pseudomonas Lung Infections	Tobi (Tobramycin Inhalation Solution)	Aminoglycoside	Marketed	$ 296
Gilead	CF Patients with Pseudomonas Lung Infections	Cayston (Aztreonam for Inhalation Solution)	Monobactam	Marketed	Not Reported
Forrest	CF Patients with Pseudomonas Lung Infections	Colomycin (Colistimethate Sodium for Inhalation)	Polymixin	Marketed in Europe only	Not Reported
Chiesi	CF Patients with Pseudomonas Lung Infections	Bramitob (Tobramycin Inhalation Solution)	Aminoglycoside	Marketed in some European countries	Not Reported
Novartis	CF Patients with Pseudomonas Lung Infections	Tobi Podhaler (tobramycin inhalation powder)	Aminoglycoside	Marketed in EU and Canada	Not Reported

Examples of competitive therapies in development include inhaled antibiotic products to treat chronic respiratory infections due to Pseudomonas. These include levofloxacin by Aptalis Pharma, dry powder ciprofloxacin by Bayer AG, liposomal ciprofloxacin by Aradigm Corporation, liposomal tobramycin by Axentis Pharma and a combination of fosfomycin/tobramycin by Gilead. Therapeutic antibodies and other technologies are also being developed to treat Pseudomonas lung infections by other potential competitors including Kalobios Pharmaceuticals, Inc., Kenta Biotech Ltd. and Aridis Pharmaceuticals. Although therapeutic antibodies are potential competitors, the early studies conducted by Kalobios are using these compounds as adjunctive/complementary therapy to an inhaled antibiotic.

In addition, Kalydeco (ivacaftor) by Vertex was approved in January 2012 by the FDA as the first drug targeted to treat the underlying cause of a rare form of CF representing about 4% of patients with CF. The potential impact on inhaled antibiotic products of Kalydeco or similar products approved by regulatory authorities in the future is uncertain. Vertex also has other drugs in development to treat more common forms of CF.

GOVERNMENT REGULATION

FDA Approval Process

In the U.S., pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve and even accept for review pending new drug applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product development in the U.S. typically involves non-clinical laboratory and animal tests, the submission to the FDA of a notice of claimed investigational exemption or an investigational new drug application, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to

establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

Index

A 30-day waiting period after the submission of an original IND is required prior to the commencement of clinical testing in humans. If the FDA has not placed the proposed clinical trial on hold within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations, good clinical practices (GCP), as well as under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary clinical hold or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes, among other things, that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board (IRB), for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential Phases, but the Phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication or indications, dosage tolerance and optimum dosage and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved new drug application are also subject to annual product and establishment user fees. These fees are typically increased annually.

The FDA has 60 days from its receipt of a NDA to determine whether the application will be accepted for filing based on the FDA's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of new drug applications. Most such applications for non-priority drug products are reviewed within ten months. The review process may be extended by FDA for three additional months to consider certain information or clarification regarding information already provided in the submission.

The FDA may refer applications for novel drug products or drug products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. FDA will not approve the product unless compliance with current good manufacturing practices is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After FDA evaluates the NDA and the manufacturing and testing facilities, it issues an approval letter, an approvable letter or a complete response letter. Both approvable and complete response letters generally outline the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

Index

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling restrictions that can materially affect the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Other Regulatory Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet.

Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product.

In addition, quality control as well as drug manufacture, packaging, and labeling procedures must continue to conform to current good manufacturing practices (cGMPs) after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA during which the FDA inspects manufacturing facilities to access compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs.

Regulatory authorities may withdraw product approvals or request product recalls if a Company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S. We have obtained orphan drug designation for CF patients who have Pseudomonas lung infections in both the United States (U.S.) and the EU. We have also obtained orphan drug designation in the U.S. for the treatment of lung infections in patients with non-CF bronchiectasis. We applied for orphan drug designation for NTM infections in the U.S. in 2011. In response to our application, the FDA has requested in vivo or clinical data in support of our application for orphan drug designation. We plan to file for orphan drug designation for NTM lung infections again in the U.S. and in the EU after obtaining additional pre-clinical data..

After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of

the regulatory review and approval process. The first NDA applicant with FDA orphan drug designation for a particular active ingredient to receive FDA approval of the designated drug for the disease indication for which it has such designation, is entitled to a seven-year exclusive marketing period (Orphan Drug Exclusivity) in the U.S. for that product, for that indication. During the seven-year period, the FDA may not finally approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

Index

The EMA grants orphan drug designation to promote the development of products that may offer therapeutic benefits for life-threatening or chronically debilitating conditions affecting not more than five in 10,000 people in the EU. In addition, orphan drug designation can be granted if the drug is intended for a life threatening, seriously debilitating or serious and chronic condition in the EU and that without incentives it is unlikely that sales of the drug in the EU would be sufficient to justify developing the drug. Orphan drug designation is only available if there is no other satisfactory method approved in the EU of diagnosing, preventing or treating the condition, or if such a method exists, the proposed orphan drug will be of significant benefit to patients.

Orphan drug designation provides opportunities for free protocol assistance and fee reductions for access to the centralized regulatory procedures before and during the first year after marketing approval, which reductions are not limited to the first year after marketing approval for small and medium enterprises. In addition, if a product which has an orphan drug designation subsequently receives EMA marketing approval for the indication for which it has such designation, the product is entitled to orphan drug exclusivity, which means the EMA may not approve any other application to market the same drug for the same indication for a period of ten years. The exclusivity period may be reduced to six years if the designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Competitors may receive marketing approval of different drugs or biologics for the indications for which the orphan product has exclusivity. In order to do so, however, they must demonstrate that the new drugs or biologics provide a significant benefit over the existing orphan product. This demonstration of significant benefit may be done at the time of initial approval or in post-approval studies, depending on the type of marketing authorization granted.

Pediatric Information

Under the Pediatric Research Equity Act of 2003 (PREA), NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

Regulation Outside the U.S.

In addition to regulations in the U.S., we will be subject to a variety of regulations in other jurisdictions governing clinical studies of our candidate products. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of countries outside the U.S. before we can commence clinical studies or marketing of the product in those countries. The requirements for approval and the approval process vary from country to country, and the time may be longer or shorter than that required for FDA approval.

To obtain regulatory approval of a drug under EU regulatory systems, we may submit marketing authorizations either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by certain biotechnological processes and optional for those which are highly innovative, provides for the grant of a single marketing authorization that is valid for all EU member states. The decentralized procedure provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one member state, known as the reference member state. Under this procedure, an applicant submits an application, or dossier, and related materials including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state’s assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to the public health, the disputed points may eventually be

referred to the European Commission, whose decision is binding on all member states.

Index

Pediatric Investigation Plan

On December 10, 2010, we received Positive Opinion of the Pediatric Committee of the European Medicines Agency on the agreement of a Pediatric Investigation Plan, on the granting of a deferral, and on the granting of a waiver for amikacin (sulfate) nebulizer suspension for inhalation use, in the Treatment of Pseudomonas aeruginosa lung infection/colonization in cystic fibrosis patients (EMA-000525-PIP01-08), in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council of The European Medicines Agency.

Medical Device Regulation

ARIKACE is administered via inhalation through an optimized, investigational eFlow Nebulizer System, which is a medical device that is also subject to extensive government regulation. The medical device must be approved by FDA before ARIKACE can be commercialized.

Based on the risks and benefits of this medical device, FDA classifies it as Class II, which imposes a specific level of regulatory control. FDA's statutory mechanism for reviewing such a Class II medical device before clearance to the U.S. market is a Premarket Notification 510(k), detailed in section 510(k) of the Federal Food, Drug, and Cosmetic Act. This 510(k) application, which will be submitted for review and subsequent clearance by FDA in tandem with the aforementioned NDA, will have drug-specific indications for use, clearing it to market only for use with the pharmaceutical product. The application includes, among other items, pertinent device and labeling information, biocompatibility and electrical safety/compatibility test results, and performance data with the pharmaceutical product. This documentation must demonstrate the safety and efficacy of the medical device, as well as its substantial equivalence to previously cleared medical devices, in order for FDA to clear the subject medical device to the U.S. market.

Similar to an NDA-approved product, the medical device is subjected to certain post-clearance requirements. Those requirements include continuing Quality System compliance, Medical Device Reporting, and promotional material regulations.

In addition to regulations in the U.S., we will be subject to a variety of regulations in other jurisdictions governing the medical device. Whether or not we obtain FDA approval for a product and the medical device that will be used with ARIKACE, we must obtain approval of a product and the medical device by the comparable regulatory authorities of countries outside the U.S. before we can commence marketing of the product in those countries. The requirements for approval and the approval process vary from country to country, and the time may be longer or shorter than that required for FDA approval.

Under certain harmonized medical device approval/clearance regulations outside the U.S., reference to U.S. clearance permits fast-tracking of market clearance. Other regions are harmonized with EU standards, and therefore recognize the CE mark (Conformité Européene, which means European Conformity) as a declaration of conformity to applicable standards. CE mark is standard designation for EU member States for market authorization, as 510k designation is for U.S.

EMPLOYEES

As of December 31, 2011, we had a total of 42 employees, including 10 in regulatory and clinical, 18 in technical operations and manufacturing and 14 in finance/administration and commercial.

Our success depends in large measure on our ability to attract and retain capable executive officers and highly skilled employees who are in great demand. None of our employees are represented by a labor union and we believe that our

relations with our employees are generally good. Generally, our employees are at-will employees. However, we have entered into employment agreements with certain of our executive officers.

AVAILABLE INFORMATION

We file electronically with the U.S. Securities and Exchange Commission (SEC) our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. We make available on our website at http://www.insmed.com, free of charge, copies of these reports as soon as reasonably practicable after filing these reports with, or furnishing them to, the SEC. The public can also obtain materials that we file with the SEC through the SEC's website at http://www.sec.gov or at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. Information on the operation of the Public Reference Room is available by calling the SEC at 800-SEC-0330.

Index

Also available through our website's "Investor Relations -- Corporate Governance" page are charters for the Audit, Compensation and Nominations and Governance committees of our board of directors, our Corporate Governance Guidelines, and our Code of Business Conduct and Ethics.

The references to our website and the SEC's website are intended to be inactive textual references only. Neither the contents of our website, nor the contents of the SEC's website, are incorporated by reference herein.

ITEM 1A. RISK FACTORS

Our business is subject to substantial risks and uncertainties. Any of the risks and uncertainties described below, either alone or taken together, could materially and adversely affect our business, financial condition, results of operations or our prospects for growth. In addition, these risks and uncertainties could cause actual results to differ materially from those expressed or implied by forward-looking statements contained in this Form 10-K (please read the "Cautionary Note Regarding forward-Looking Statements" appearing at the beginning of this Form 10-K). The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially and adversely affect our business, financial condition, results of operations, prospects and the value of an investment in our common stock and could cause actual results to differ materially from those expressed or implied by forward looking statements.

Risks related to Development and Commercialization of our Product Candidates

We depend heavily on the success of our most advanced product candidate, ARIKACE. U.S. clinical trials of ARIKACE for CF patients with Pseudomonas lung infections have been placed on clinical hold by the FDA and we may not proceed with the development of ARIKACE for treatment of CF patients in the U.S. If we are unable to commercialize ARIKACE, need to limit the scope of our ARIKACE program, or experience significant delays in development, our business will be materially harmed.

We are investing a significant portion of our efforts and financial resources in the development of ARIKACE, our most advanced product candidate. 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. In August 2011, we announced that the FDA placed a clinical hold on our Phase 3 clinical trials for ARIKACE in CF patients with Pseudomonas lung infections and NTM patients due to the results of a long-term rat carcinogenicity study.

The FDA has lifted the clinical hold for ARIKACE in NTM and we are proceeding with a Phase 2 trial in NTM patients.

The FDA clinical hold for CF continues to be in place and we do not know whether or when the clinical hold for the development of ARIKACE for CF patients will be lifted.

As a result of the clinical holds for CF and NTM, we, among other things, suspended the recruitment and enrollment of patients. We have begun the work necessary to initiate a Phase 2 NTM trial. We may not proceed with the Phase 3 clinical trial in CF in the U.S. as a result of clinical hold. If we are not able to continue development of ARIKACE in one or both of these indications or if our progress in development of ARIKACE is delayed significantly, our business, results of operations, financial condition and our prospects will be adversely affected. However, we currently expect to commence patient accrual in the second quarter of 2012 for a Phase 3 clinical study of ARIKACE for CF patients with Pseudomonas lung infections to support potential approval in Europe and potentially other countries outside the U.S. We plan to conduct the study in Europe.

The key elements of these study designs and regulatory paths have been agreed to with the EMA and with the regulatory agencies in the individual countries in which the trials will be conducted.

Index

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.

We have not completed the research and development stage of any of our product candidates other than IPLEX, which we no longer market. If we are unable to successfully commercialize our products, it will materially adversely affect our business, financial condition, results of operations and our growth prospects.

Our long-term viability and growth depend on the successful commercialization of ARIKACE and potentially other product candidates that lead to revenue and profits. Pharmaceutical product development is an expensive, high risk, lengthy, complicated, resource intensive process. In order to conduct the development programs for our products, we must, among other things, be able to successfully:

- Identify potential drug product candidates;
- Design and conduct appropriate laboratory, preclinical and other research;
- Submit for and receive regulatory approval to perform clinical studies;
- Design and conduct appropriate preclinical and clinical studies according to good laboratory and good clinical practices;
- Select and recruit clinical investigators;
- Select and recruit subjects for our studies;
- Collect, analyze and correctly interpret the data from our studies;
- Submit for and receive regulatory approvals for marketing; and
- Manufacture the drug product candidates according to cGMP.

The development program with respect to any given product will take many years and thus delay our ability to generate profits. In addition, potential products that appear promising at early stages of development may fail for a number of reasons, including the possibility that the products may require significant additional testing or turn out to be unsafe, ineffective, too difficult or expensive to develop or manufacture, too difficult to administer or unstable. If we do not proceed with the development of our ARIKACE program in the CF or NTM indications, certain organizations that provided funding to us for such developmental efforts may elect to proceed with the development of these indications. Failure to successfully commercialize our products will adversely affect our business, financial condition, results of operations and our growth prospects.

If our proposed treatment population for CF or NTM is limited by the FDA, our preclinical studies do not produce positive results or 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 in the U.S., Europe or other countries.

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 long-term rat inhalation carcinogenicity study with ARIKACE are observed in a non-rodent model. We have initiated the work necessary to begin the dog inhalation toxicity study during the second quarter of 2012. We have not reached agreement with the FDA regarding the clinical hold for CF and the study design for Phase 3 clinical trials in CF patients with Pseudomonas lung infections. The FDA has required us to conduct a Phase 2 clinical trial in adult NTM patients intended to provide proof-of-concept efficacy and safety data for ARIKACE in NTM.

Index

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;
- Enrollment in the clinical trials may take longer than expected or the clinical trials as designed may not allow for sufficient patient accrual to complete enrollment of the trial;
- We may decide to limit or abandon our commercial development program;
- 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 to submit information to regulatory authorities, Ethics Committees, IRBs 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 may 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;
- We may not be able to demonstrate that a product candidate provides an advantage over current standard of care or future competitive therapies in development;
- 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.

We have been informed by the FDA that its decision to place a clinical hold on our Phase 3 clinical trials for ARIKACE in CF patients and patients with NTM lung infections was based on the results of a long-term rat inhalation carcinogenicity study. While the FDA has removed the clinical hold for NTM, the clinical hold on our Phase 3 clinical

trials for ARIKACE in CF patients remains in place. There can be no assurance that the FDA will allow us to further develop ARIKACE for CF patients .

Index

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 have and may continue to increase if we experience further delays in testing or approvals. We do not know what impact the remaining clinical hold for CF will have on our clinical programs for ARIKACE. In addition, we do not know whether any additional preclinical tests, other than the dog inhalation toxicity study or clinical trials, will be initiated, 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.

We have limited experience in conducting and managing the preclinical development activities and clinical trials necessary to obtain regulatory approvals, including approval by the FDA.

We have limited experience in conducting and managing the preclinical development activities and clinical trials necessary to obtain regulatory approvals, including approval by the FDA. We have not completed a Phase 3 clinical trial for, obtained regulatory approval for nor commercialized any of our product candidates following our Merger with Transave. Our limited experience might prevent us from successfully designing or implementing a clinical trial. We have limited experience in conducting and managing the application process necessary to obtain regulatory approvals and we might not be able to demonstrate that our product candidates meet the appropriate standards for regulatory approval. If we are not successful in conducting and managing our preclinical development activities or clinical trials or obtaining regulatory approvals, we might not be able to commercialize our lead product candidate, or might be significantly delayed in doing so, which will materially harm our business.

We may not be able to enroll enough patients to complete our clinical trials.

The completion rate of clinical studies of our products is dependent on, among other factors, the patient enrollment rate. Patient enrollment is a function of many factors, including:

- Investigator identification and recruitment;
- Regulatory approvals to initiate study sites;
- Patient population size;
- The nature of the protocol to be used in the trial;
- Patient proximity to clinical sites;
- Eligibility criteria for the study;

- The patients' willingness to participate in the study;
- Competition from other companies' clinical studies for the same patient population; and

Index

- Ability to obtain comparator drug or medical device.

We believe our procedures for enrolling patients have been appropriate. However, delays in patient enrollment would increase costs and delay ultimate commercialization and sales, if any, of our products.

The commercial success of any product candidates that we may develop, including ARIKACE, will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Any products that we bring to the market, including ARIKACE, may not gain market acceptance by physicians, patients, third-party payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- The prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- The efficacy and potential advantages over alternative treatments;
- The pricing of our product candidates;
- Relative convenience and ease of administration;
- The willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- The strength of marketing and distribution support and timing of market introduction of competitive products;
- Publicity concerning our products or competing products and treatments; and
- Sufficient third party insurance coverage or reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical and clinical trials, market acceptance of the product will not be known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful. Such efforts to educate the marketplace may require more resources than are required by the conventional technologies marketed by our competitors.

Risks Related to Our Financial Condition and Capital Requirements

We have a history of operating losses. We expect to incur operating losses for the foreseeable future and may never achieve or maintain profitability.

We are a biopharmaceutical company focused on the development of innovative inhaled pharmaceuticals for the site-specific treatment of serious lung diseases. We have incurred losses each previous year of operation, except in 2009, when we sold our manufacturing facility and other Follow-On Biologics (FOB) assets to Merck. We expect to continue incurring operating losses for the foreseeable future. The process of developing and commercializing our products requires significant pre-clinical and clinical testing as well as regulatory approvals for commercialization and marketing before we are allowed to begin product sales. In addition, commercialization of our drug candidates likely would require us to establish a sales and marketing organization and contractual relationships to enable product

manufacturing and other related activities. We expect that our activities, together with our general and administrative expenses, will continue to result in substantial operating losses for the foreseeable future. As of December 31, 2011, our accumulated deficit was $294.2 million. For the year ended December 31, 2011, our consolidated net loss was $59.7 million.

To achieve and maintain profitability, we need to generate significant revenues from future product sales. This will require us to be successful in a range of challenging activities, including:

Index

- Obtaining marketing approval for the marketing of ARIKACE and possibly other product candidates which have yet to be developed and which would also require marketing approval;
- Commercializing ARIKACE and any other product candidates for which we obtain marketing approval; and
- Achieving market acceptance and reimbursement of ARIKACE and any other product candidates for which we obtain marketing approval in the medical community and with patients and third-party payors.

ARIKACE will require marketing approval and investment in commercial capabilities, including manufacturing and sales and marketing efforts, before its product sales generate any revenues for us. Because of the numerous risks and uncertainties associated with drug development and commercialization, we are unable to predict the extent of any future losses. We may never successfully commercialize any products, generate significant future revenues or achieve and sustain profitability.

We expect that we will need additional funds in the future to continue our operations, but we face uncertainties with respect to our access to capital.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to incur substantial research and development expenses. We may need to seek additional funding in order to complete any clinical trials related to ARIKACE, seek regulatory approvals of ARIKACE, launch ARIKACE and continue our other clinical and preclinical programs. We may also require additional future capital in order to continue our other research and development activities or to acquire complementary technology. As of December 31, 2011, we had $78.3 million of cash and investments on hand. If adequate funds are not available to us on a timely basis, we may be required to reduce or eliminate research and development programs or commercial efforts.

Our future capital requirements will depend on many factors, including factors associated with:

- Phase 2 and Phase 3 clinical trials and commercialization of ARIKACE;
- Non-clinical and clinical testing;
- Process development and scale up for manufacturing;
- Manufacturing;
- Obtaining marketing, sales and distribution capabilities;
- Obtaining regulatory approvals;
- Research and development, including formulation development
- Retaining employees and consultants;
- Filing and prosecuting patent applications and enforcing patent claims;
- Establishing strategic alliances and collaborations with third-parties; and
- Current and potential future litigation.

We may also need to spend more funds than currently expected because we may further change or alter drug development plans, acquire additional drugs or drug candidates or we may misjudge our costs. We have no committed sources of capital and do not know whether additional financing will be available when needed, or, if available, that the terms will be favorable. There can be no assurance that our cash reserves together with any subsequent funding will be sufficient for our capital requirements. The failure to satisfy our capital requirements will adversely affect our business, financial condition, results of operations and future prospects.

Index

We may seek additional funding through strategic alliances, private or public sales of our securities, debt financing or licensing all or a portion of our technology. Such funding may significantly dilute existing shareholders or may limit our rights to our currently developing technology.

Our supply of IPLEX was fully depleted in the fourth quarter of 2011, and we currently have no material source of operating revenue.

Our revenue from the EAP and the sale of IPLEX has previously been our only material source of operating revenue. Unless we can execute one or more income generating transactions, we will have no material sources of operating revenue. We expect to continue to incur substantial additional operating losses for at least the next several years as we continue to develop ARIKACE and potentially seek to commercialize the product.

If we are not successful in our efforts to evaluate potential future IPLEX initiatives and to identify and engage in possible out- licensing opportunities for IPLEX, we may not derive any future revenues from IPLEX.

We are currently evaluating possible out-licensing opportunities for IPLEX. We may have difficulty identifying possible markets and prospective partners for out-licensing. Even if we are able to enter into out-licensing arrangements, we may not derive any revenue from those arrangements.

We may be unable to use our net operating losses.

We have substantial tax loss carry forwards for U.S. federal income tax purposes. Our ability to use such carry forwards to offset future income or tax liability is limited under section 382 of the Internal Revenue Code of 1986, as amended. Changes in the ownership of our stock, including those resulting from the issuance of shares of our common stock upon exercise of outstanding warrants or options, may further limit or eliminate our ability to use our net operating losses.

Risks Related to Regulatory Matters

We cannot be certain that we will obtain regulatory approvals in the U.S., Europe or other countries. If we fail to obtain such approvals, we will not be able to commercialize our products.

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 processes required to perform a clinical study in both the U.S. and Europe include evaluation of preclinical studies and clinical studies, as well as the evaluation of our manufacturing process. These processes are 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 placed a clinical hold on our Phase 3 clinical trials for ARIKACE in CF patients with Pseudomonas lung infections and patients with NTM lung infections based on the results of a long-term rat inhalation carcinogenicity study with ARIKACE, our leading drug candidate. The FDA clinical hold continues to be in place for our Phase 3 clinical trial for ARIKACE in CF patients in one of only two planned treatment indications. We do not know whether or when the FDA will allow us to continue the U.S. Phase 3 clinical trials in CF. The clinical hold for NTM patients has been lifted and we are proceeding with a Phase 2 clinical trial. 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.

Index

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, results of operations or prospects.

To market our products outside of the U.S and, Europe, we and our collaborative partners 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 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. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in others. In addition, we may be subject to fines, suspension or withdrawal of marketing approvals, product recalls, seizure of products, operating restrictions and criminal prosecution if we fail to comply with applicable foreign regulatory requirements. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. The failure to obtain such approvals may materially adversely affect our business, financial condition, results of operations or future prospects.

In our clinical studies, ARIKACE must be administered via an optimized, investigational eFlow Nebulizer System (PARI Pharma GmbH), manufactured by a private German company, PARI. This nebulizer system has not received regulatory approval in the U.S., EU or any other countries. For ARIKACE to be successfully developed and commercialized, the nebulizer must satisfy certain regulatory requirements.

We are not medical device experts. For ARIKACE clinical trials to be conducted, we must have an adequate supply of the investigational optimized, investigational eFlow Nebulizer System and PARI must be able to supply the system. We are dependent upon PARI being able to provide an adequate supply of the nebulizers both for the clinical trials in the event ARIKACE receives marketing approval. These nebulizers must be in good working order and meet specific performance characteristics. In addition, both the drug, ARIKACE, and the medical device, optimized, investigational eFlow Nebulizer System, must receive regulatory approval before we can market ARIKACE and the medical device.

Even if we obtain marketing approval for ARIKACE or any of our other product candidates, we will continue to face extensive regulatory requirements and our products may face future development and regulatory difficulties.

Even if marketing approval in the U.S. is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing, including risk evaluation and mitigation strategies, or impose ongoing requirements, including with respect to:

- Labeling, such as black box or other warnings or contraindications;
- Post-market surveillance, post-market studies or post-market clinical trials;
- Packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of safety and other post-market information;

- Monitoring and reporting adverse events and instances of the failure of a product to meet the specifications in the NDA;
- Changes to the approved product, product labeling or manufacturing process;
- Advertising and other promotional material; and

Index

- Disclosure of clinical trial results on publicly available databases.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. The distribution, sale and marketing of our products are subject to a number of additional requirements, including:

- State wholesale drug distribution laws and the distribution of our product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act;

- Sales, marketing and scientific or educational grant programs must comply with the anti-kickback and fraud and abuse provisions of the Social Security Act, the transparency provision of the Patient Protection and Affordable Care Act and an associated reconciliation bill that became law in March 2010, which we refer to collectively as the Health Care Reform Law, the False Claims Act and similar state laws; and

- Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veteran's Health Care Act of 1992, and if products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply.

All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

We are also subject to changes or revisions to these laws and regulations that may make gaining regulatory approval, reimbursement and pricing more difficult or at least subject to different criteria and standards.

If we or any third parties involved in our commercialization efforts fail to comply with applicable regulatory requirements, a regulatory agency may:

- Issue warning letters or untitled letters asserting that we are in violation of the law;

- Seek an injunction or impose civil or criminal penalties or monetary fines;

- Suspend or withdraw marketing approval;

- Suspend any ongoing clinical trials;

- Refuse to approve pending applications or supplements to applications submitted by us;

- Suspend or impose restrictions on operations, including costly new manufacturing requirements;

- Seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall;

- Refuse to allow us to enter into supply contracts, including government contracts;

- Impose civil monetary penalties; or

- Pursue civil or criminal prosecutions and fines against our company or responsible officers.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. The occurrence of any event or penalty described above may inhibit

our ability to commercialize our product candidates and generate revenues.

Index

Even if we obtain marketing approval for ARIKACE or any of our other product candidates, adverse effects discovered after approval could limit the commercial profile of any approved product.

If we obtain marketing approval for ARIKACE or any other product candidate that we develop, we or others may later discover, after use in a larger number of subjects for longer periods of time than in clinical trials, that our products could have adverse effect profiles that limit their usefulness or require their withdrawal. This discovery could have a number of potentially significant negative consequences, including:

- Regulatory authorities may withdraw their approval of the product;
- Regulatory authorities may require the addition of labeling statements, such as black box or other warnings or contraindications;
- Regulatory authorities may require us to issue specific communications to healthcare professionals, such as "Dear Doctor Letters;"
- Regulatory authorities may impose additional restrictions on marketing and distribution of the products;
- Regulatory authorities may issue negative publicity regarding the product, including safety communications;
- We may be required to change the way the product is administered, conduct additional clinical studies or restrict the distribution of the product;
- We could be sued and held liable for harm caused to subjects; and
- Our reputation may suffer.

Any of these events could prevent us from maintaining market acceptance of the affected product candidate, could cause substantial reduction of sales, could substantially increase the costs of commercializing our product candidates, and could cause significant financial losses.

If we are unable to obtain adequate reimbursement from governments or third-party payors for any products that we may develop or if we are unable to obtain acceptable prices for those products, our prospects for generating revenue and achieving profitability will suffer.

Our prospects for generating revenue and achieving profitability will depend heavily upon the availability of adequate reimbursement for the use of our approved product candidates from governmental and other third-party payors, both in the U.S. and in other markets. Reimbursement by a third party payor may depend upon a number of factors, including the third party payor's determination that use of a product is:

- A covered benefit under its health plan;
- Safe, effective and medically necessary;
- Appropriate for the specific patient;
- Cost-effective; and
- Neither experimental nor investigational.

Obtaining reimbursement approval for a product from each government or other third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to each payor. We may not be able to provide data sufficient to gain acceptance with respect to reimbursement or we might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to such payors' satisfaction. Such studies might require us to commit a significant amount of management time and financial and other resources. Even when a payor determines that a product is eligible for reimbursement, the payor may impose coverage limitations that preclude payment for some uses that are approved by the FDA or non-U.S. regulatory authorities. In addition, there is a risk that full reimbursement may not be available for high priced products. Moreover, eligibility for coverage does not imply that any product will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Subsequent approvals of competitive products could result in a detrimental change to the reimbursement of our products.

Index

A primary trend in the U.S. healthcare industry and elsewhere is toward cost containment. We expect changes in the Medicare program and increasing emphasis on managed care to continue to put pressure on pharmaceutical product pricing. For example, the Medicare Prescription Drug Improvement and Modernization Act of 2003 provides a new Medicare prescription drug benefit that began in 2006 and mandates other reforms. While we cannot predict the full outcome of the implementation of this legislation, it is possible that the new Medicare prescription drug benefit, which will be managed by private health insurers and other managed care organizations, will result in additional government reimbursement for prescription drugs, which may make some prescription drugs more affordable but may further exacerbate industry wide pressure to reduce prescription drug prices. If one or more of our product candidates reaches commercialization, such changes may have a significant impact on our ability to set a price we believe is fair for our products and may affect our ability to generate revenue and achieve or maintain profitability.

In addition, in both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or, collectively, the Health Care Reform Law, was enacted. The Health Care Reform Law broadly intends to expand access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and also may increase our regulatory burdens and operating costs. We expect further federal and state proposals and health care reforms to continue to be proposed by legislators, which could limit the prices that can be charged for the products we develop and may limit our commercial opportunity.

We will need FDA approval as well as approval of other regulatory authorities in jurisdictions outside the U.S. of our proposed trade name, ARIKACE, and any failure or delay associated with such approval may delay the commercialization of ARIKACE.

Any trade name we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office (PTO). The FDA typically conducts a rigorous review of proposed trade names, including an evaluation of potential for confusion with other trade names and medical error. The FDA may also object to a trade name if it believes the name inappropriately implies medical claims. If the FDA objects to our proposed trade name, ARIKACE, we may be required to adopt an alternative name for our product candidate. Even after approval, the FDA may request that we adopt an alternative name for the product if adverse event reports indicate a potential for confusion with other trade names and medical error. If we are required to adopt an alternative name, the commercialization of ARIKACE could be delayed or interrupted, which would limit our ability to commercialize ARIKACE and generate revenues.

Index

Risks Related to Dependence on Third Parties

We may not have or be able to obtain sufficient quantities of our products to meet our required supply for clinical studies or commercialization requirements.

We do not have any in-house manufacturing capability other than for development and characterization ,and depend completely on a small number of third-party manufacturers and suppliers for the manufacture of our products on a clinical or commercial scale. Arikace and the nebulizer each are supplied by a sole manufacturer. The inability of the supplier to fulfill supply requirements of the Company could materially impact future operating results. A change in the relationship with this supplier, or an adverse change in their business, could materially impact future operating results. We do not have long-term commercial agreements with all of these third parties, and if they are unable or unwilling to perform for any reason, we may not be able to locate suppliers or enter into favorable agreements with them. Any inability to acquire sufficient quantities of our components in a timely manner from these third parties could delay clinical trials or commercialization and prevent us from developing and distributing our products in a cost-effective manner or on a timely basis. In addition, manufacturers of our components may be subject to cGMP and similar foreign standards and we do not have control over compliance with these regulations by our manufacturers. If one of our contract manufacturers fails to maintain compliance, the production of our products could be interrupted, resulting in delays and additional costs. In addition, if the facilities of such manufacturers do not pass a pre-approval or post-approval plant inspection, the FDA will not grant approval and may institute restrictions on the marketing or sale of our products.

We are reliant on third-party manufactures and suppliers to meet the distribution demands of our clinical supplies and future commercial products. Delays in receipt of materials, scheduling, release, custom's control and regulatory compliance issues may adversely impact our ability to initiate, maintain or complete clinical trials that we are sponsoring or may adversely impact commercialization. Commercial manufacturing and supply agreements have not been established. Issues arising from scale-up, facility construction, environmental controls, equipment requirements, local and federal permits and allowances or other factors may have an adverse impact on our ability to manufacture the product.

We may be unable to obtain an adequate supply of nebulizer devices for timely completion of our clinical studies and commercialization. The failure to obtain these medical devices may delay the development and commercialization of our product candidates.

We are dependent upon the PARI investigational e-Flow Nebulizer System and PARI Pharma GmbH for the production and supply of nebulizer devices. We may encounter delays in the delivery of the medical devices to us due to manufacturing delays, regulatory actions directed against the manufacturer, or issues in the shipping of the medical devices. Such delays may affect the enrollment and treatment schedules of patients and delay the receipt of evaluative clinical data. Such delays could also result in a delay in obtaining marketing approval for one or more of our product candidates. Our product development costs will also increase if we experience delays in the delivery of nebulizer devices to us.

We rely on collaborative relationships for our success. If we are unable to form and sustain these relationships, or if any collaboration arrangements that we may enter into are not successful, our ability to develop and commercialize our products will be materially adversely affected.

We currently rely and will in the future rely on a number of significant collaborative relationships for intellectual property rights, research funding, manufacturing, analytical services, preclinical development, clinical development and sales and marketing. For example, almost all of our clinical trial work is done in collaboration with academic institutions and we have licensed intellectual property to permit the development, manufacture and commercialization

of our products. Reliance on collaborative relationships poses a number of risks, including the following:

- We may face significant competition in seeking appropriate collaborators;
- Collaboration arrangements are complex and time consuming to negotiate, document and implement;
- We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements that we might pursue on favorable terms;

Index

- We may not be able to effectively control whether our corporate partners will devote sufficient resources to our programs or products;

- Disputes may arise in the future with respect to the ownership of rights to technology developed with, licensed to or licensed from corporate partners;

- Disagreements with corporate partners are difficult to resolve and could result in loss of intellectual property rights, delay or terminate the research, development or commercialization of product candidates or result in litigation or arbitration;

- Contracts with our corporate partners may fail to provide sufficient protection of our intellectual property;

- We may have difficulty enforcing the contracts if one of these partners fails to perform;

- Corporate partners have considerable discretion in electing whether to pursue the development of any additional products and may pursue technologies or products either on their own or in collaboration with our competitors; and

- Corporate partners with marketing rights may choose to devote fewer resources to the marketing of our products than they do to products of their own development.

A great deal of uncertainty exists regarding the success of any current and future collaborative efforts. Failure of these efforts could delay, impair or prevent the development and commercialization of our products and adversely affect our business, financial condition, results of operations and prospects.

Our growth depends on technologies that may not be available or, if available and licensed, may not be available on terms acceptable to us.

As part of our business strategy, we expect to in-license new products and technologies. Nonetheless, we cannot assure you that we will identify suitable products or enter into such license agreements on acceptable terms.

We may enter into collaborative relationships that would involve our collaborators conducting proprietary development programs. Any conflict with our collaborators could limit our ability to obtain future collaboration agreements and negatively influence our relationship with existing collaborators. Disagreements with collaborators may also develop over the rights to our intellectual property.

Certain of our collaborators could also be or become competitors. Our collaborators could harm our product development and commercialization efforts by:

- Developing competing products;

- Precluding us from entering into collaborations with their competitors;

- Failing to obtain regulatory approvals;

- Terminating their agreements with us prematurely; or

- Failing to devote sufficient resources to the development and commercialization of products.

42

Index

Risks Related to Our Intellectual Property

We may not accurately predict the protection afforded by our patents and proprietary technology.

Our success will depend in part on our ability to protect proprietary technology and to obtain patent protection for our products, prevent third parties from infringing on our patents and refrain from infringing on the patents of others, both domestically and internationally.

In addition, the patent situation in the field of biotechnology and pharmaceuticals generally is highly uncertain and involves complex legal, technical, scientific and factual questions. We intend to actively pursue patent protection for products resulting from our research and development activities that have significant potential commercial value. We may not be able to obtain additional issued patents relating to our technology or products.

Even if issued, patents issued to us or our licensors may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, which could limit our ability to stop competitors from marketing similar products or reduce the term of patent protection we may have for our products. There can be no assurance that any patents obtained will afford us adequate protection or provide us with any meaningful competitive advantages against these competitors.

Changes in either patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. In addition, any patents we procure may require cooperation with companies holding related patents and we may have difficulty forming a successful relationship with such other companies.

Third parties may claim that we are infringing upon or have misappropriated their proprietary rights. Various third parties have obtained, and are attempting to obtain, patent protection relating to the production and use of our approved product and product candidates. We can give no assurances as to whether any issued patents, or patents that may later issue to third parties, would affect our contemplated commercialization of ARIKACE or any other product. We can give no assurances that such patents can be avoided, invalidated or licensed. With respect to any infringement claim asserted by a third party, we can give no assurances that we will be successful in the litigation or that such litigation would not have a material adverse effect on our business, financial condition, results of operation or prospects. In the event of a successful claim against us for infringement or misappropriation of a third party's proprietary rights, we may be required to:

- Pay damages, including up to treble damages, and the other party's attorneys' fees, which may be substantial;
- Cease the development, manufacture, marketing and sale of products or use of processes that infringe the proprietary rights of others;
- Expend significant resources to redesign our products or our processes so that they do not infringe the proprietary rights of others, which may not be possible;
- Redesign our products or processes to avoid third-party proprietary rights, which means we may suffer significant regulatory delays associated with conducting additional clinical trials or other steps to obtain regulatory approval; and
- Obtain one or more licenses arising out of a settlement of litigation or otherwise from third parties for the infringed proprietary rights, which may not be available to us on acceptable terms or at all.

Furthermore, litigation with any third party, even if the allegations are without merit, would likely be expensive and time-consuming and divert management's attention.

Any conclusions we may have reached regarding non-infringement and invalidity are based in part on a review of publicly available databases and other information. There may be information not available to us or otherwise not reviewed by us that might change our conclusions. Moreover, as described above, the scope and validity of patent claims are determined based on many facts and circumstances, and in a litigation, a court may reach a different conclusion on any given patent claim from the conclusions that we have reached.

Index

In addition, we may have to undertake costly litigation to enforce any patents issued or licensed to us or to determine the scope and validity of another party's proprietary rights. We can give no assurances that a court of competent jurisdiction would validate our issued or licensed patents. An adverse outcome in litigation or interference or other proceeding in any court or patent office could materially adversely affect our ability to develop and commercialize our product candidates.

If our settlement agreement with Tercica and Genentech (now Ipsen and Roche, respectively) is terminated, we will no longer have a license to manufacture IPLEX.

As part of our settlement agreement with Genentech and Tercica, we entered into a Consent Judgment and Permanent Injunction in the U.S. District Court for the Northern District of California, which permanently enjoins us from using or selling any products containing rhIGF-1 using any methods infringing the patents held by Genentech and Tercica. If our settlement agreement with Tercica and Genentech is terminated, the Consent Judgment and Permanent Injunction against us will survive termination, and we would no longer have a license to manufacture IPLEX using the present process without incurring significant penalties and royalties.

Risks related to Our Industry

Our agreement with Merck prohibits us from competing with Merck in the FOB arena.

In connection with the sale of our FOB platform to Merck in March 2009, we agreed not to compete, directly or indirectly, in the U.S. with Merck in the business of developing, marketing or manufacturing the FOB products or product candidates we sold to Merck for a period of five years beginning March 31, 2009. As a result, our ability to enter into licensing arrangements with third parties for FOB product candidates will be significantly limited.

We operate in a highly competitive and changing environment, and if we are unable to adapt to our environment, we may be unable to compete successfully.

Biotechnology and related pharmaceutical technology have undergone and are likely to continue to experience rapid and significant change. We expect that the technologies associated with biotechnology research and development will continue to develop rapidly. Our future success will depend in large part on our ability to maintain a competitive position with respect to these technologies and to obtain and maintain protection for our intellectual property. Any compounds, products or processes that we develop may become obsolete before we recover any expenses incurred in connection with their development. Rapid technological change could make our products obsolete, and materially adversely affect our business, financial condition, results of operations or future prospects.

We expect that successful competition will depend, among other things, on product efficacy, safety, reliability, availability, timing and scope of regulatory approval and price. Specifically, we expect crucial factors will include the relative speed with which we can develop products, complete the clinical testing and regulatory approval processes and supply commercial quantities of the product to the market. We expect competition to increase as technological advances are made and commercial applications broaden.

In each of our potential product areas, we face substantial competition from large pharmaceutical, biotechnology and other companies, universities and research institutions. Relative to us, most of these entities have substantially greater capital resources, research and development staffs, facilities and experience in conducting clinical studies and obtaining regulatory approvals, as well as in manufacturing and marketing pharmaceutical products. Many of our competitors may achieve product commercialization or patent protection earlier than us. Furthermore, we believe that our competitors have used, and may continue to use, litigation to gain a competitive advantage. Finally, our competitors may use different technologies or approaches to the development of products similar to the products we

are seeking to develop.

Competitors could develop and gain FDA approval of products containing amikacin, which could adversely affect our competitive position in all ARIKACE related indications for which we are currently developing products.

In the event there are other amikacin products approved by the FDA to treat indications other than those covered by ARIKACE, physicians may elect to prescribe a competitor's product containing amikacin or to treat the indications for which ARIKACE may receive approval, which is commonly referred to as off-label use. While under FDA regulations a competitor is not allowed to promote off-label use of its product, the FDA does not regulate the practice of medicine and as a result cannot direct physicians as to what product to prescribe to their patients. As a result, we would have limited ability to prevent off-label use of a competitor's product containing amikacin to treat any diseases for which we have received FDA approval, even if it violates our patents and we have orphan drug exclusivity for the use of amikacin to treat such diseases. This would reduce our revenues and harm our business.

Index

Competitors could develop and gain FDA approval of antibiotic products that are more effective, safer, more tolerable, more convenient or less expensive, which could adversely affect our competitive position in all ARIKACE related indications for which we are currently developing products.

We are aware of other companies developing potentially competitive products, which include oral, systemic or inhaled antibiotic products to treat chronic respiratory infections due to Pseudomonas. If any of our competitors develops a product that is more effective, safer, more tolerable, more convenient or less expensive than ARIKACE, it would adversely affect our ability to generate revenues. We may also face lower priced generic competitors where third-party payors will encourage their use or lower-priced versions of our product or competing products imported into the U.S. from Canada, Mexico and other countries where there are government price controls or other market dynamics that make the products lower priced.

Competitors could develop and gain FDA approval of products that treat the underlying cause of CF in a broader range of CF patients than Kalydeco by Vertex.

Kalydeco (ivacaftor) by Vertex was approved in January 2012 by the FDA as the first drug targeted to treat the underlying cause of a rare form of CF representing about 4% of patients with CF. Vertex also is studying Kalydeco in combination with another drug candidate for a more common CF mutation. The potential impact of Kalydeco (or similar products approved in the future) on inhaled antibiotic use in CF is uncertain at this time, and it is possible that these therapies could decrease the percentage of CF patients who acquire Pseudomonas lung infections and decrease the need for inhaled antibiotics.

If another party obtains orphan drug exclusivity for a product that is essentially the same as a product we are developing in a particular indication, we may be precluded or delayed from commercializing the product in that indication.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S. The Company that obtains the first marketing approval from the FDA for a designated orphan drug for a rare disease receives marketing exclusivity for use of that drug for the designated condition for a period of seven years. Similar laws exist in EU. If a competitor obtains approval of the same drug for the same indication or disease before us, we would be blocked from obtaining approval for our product for seven or more years, unless our product can be shown to be clinically superior. In addition, more than one drug may be approved by the FDA for the same orphan indication or disease as long as the drugs are different drugs. As a result, even if our product is approved and receives orphan drug exclusivity, as in the case of our drugs ARIKACE and IPLEX, the FDA can still approve different drugs for use in treating the same indication or disease covered by our product, which could create a more competitive market for us.

Index

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information.

In order to protect our proprietary technology and processes, we rely in part on confidentiality agreements with our corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our ability to successfully compete in the industry.

Our research, development and manufacturing activities used in the production of ARIKACE involve the use of hazardous materials, which could expose us to damages that could materially adversely affect our results of operations and financial condition.

Our research, development and manufacturing activities for ARIKACE involve the controlled use of hazardous materials and chemicals. Our contract manufacturer has the facilities and equipment for the appropriate handling of such material at our current scale of operations. However, if any liability arises, we could be liable for any losses incurred by the contract manufacturer, which could materially adversely affect our results of operations and financial conditions. Future plans may require scale-up of our process for either development of commercialization, which may necessitate new facilities and equipment. Permits to obtain and operate our processes may require local and/or state approval, which might not be easily obtained.

We may be subject to product liability claims if our products harm people, and we have only limited product liability insurance.

The manufacture and sale of human therapeutic products involve an inherent risk of product liability claims and associated adverse publicity. We currently have only limited product liability insurance for our products. We do not know if we will be able to maintain existing or obtain additional product liability insurance on acceptable terms or with adequate coverage against potential liabilities. This type of insurance is expensive and may not be available on acceptable terms. If we are unable to obtain or maintain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims, we may be unable to commercialize our products. A successful product liability claim brought against us in excess of our insurance coverage, if any, may require us to pay substantial amounts and have a material adverse effect on our business, financial condition, results of operations or future prospects.

Risks Related to Employee Matters and Managing Growth

We are dependent upon retaining and attracting key personnel and others, the loss of whose services could materially adversely affect our business, financial condition, results of operations and prospects.

We depend highly on the principal members of our scientific and management personnel, the loss of whose services might significantly delay or prevent the achievement of our research, development or business objectives. Our success depends, in large part, on our ability to attract and retain qualified management, scientific and medical personnel, and on our ability to develop and maintain important relationships with commercial partners, leading research institutions and key distributors.

Competition for skilled personnel in our industry and market is very intense because of the numerous pharmaceutical and biotechnology companies that seek similar personnel. These companies may have greater financial and other

resources, offer a greater opportunity for career advancement and have a longer history in the industry than we do. We also experience competition for the hiring of our scientific and clinical personnel from universities, research institutions, and other third parties. We cannot assure that we will attract and retain such persons or maintain such relationships. We have key person insurance of $1 million for Mr. Whitten, our CEO, but do not have such coverage for other employees.

We expect that our potential expansion into areas and activities requiring additional expertise, such as further clinical trials, governmental approvals, manufacturing, sales, marketing and distribution will place additional requirements on our management, operational and financial resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees.

Index

Our potential growth could require significant capital expenditures and may divert financial resources from other projects, such as the anticipated commercialization of ARIKACE or development of additional product candidates. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate or increase our revenues could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize ARIKACE and our other product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Risks Related to our Common Stock and Listing on the NASDAQ Capital Market

The market price of our stock has been and may continue to be highly volatile, and historically we have never paid dividends on our common stock, and we have no plans to pay dividends in the foreseeable future.

Our common stock is listed on the NASDAQ Capital Market under the ticker symbol INSM. The market price of our stock has been and may continue to be highly volatile, and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control. These factors may include:

- Our listing status on the NASDAQ Capital Market;
- Results of our clinical studies and preclinical studies, or those of our corporate partners or our competitors;
- Delays in timing of pre-clinical, clinical development and regulatory filings and delays regarding our inability to obtain potential approvals
- Strategic business decisions;
- Developments in our relationships with corporate partners;
- Developments affecting our corporate partners;
- Negative regulatory action or regulatory approval with respect to our announcement or our competitors' announcements of new products;
- Government regulation, reimbursement changes and governmental investigation or audits related to us or to our products;
- Developments related to our patents or other proprietary rights or those of our competitors;
- Other competitor developments;
- Changes in the position of securities analysts with respect to our stock or changes in stock ownership by investors;
- Operating results below the expectations of public market analysts and investors; and
- The need or perceived need to raise additional capital.

In addition, the stock market has from time to time experienced extreme price and volume fluctuations, which have particularly affected the market prices for emerging biotechnology and pharmaceutical companies, and which have often been unrelated to their operating performance. These broad market fluctuations may adversely affect the market price of our common stock.

47

Index

In the past, when the market price of a stock has been volatile, holders of that stock have often instituted securities class action litigation against the Company that issued the stock. If any of our shareholders bring a lawsuit against us, we could incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of our management.

Future sales of substantial amounts of common stock in the public market, or the possibility of such sales occurring, could also adversely affect prevailing market prices for our common stock or our future ability to raise capital through an offering of equity securities. At the time of the Merger, certain former Transave stockholders holding approximately 40% of our shares of common stock as of December 1, 2010, entered into lock-up arrangements with us in connection with the Merger and could only dispose of their shares beginning 180 days following the closing date of the Merger (or May 30, 2011). Thereafter, these shareholders may dispose of up to one-third of their shares received in the Merger during each six-month period following May 30, 2011 (with each additional one-third increment being cumulative). These lock-up arrangements expire on May 30, 2012, and these shareholders may dispose of their shares freely after such date. Other than the shares of our common stock subject to lock-up arrangements, all of our common stock is freely tradable in the public market without restriction under the Securities Act, unless these shares are held by our "affiliates," as that term is defined in Rule 144 under the Securities Act.

Historically we have never paid dividends on our common stock and we currently intend to retain our future earnings, if any, to fund the development and growth of our businesses and, therefore, we do not anticipate paying any cash dividends from earnings in the foreseeable future. The remaining available proceeds from the sale of our FOB assets to Merck will be primarily used for the Phase 3 trials and commercialization efforts directed towards ARIKACE.

If we fail to meet the continued listing requirements of the NASDAQ Capital Market, our common stock may be delisted from the NASDAQ Capital Market, which may cause the value of an investment in our common stock to substantially decrease.

We may be unable to meet the continued listing requirements of the NASDAQ Capital Market. If a delisting from the NASDAQ Capital Market were to occur, our common stock would be eligible, upon the application of a market maker, to trade on the OTC Bulletin Board or in the "pink sheets." These alternative markets are generally considered to be less efficient than, and not as broad as, the NASDAQ Capital Market or the NASDAQ Global Market. Therefore, delisting of our common stock from the NASDAQ Capital Market could adversely affect the trading price of our common stock and could limit the liquidity of our common stock and therefore could cause the value of an investment in our common stock to decrease.

Exercise of warrants and options issued by us will dilute the ownership interest of existing shareholders.

As of March 9, 2012, the warrants issued by us in May 2007 were exercisable for up to approximately 160,000 shares of our common stock.

As of March 9, 2012, our outstanding restricted stock, restricted stock units and stock options to our employees, officers, directors and consultants were exercisable for up to 143,851 shares of our common stock.

The conversion or exercise of some or all of our warrants, restricted stock, restricted stock units and options will dilute the ownership interests of existing shareholders. Any sales in the public market of the common stock issuable upon such conversion or exercise could adversely affect prevailing market prices of our common stock.

Certain provisions of Virginia law, our articles of incorporation and our amended and restated bylaws make a hostile takeover by a third party difficult.

Certain provisions of Virginia law and our articles of incorporation and amended and restated bylaws could hamper a third party's acquisition of, or discourage a third party from attempting to acquire control of us. The conditions could also limit the price that certain investors might be willing to pay in the future for shares of our common stock. These provisions include:

Index

- A provision allowing us to issue preferred stock with rights senior to those of the common stock without any further vote or action by the holders of the common stock. The issuance of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of common stock or could adversely affect the rights and powers, including voting rights, of the holders of the common stock. In certain circumstances, such issuance could have the effect of decreasing the market price of the common stock;

- The existence of a staggered board of directors in which there are three classes of directors serving staggered three-year terms, thus expanding the time required to change the composition of a majority of directors and perhaps discouraging someone from making an acquisition proposal for us;

- The amended and restated bylaws' requirement that shareholders provide advance notice when nominating our directors;

- The inability of shareholders to convene a shareholders' meeting without the chairman of the board, the president or a majority of the board of directors first calling the meeting; and

- The application of Virginia law prohibiting us from entering into a business combination with the beneficial owner of 10% or more of our outstanding voting stock for a period of three years after the 10% or greater owner first reached that level of stock ownership, unless we meet certain criteria.

In addition, for ten years we had a "poison pill" shareholder rights plan, which expired in May 2011 without extension. Under Virginia law, our board of directors may implement a new shareholders rights plan without shareholder approval. Our board of directors intends to regularly consider this matter, even in the absence of specific circumstances or takeover proposals, to facilitate its ability in the future to act expeditiously and appropriately should the need arise.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

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 laboratory and office space at 9 Deer Park Drive. From September 2011 through December 2011, we subleased the new facility from the existing lessor, a large pharmaceutical company that had vacated the facility. The lease for the same building commenced with our current landlord, Princeton Corporate Plaza LLC, beginning in January 2012 and will expire 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 also retained approximately 1,350 sq. ft. of lab space at 11 Deer Park Drive under a lease, which also expires in December 2014. The additional space at 11 Deer Park Drive will be utilized to support the manufacture of ARIKACE for our clinical programs. Total financial obligations through the term of the new facility lease are approximately $2.1 million. We determined that the larger facility is required for our growing clinical, regulatory and development efforts in support of our ARIKACE programs in CF and NTM.

The annual cash costs for our New Jersey facilities including utilities and services in 2011 and 2010 were approximately $1.0 and $1.0 million, respectively, under an operating lease that expires in December 2014.

Our previous headquarters located in Richmond, Virginia, where we occupied approximately 18,000 square feet of space for corporate and development activities under a lease expiring in October 2016 has been closed and our current plan is to sublet this space. Our Richmond lease contains annual rent escalations of 3%. Our annual cash cost for the

Virginia space including utilities and services in fiscal 2011 and 2010 were approximately $0.5 and $0.4 million, respectively. Commitments for the Richmond office lease through October 2016 term are approximately $2.3 million. At December 31, 2011, we have recorded a net present value charge of $1.2 million in general and administrative expenses associated with the vacant Richmond facility.

Index

We believe that our existing New Jersey facilities are adequate for our current needs.

ITEM 3. LEGAL PROCEEDINGS

Cacchillo v. Insmed

On October 6, 2010, a complaint was filed against us by Angeline Cacchillo ("Plaintiff") in the U.S. District Court for the Northern District of New York (the "Court"), captioned Cacchillo v. Insmed, Inc., No. 1:10-cv-0199, seeking monetary damages and a court order requiring Insmed to support her compassionate use application to the FDA and if approved, to provide her with IPLEX. Plaintiff was a participant in the Phase 2 clinical trial of IPLEX sponsored by us evaluating the effectiveness of the investigational drug in patients with type 1 myotonic muscular dystrophy ("MMD").

In the complaint, Plaintiff alleged (i) violation of constitutional due process and equal protection by depriving Plaintiff of continued access to IPLEX, (ii) fraudulent inducement to enter the Phase 2 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 U.S. Court of Appeals for the Second Circuit, which affirmed the trial court's order denying the Plaintiff's motion for a preliminary injunction.

We filed a motion with the Court to dismiss all of the outstanding claims, and on June 29, 2011, the Court dismissed six of Plaintiff's claims, leaving outstanding the claims for (i) fraudulent inducement, (ii) negligent misrepresentation, and (iii) breach of contract. We filed an answer and affirmative defenses with the Court on July 12, 2011. Plaintiff's claim for monetary damages and specific performance with respect to these claims remains outstanding. The Court has scheduled a trial date in October 2012.

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. Insmed

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. Insmed 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 Insmed Incorporated, River Acquisition Co., Transave, LLC, Transave and TVM V Life Science Ventures GmbH & Co. KG, in its capacity as stockholders' agent (the "Merger Agreement"). 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 Merger. In addition, pursuant to the terms of the settlement, we agreed to pay plaintiff's legal fees and expenses.

Pilkiewicz v. Transave LLC

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

Index

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

Under the terms of the Merger Agreement, certain of the former stockholders of Transave are obligated to indemnify us for certain liabilities in connection with the appraisal action. We believe that the allegations contained in the amended petition are without merit and we intend to continue to vigorously defend this action. It is not possible at this time to estimate the amount of loss or range of possible loss, if any, that might result from an adverse resolution of this action.

From time to time, we are a party to various 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 4. (REMOVED AND RESERVED)

Index

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock began trading on the NASDAQ Small Cap Market on June 1, 2000, and moved to the NASDAQ Global Market (formerly the NASDAQ National Market) on August 8, 2000. On February 29, 2009, our common stock was transferred from the NASDAQ Global Market to the NASDAQ Capital Market following a decision by NASDAQ's listing panel.

Our trading symbol is "INSM." Beginning March 2, 2011, we temporarily traded under the symbol "INSMED" following the reverse stock split for a period of approximately 20 days. The following table lists, for the periods indicated, the high and low sale prices per share for our common stock as reported on the NASDAQ Capital Market for both fiscal 2011 and fiscal 2010 adjusted for the one-for-ten reverse stock split.

Fiscal Year 2011	High	Low
Fourth Quarter	$ 5.23	$ 2.64
Third Quarter	12.62	3.20
Second Quarter	13.50	6.70
First Quarter	6.89	4.69
Fiscal Year 2010	High	Low
Fourth Quarter	$ 7.30	$ 5.70
Third Quarter	7.70	6.20
Second Quarter	12.10	5.90
First Quarter	13.20	7.50

On March 9, 2012, the last reported sale price for our common stock on the NASDAQ Capital Market was $3.96 per share. As of March 9, 2012, there were approximately 130 holders of record of our common stock.

We have never declared or paid dividends on our common stock. We anticipate that we will retain all earnings, if any, to support operations and to finance the growth and development of our business. Therefore, we do not expect to pay cash dividends from earnings in the foreseeable future. Any future determination as to the payment of dividends will be at the sole discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements and other factors our board of directors deems relevant.

Index

PERFORMANCE GRAPH

ITEM 6. SELECTED FINANCIAL DATA

In the table below, we present historical financial data for the past five years of our operations. We have prepared this information using consolidated financial statements for each of the five years ended December 31, 2011. The financial statements for each of the five fiscal years ended December 31, 2011, have been audited by Ernst & Young LLP, our independent registered public accounting firm. Ernst & Young LLP's report on the consolidated financial statements as of December 31, 2011 and 2010, and for the years ended December 31, 2011, 2010 and 2009 appears elsewhere herein.

When you read this selected historical financial data, it is important that you also read the historical financial statements and related notes in our annual and quarterly reports filed with the Securities and Exchange Commission as well as "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Index

	Year Ended December 31,				
	2007	2008	2009	2010	2011
	(in thousands, except per share data)				
Historical Statement of Operations Data:					
Revenues	$ 7,581	$ 11,699	$ 10,373	$ 6,921	$ 4,417
Operating expenses:					
Cost of goods sold	576	-	-	-	-
Research and development	19,198	21,047	9,207	4,757	27,917
General and administrative	8,246	5,063	9,840	10,256	12,229
Impairment loss	-	-	-	-	25,990
Total operating expenses	28,020	26,110	19,047	15,013	66,136
Operating loss	(20,439)	(14,411)	(8,674)	(8,092)	(61,719)
Gain on sale of asset, net	-	-	127,474	-	1
Interest income	1,159	500	808	1,845	2,064
Interest expense	(682)	(1,256)	(781)	(109)	(10)
Loss on investments	-	(500)	-	-	-
(Loss) income before income taxes	(19,962)	(15,667)	118,827	(6,356)	(59,664)
Income tax expense	-	-	(477)	(78)	-
Net (loss) income	(19,962)	(15,667)	118,350	(6,434)	(59,664)
Accretion of beneficial conversion feature	-	-	-	-	(9,175)
Net (loss) income attributable to common stockholders	$ (19,962)	$ (15,667)	$ 118,350	$ (6,434)	$ (68,839)
Basic and diluted net (loss) income attributable to common stockholders per common share	$ (1.74)	$ (1.28)	$ 9.31	$ (0.49)	$ (2.95)
Weighted average basic and diluted common shares outstanding	11,468	12,213	12,712	13,250	23,348
Historical Balance Sheet Data:					

Cash, cash equivalents and short-term investments	$ 16,479	$ 2,397	$ 122,181	$ 108,049	$ 76,272
Certificate of deposit	$ 2,085	$ 2,085	$ 2,085	$ 2,176	$ 2,085
Total assets	$ 19,500	$ 4,758	$ 126,695	$ 196,265	$ 139,833
Long-term debt, net	$ 2,113	$ 487	$ -	$ -	$ -
Net Stockholders' equity (deficit)	$ 11,488	$ (2,823)	$ 123,914	$ 192,843	$ 134,267

Index

ITEM 7.MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion also should be read in conjunction with the Consolidated Financial Statements and notes thereto.

OVERVIEW

Insmed® Incorporated is a development-stage biopharmaceutical company with expertise in proprietary, advanced liposomal technology designed specifically for inhalation lung delivery. We develop innovative inhaled treatments for serious lung infections. Our proprietary liposomal technology is designed specifically for delivery of pharmaceuticals to the lung, and we believe it 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 on orphan markets with high unmet medical needs, which we believe presents a significant opportunity, as their challenge 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 aeruginosa (hereafter referred to as Pseudomonas) lung infections in cystic fibrosis (CF) patients and patients with non-tuberculous mycobacterial (NTM) lung infections.

We completed the Merger on December 1, 2010, with Transave, a privately-held, NJ-based pharmaceutical company focused on the development of differentiated and innovative inhaled pharmaceuticals for the site-specific treatment of serious lung infections. Our integration with Transave was completed in 2011 including the relocation of corporate headquarters to Monmouth Junction, New Jersey, and cessation of operations at the Richmond, Virginia, location as of December 31, 2011. On March 2, 2011, we completed a one-for-ten reverse stock split of our common stock. Unless otherwise noted, the per share amounts in this 10-K give retroactive effect to the reverse stock split for all periods presented.

After giving effect to the Merger, former Transave stockholders had approximately a 46.7% equity interest in the combined Company (on an as-converted, fully diluted basis), and legacy Insmed Incorporated shareholders had a 53.3% equity interest. The shares retained by us pursuant to the Merger agreement with Transave (approximately 1.76 million shares of common stock after giving effect to the conversion of the Series B Preferred Stock and the one-for-ten reverse stock split of our common stock) will be delivered on June 12, 2012 to certain former Transave stockholders, subject to reduction for any claims and indemnification payments that are pending.

KEY COMPONENTS OF OUR STATEMENT OF OPERATIONS

Revenues

Our revenue consists of secondary revenue streams for IPLEX® 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 ceased in December 2011, when our IPLEX inventory was fully depleted.

Research and Development Expenses

Research and development expenses consist primarily of salaries and related expenses, cost to develop and manufacture drug candidates, patent protection costs, amounts paid to contract research organizations, hospitals and

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

Index

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. In August 2011 the Food and Drug Administration (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. In January 2012 following the filing of a complete clinical response to requests for information from the FDA, the agency lifted the clinical hold of ARIKACE in the NTM indication noting that the company could initiate a Phase 2 clinical trial for patients with NTM under an agreed protocol. The clinical hold for ARIKACE in the CF indication in the U.S. currently remains in place, and we continue to have dialogue with the FDA to attempt to lift the CF clinical hold. In February 2012 the company announced that it would be initiating the ARIKACE NTM trial as a Phase 2 trial, as well as the previously planned Phase 3 trial for ARIKACE in the CF indication in Europe. Also In February 2012, we filed our complete response to the FDA clinical hold on the U.S. study of ARIKACE in CF patients with Pseudomonas infection. We will continue discussions with the FDA to pursue removal of the clinical hold on ARIKACE in U.S. for the treatment of CF patients with Pseudomonas lung infections.

We are moving forward with the ARIKACE clinical development program in CF in Europe. The European study in CF patients with Pseudomonas lung infections will be a randomized, phase 3 trial comparing ARIKACE 560 mg, delivered once daily via an optimized, investigational eFlow Nebulizer System, to TOBI®(1) (inhaled tobramycin solution), which is a marketed inhaled antibiotic that is delivered twice daily. The Company anticipates that the study will be conducted in approximately 300 patients. The primary endpoint will be change in pulmonary function (FEV-1) measured after three 28 day on-treatment and three 28 day off-treatment cycles (about six months). A key secondary endpoint will be time to pulmonary exacerbation. The study design was previously agreed upon by Insmed and the European Medicines Agency. Eligible patients will have the option to participate in a longer term open-label safety study. The Company expects to begin enrolling patients in the phase 3 European clinical study in the second quarter of 2012.

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 2012 and the foreseeable future.

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 clinical hold for ARIKACE in the CF indication in the U.S. could remain in place or that necessary regulatory approvals may not be obtained. In addition, the duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during the clinical trial, including, among others, the following:

- the number of patients that ultimately participate in the trial;

- the duration of patient follow-up that is determined to be appropriate in view of results;
- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patient subjects; and

Index

- 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. In August 2011, we announced that in separate actions the FDA had placed a clinical hold on our Phase 3 clinical trials for ARIKACE in CF patients with Pseudomonas lung infections and for patients with NTM lung infections. The FDA informed us that this decision was based on an initial review of the results of a long-term rat inhalation carcinogenicity study with ARIKACE. In August 2011, we announced that the FDA had placed the clinical trial programs for CF and NTM on clinical hold due to findings from a two-year rat inhalation carcinogenicity study. As part of the study, rats were given ARIKACE daily by inhalation for almost two years. Two of the 120 rats receiving the highest dose had a single lung tumor. These rats received ARIKACE doses that are much greater than the doses to be administered to humans. The relevance of the observed rat tumors to the use of ARIKACE in humans is unknown. ARIKACE was not associated with changes that may lead to tumors in shorter-term studies that we conducted in other animals. Additionally, in a standard series of tests that we performed, ARIKACE was not shown to be genotoxic. The FDA requested additional information on ARIKACE and data from the rat study. As a result of the clinical hold, we suspended initiation of the ARIKACE Phase 3 clinical trial programs, including the recruitment and enrollment of patients.

We provided the requested information to the FDA in August and were informed by the FDA that, based on its review of the information provided to date, including the rat inhalation carcinogenicity study results, the FDA had insufficient information to assess the risks for ARIKACE in CF patients. In October 2011, the FDA notified us that the FDA was continuing the clinical hold previously placed on our Phase 3 clinical trial for ARIKACE in CF patients with Pseudomonas lung infections and in patients with NTM lung infections. Regarding the clinical hold for CF patients with Pseudomonas lung infections, the FDA requested additional information from the us, including that we conduct a nine-month dog inhalation toxicity study of ARIKACE to determine if the findings of the rat inhalation carcinogenicity study are also observed in a non-rodent model and to propose a CF patient population/disease state in which the risk-benefit profile of ARIKACE may be more favorable. We were informed during further dialogue with the FDA that if we chose to proceed, the required nine-month dog inhalation toxicity study of ARIKACE could be conducted in parallel with the CF Phase 3 clinical trials in human subjects. Regarding the clinical hold for patients with NTM lung infections, the FDA requested we conduct a Phase 2 clinical trial in adult (age 18 and older) NTM patients to provide proof-of-concept efficacy and safety data for ARIKACE in NTM patients.

In January 2012, the FDA lifted the clinical hold on ARIKACE in patients with NTM lung infections. We intend to conduct, as requested by the FDA, a Phase 2 clinical trial in adult NTM patients to provide proof-of-concept efficacy and safety data for ARIKACE in NTM patients. We expect to begin enrolling patients in the Phase 2 clinical trial in mid-2012. We have also begun the work required to allow the Company to initiate the nine-month dog inhalation toxicity study in the second quarter of 2012.

In February 2012, we filed our complete response to the FDA clinical hold on the U.S. study of ARIKACE in CF patients with Pseudomonas infection. We will continue discussions with the FDA to pursue removal of the clinical hold on ARIKACE in U.S. for the treatment of CF patients with Pseudomonas lung infections. 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.

Index

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits and other related costs, including stock-based compensation, for personnel serving in our executive, finance, accounting, legal, market research and human resource functions, and professional fees for legal, including patent-related expenses, consulting, tax and accounting services. Our general and administrative expenses also include facility and related costs not included in research and development expenses, insurance, depreciation and general corporate expenses. We expect that our general and administrative expenses will increase with the continued development and commercialization of our product candidates.

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

Comparison of Years Ended December 31, 2011 and 2010

Net loss attributable to common stockholders for the year ended December 31, 2011 was $68.8 million (or $2.95 per common share – basic and diluted) compared with a net loss of $6.4 million (or $0.49 per common share – basic and diluted) for the year ended December 31, 2010. The net loss attributable to common stockholders in 2011 includes the $26 million non-cash charge from the impairment adjustment in the third quarter of 2011 and the conversion of the Series B Preferred Stock and a non-cash charge incurred in the first quarter of 2011 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 $0.39 for the year ended December 31, 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

For the year-ended December 31, 2011, revenues totaled $4.4 million, as compared with $6.9 million for the year-ended December 31, 2010. The $2.5 million reduction was primarily due to year-over-year decrease of $3.5 million in cost recovery from our IPLEX EAP in Europe, offset with $1.0 million in license fees from the licensing of patent technology related to Insmeds CISPLATIN Lipid Complex.

Research and Development Expenses

Research and development expenses for the years ended December 31, 2011 and 2010, comprised the following.

58

Index

	Year Ended December 31,		Increase (Decrease)	
	2011	2010	$	%
	(in thousands)			
Clinical development	$ 14,883	$ 1,255	$ 13,628	1086 %
Clinical manufacturing	4,790	318	4,472	1406 %
Regulatory and quality assurance	2,555	728	1,827	251 %
Compensation and related	5,689	2,456	3,233	132 %
	$ 27,917	$ 4,757	$ 23,160	487 %

Research and development expenses increased to $27.9 million in 2011 from $4.8 million in 2010. The increase of $23.2 million in 2011 is solely attributable to the research and development of ARIKACE program and the manufacturing of supply to support the planned studies.

Clinical development expenses increased $13.6 million in 2011 compared with 2010 as a result of the planning efforts for the ARIKACE studies and the final payments for an earlier carcinogenicity study associated with the ARIKACE development program. The $4.5 million increase in clinical manufacturing expenses from 2011 to 2010 is attributable to the manufacturing of ARIKACE for use in these studies.

The regulatory and quality assurance increase of $1.8 million in the year ended 2011 compared with 2010 is also attributable to the planning associated with the clinical studies, noted above.

Higher compensation and related expenses of $3.2 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 11 as of December 31, 2010 to 28 as of December 31, 2011 due primarily to the introduction of the ARIKACE development program, which became our lead development program following the Merger with Transave in December 2010.

General and Administrative Expenses

General and administrative expenses increased to $12.2 million in 2011 from $10.3 million in 2010. The $1.9 million increase was due primarily to a $1.2 million charge in the fourth quarter of 2011 resulting from the closure of the Richmond office following cessation of IPLEX EAP activities in December 2011 and to an increase in headcount and average per salary headcount to provide administrative support for the full-scale development of ARIKACE. Overall general and administrative headcount increased from approximately 7 as of December 31, 2010 to 14 as of December 31, 2011 in support of the larger business and development program following the Merger with Transave in December 2010.

Impairment Loss

Impairment loss was $26.0 million for the year ended December 31, 2011 compared with zero for the same period in 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, or IPR&D intangible and goodwill assets due to the material impact of a clinical hold on our ARIKACE development program. In January 2012, the FDA lifted the clinical hold on ARIKACE in the NTM indication. In February 2012 the Company announced that it would be initiating the ARIKACE NTM trial as a Phase 2 trial, as well as the previously planned Phase 3 trial for ARIKACE in the CF indication in Europe. Also In February 2012, we filed our complete response to the FDA clinical hold on the U.S. study of ARIKACE in CF patients with Pseudomonas infection. We will continue discussions with the FDA to pursue removal of the clinical hold on ARIKACE in U.S. for the treatment of CF patients with Pseudomonas lung infections.

As a result of these events, the Company believes that the October 1, 2011 valuation of the overall IPR&D is reasonable and that no additional impairment of IPR&D exists as of December 31, 2011.

The Company used the multi-period excess earnings method ("MPEEM"), which is a form of the income approach to derive the fair value of IPR&D intangible and goodwill assets. This approach calculates fair value by estimating future cash flows attributable to the assets and then discounting these cash flows to a present value using a risk-adjusted discount rate. A market based valuation approach was not considered given a lack of revenues and profits for the Company. This approach requires significant management judgment with respect to future volume, revenue and expense growth rates, changes in working capital use, appropriate discount rates and other assumptions and estimates. The estimates and assumptions used are consistent with our business plans. The use of alternative estimates and assumptions could increase or decrease the estimated fair value of the asset, and potentially result in different impacts to Insmed's results of operations. Actual results may differ from management's estimates.

Index

Investment Income and Interest Expense

Investment income, net of interest expense, increased to $2.1 million in 2011 from $1.7 million in 2010. The $0.3 million increase is a result of improved returns on our short-term investments totaling $61.4 million as of December 31, 2011, despite a decrease in overall short-term investment balances year over year. The reduction in interest expense in 2011 compared with 2010 was entirely due to the elimination of convertible notes, which were fully repaid in March 2010.

Comparison of Years Ended December 31, 2010 and 2009

Net loss for the year ended December 31, 2010 was $6.4 million (or $0.49 per common share – basic and diluted), compared with net income of $118.4 million, (or $9.30 per common share – basic and $9.31 per common share - diluted), for the year ended December 31, 2009. The $124.8 million variance from 2009 to 2010 was due to a $127.0 million after tax gain on the sale of our FOB assets to Merck & Co., Inc., in 2009.

Revenue

For the year-ended December 31, 2010, revenues totaled $6.9 million, as compared with $10.4 million for the year-ended December 31, 2009. The $3.5 million decrease was primarily due to a year-over-year decrease of $2.3 million in cost recovery from our IPLEX EAP in Europe, a $1.0 million reduction in grant revenue related to the 2009 receipt of a $1.0 million grant from the Muscular Dystrophy Association and $0.1 million in reduced royalties.

Research and Development Expenses

Research and development expenses for the years ended December 31, 2010 and 2009 comprised the following:

	Year Ended December 31,		Increase (Decrease)	
	2010	2009	$	%
	(in thousands)			
Clinical development	$1,255	$500	$755	151 %
Clinical manufacturing	318	1,721	(1,403)	-82 %
Regulatory and quality assurance	728	995	(267)	-27 %
Compensation and related	2,456	5,991	(3,535)	-59 %
	$4,757	$9,207	$(4,450)	-48 %

Research and development expenses decreased to $4.8 million in 2010 from $9.2 million in 2009. The decrease of $4.5 million in 2010 is attributable to a reduction in manufacturing costs following the sale of Insmed's FOB assets in March 2009, partially offset by the ARIKACE related research and development expenses incurred in December 2010.

General and Administrative Expenses

General and administrative expenses increased to $10.3 million in 2010 from $9.8 million in 2009. The $0.4 million increase was due largely to the increased finance, legal and consulting fees related to the business combination with Transave on December 1, 2010.

Index

Investment Income and Interest Expense

Investment income, net of interest expense increased to $1.7 million in 2010 from less than $0.1 million in 2009. The increase is a result of increased cash position from 2009 to 2010, and improved returns on our short-term investments totaling $97.3 million as of December 31, 2010. The reduction in interest expense in 2010 compared with 2009 was due to the elimination of debt discount amortization.

Gain on Sale of Asset, Net

The gain on sale of asset, net decrease to zero in 2010 from $127.5 million in 2009, represents the gain on sale of the Company's FOB assets to Merck in 2009.

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. 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. 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 terminated in the fourth quarter of 2011. As of December 31, 2011, we had total cash, cash equivalents, short-term investments and certificate of deposits on hand of $78.4 million, consisting of $76.3 million in cash and short-term investments and $2.1 million in a certificate of deposit, as compared with $110.2 million of cash, cash equivalents, short term investments and certificate of deposit on hand as of December 31, 2010. The $31.7 million decrease in total cash and investments was due to the funding of operations, primarily research and development activities. Our working capital was $72.9 million as of December 31, 2011.

Even though we believe we currently have sufficient funds to meet our financial needs for 2012, 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 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 $30.2 million, $7.7 million and $11.0 million for the years ended December 31, 2011, 2010 and 2009, respectively. Net cash used in operating activities in 2011 related primarily to a net loss of $59.7 million from higher operating expenses and decreased revenues, partially offset by a non-cash charge of $26.0 million for intangible and goodwill impairment loss. Net cash used in operating activities in 2010 related to a net loss of $6.4 million and a $1.7 million increase in working capital. Net cash used in operating activities in 2009 related primarily to the add back for gain on sale of FOB assets of $127.5 million and an increase in working capital of $2.8 million offset by net income of $118.5 million.

Net cash provided by investing activities was $34.4 million, $6.0 million and $18.7 million for the years ended December 31, 2011, 2010 and 2009, respectively. The net cash provided by investing activities in 2011 was primarily a result of $36.5 million from the sale of short-term investments partially offset by asset purchases of $1.2 million. The net cash provided by investing activities in 2010 was primarily a result of $12.7 million from the sale of short-term investments partially offset by $6.7 million used in the Merger. The net cash provided by investing activities in 2009 was primarily a result of $127.5 million cash received from the sale of FOB assets partially offset by $108.7 million used in the purchase of short-term investments.

Net cash (used in) provided by financing activities was $(0.1) million, ($0.2) million and $2.9 million for the years ended December 31, 2011, 2010 and 2009, respectively. Net cash used in financing activities in 2011 was primarily a result of capital lease obligation payments. Net cash used in financing activities in 2010 was due to the final payment of the 2005 convertible notes. Net cash provided by financing activities in 2009 was primarily a result of the conversion of warrants to shares and proceeds from the issuance of common stock partially offset by repayments on convertible notes.

Index

Contractual Obligations

We are obligated to make future payments under various contracts as set forth below:

	Payments Due by Years (in thousands)					
	Total	2012	2013	2014	2015	2016
Operating lease obligations	$4,495	$1,183	$1,189	$1,201	$498	$425
Capital lease obligations	287	121	102	64	-	-
Total Contractual Obligations	$4,782	$1,304	$1,291	$1,265	$498	$425

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.

Critical Accounting Policies

Preparation of financial statements in accordance with generally accepted accounting principles in the United States requires us to make estimates and assumptions affecting the reported amounts of assets, liabilities, revenues and expenses and the disclosures of contingent assets and liabilities. We use our historical experience and other relevant factors when developing our estimates and assumptions. We continually evaluate these estimates and assumptions. The accounting policies discussed below are those we consider critical to an understanding of our consolidated financial statements because their application places the most significant demands on our judgment. Actual results could differ from our estimates. For additional accounting policies, see Note 1 to our Consolidated Financial Statements – “Description of the Business and Summary of Significant Accounting Policies.”

Research and Development

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

Revenue Recognition

We record revenue from product sales when the goods are delivered and title passes to the customer. At the time of sale, estimates for sales deductions, including rebates to government agencies, are recorded. These provisions are provided for in the same period the related product sales are recorded. Following our settlement agreement with Tercica, Inc. (now Ipsen, Inc.), and Genentech, Inc. (now Hoffman-LaRoche Ltd. or Roche), on March 5, 2007, we ceased to supply IPLEX to patients and discontinued sales of IPLEX for short stature disorders as of March 7,

2007. Revenue from our EAP in Italy is recognized when the drugs have been provided to program patients and collectability is assured. Royalties that were paid to Tercica and Genentech are netted against EAP revenue. License fee income is recognized as revenue when the milestones are achieved and payments are due. Grant revenue is recognized once payment has been due.

Index

Beneficial Conversion Charge "BCC"

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 6 of the consolidated financial statements for further information about the beneficial conversion feature.

Stock-Based Compensation

We adopted the fair-value-based method of accounting for share-based payments effective January 1, 2006, using the "modified prospective transition method." Currently, we use the Black-Scholes-Merton formula to estimate the value of stock options granted to employees and expect to continue to use this option valuation model. Under that transition method, compensation cost recognized during the year included: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant date fair valued.

New Accounting Pronouncements

For a discussion of recently issued accounting pronouncements requiring adoption subsequent to December 31, 2011, see Note 1 to the consolidated financial statements included in Item 8. "Financial Statements and Supplementary Data."

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We invest excess cash in investment grade, interest-bearing securities and, at December 31, 2011, had $78.4 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 at December 31, 2011, are 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 fiscal 2011, 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.

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 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by Item 8 is set forth on pages 69-96.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Index

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 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 December 31, 2011, our Chief Financial Officer has concluded that our disclosure controls and procedures are effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended). Our internal control over financial reporting was designed to provide reasonable assurance to our management and board of directors regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles (GAAP).

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2011, based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control — Integrated Framework. Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of our internal control over financial reporting. Based on this assessment, our management concluded that, as of December 31, 2011, our internal control over financial reporting was effective.

Ernst & Young LLP, our independent registered public accounting firm, has issued an audit report on the effectiveness of our internal control over financial reporting. The report of Ernst & Young LLP is contained in Item 15 of this Annual Report on Form 10-K.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2011, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B.OTHER INFORMATION

None.

Index

PART III

ITEM 10.DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by Item 10 of Form 10-K is incorporated by reference from the discussion responsive thereto under the captions “Election of Directors” and “Section 16(A) Beneficial Ownership Reporting Compliance” in our definitive proxy statement for our 2012 annual meeting of stockholders to be filed with the Securities and Exchange Commission.

ITEM 11.EXECUTIVE COMPENSATION

The information required by Item 11 of Form 10-K is incorporated by reference from the discussion responsive thereto under the captions “Compensation Committee Report,” “Compensation Discussion and Analysis,” “Compensation Committee Interlocks and insider Participation” and “Directors Compensation” in our definitive proxy statement for our 2012 annual meeting of stockholders to be filed with the Securities and Exchange Commission.

ITEMSECURITIES OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND 12.RELATED STOCKHOLDER MATTERS

The information required by Item 12 of Form 10-K is incorporated by reference from the discussion responsive thereto under the captions “Security Ownership of Certain Beneficial Owners,” “Security Ownership of Management,” and “Compensation Discussion and Analysis” in our definitive proxy statement for our 2012 annual meeting of stockholders to be filed with the Securities and Exchange Commission.

ITEM 13.CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by Item 13 of Form 10-K is incorporated by reference from the discussion responsive thereto under the captions “Election of Directors” and “Related Party Transactions” in our definitive proxy statement for our 2012 annual meeting of stockholders to be filed with the Securities and Exchange Commission.

ITEM 14.PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by Item 14 of Form 10-K is incorporated by reference from the discussion responsive thereto under the caption “Designation of Auditors” in our definitive proxy statement for our 2012 annual meeting of stockholders to be filed with the Securities and Exchange Commission.

Index

PART IV

ITEM 15.EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this report.

1. FINANCIAL STATEMENTS. The following consolidated financial statements of the Company are set forth herein, beginning on page F-1:

(i) Report of Ernst & Young LLP, Independent Registered Public Accounting Firm

(ii) Report of Ernst & Young LLP, Independent Registered Public Accounting Firm on Internal Control over Financial Reporting

(iii) Consolidated Balance Sheets

(iv) Consolidated Statements of Operations

(v) Consolidated Statements of Stockholders' Equity

(vi) Consolidated Statements of Cash Flows

(vii) Notes to Consolidated Financial Statements

2. FINANCIAL STATEMENT SCHEDULES.

None required.

3. EXHIBITS.

The exhibits that are required to be filed or incorporated by reference herein are listed in the Exhibit Index. Exhibits 10.1, 10.2, 10.14, 10.16, 10.17, 10.20, 10.21, 10.22, 10.26, 10.27, 10.28, 10.30, 10.31. 10.32, 10.33 and 10.34 constitute management contracts or compensatory plans or arrangements required to be filed as exhibits hereto.

Index

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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 on the 13th day of March, 2012.

Insmed Incorporated
a Virginia corporation
(Registrant)

By: /s/ Timothy Whitten
Timothy Whitten
Chief Executive Officer (Principal Executive Officer) and Director

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities indicated on the 13th day of March, 2012.

Signature	Title
/s/ Donald Hayden, Jr. Donald Hayden, Jr.	Chairman of the Board
/s/ Timothy Whitten Timothy Whitten	Chief Executive Officer (Principal Executive Officer) and Director
/s/ Kevin P. Tully, C.G.A. Kevin P. Tully, C.G.A.	Chief Financial Officer (Principal Financial Officer) and Executive Vice President
/s/ Melvin Sharoky, M.D. Melvin Sharoky, M.D.	Director
/s/ Richard S. Kollender Richard S. Kollender	Director
/s/ Steinar J. Engelsen, M.D. Steinar J. Engelsen, M.D.	Director
/s/ Randall W. Whitcomb, M.D. Randall W. Whitcomb, M.D.	Director

Index

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Insmed Incorporated

We have audited the accompanying consolidated balance sheets of Insmed Incorporated as of December 31, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Insmed Incorporated at December 31, 2011 and 2010, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Insmed Incorporated's internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 13, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

MetroPark, New Jersey
March 13, 2012

Index

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Insmed Incorporated

We have audited Insmed Incorporated's internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Insmed Incorporated's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Insmed Incorporated maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Insmed Incorporated as of December 31, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2011 and our report dated March 13, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

MetroPark, New Jersey
March 13, 2012

69

Index

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

	December 31, 2011	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	$ 14,848	$ 10,743
Short-term investments	61,424	97,306
Accounts receivable	757	471
Prepaid expenses and other current assets	370	277
Total current assets	77,399	108,797
Certificate of deposit	2,085	2,176
In-process research and development	58,200	77,900
Goodwill	-	6,290
Deposits	212	-
Fixed assets, net	1,937	1,102
Total assets	$ 139,833	$ 196,265
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,334	$ 1,450
Accrued expenses	800	139
Accrued compensation	795	1,117
Accrued lease expense, current	278	
Deferred rent	156	150
Capital lease obligations, current	114	81
Deferred revenue	-	402
Total current liabilities	4,477	3,339
Accrued lease expense, long-term	923	
Capital lease obligations, long-term	166	83
Total liabilities	5,566	3,422
Stockholders' equity:		
Common stock; $.01 par value; authorized shares 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 200,000,000; issued and outstanding shares, zero in 2011 and 9,174,589 in 2010	-	918
Additional paid-in capital	427,743	423,877
Accumulated deficit	(294,174)	(234,510)
Accumulated other comprehensive income:		
Unrealized gain on investments	450	993
Total stockholders' equity	134,267	192,843
Total liabilities and stockholders' equity	$ 139,833	$ 196,265

See accompanying notes to audited consolidated financial statements

Index

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

	Years Ended December 31,		
	2011	2010	2009
License fees	$1,002	$4	129
Grant revenue	-	-	1,044
Other expanded access program income, net	3,415	6,917	9,200
Total revenues	4,417	6,921	10,373
Operating expenses:			
Research and development	27,917	4,757	9,207
General and administrative	12,229	10,256	9,840
Impairment loss	25,990	-	-
Total operating expenses	66,136	15,013	19,047
Operating loss	(61,719)	(8,092)	(8,674)
Investment income	2,064	1,845	808
Interest expense	(10)	(109)	(781)
Gain on sale of asset, net	1	-	127,474
(Loss) income before income taxes	(59,664)	(6,356)	118,827
Income tax expense	-	78	477
Net (loss) income	(59,664)	(6,434)	118,350
Less: accretion of beneficial conversion charge	(9,175)	-	-
Net (loss) income attributable to common stockholders	$(68,839)	$(6,434)	$118,350
Basic net (loss) income attributable to common stockholders per common share	$(2.95)	$(0.49)	$9.31
Weighted average basic common shares outstanding	23,348	13,250	12,712
Diluted net (loss) income attributable to common stockholders per common share	$(2.95)	$(0.49)	$9.30
Weighted average diluted common shares outstanding	23,348	13,250	12,727

See accompanying notes to audited consolidated financial statements

Index

INSMED INCORPORATED
Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)

	Common Stock	Preferred Stock	Additional Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balance at December 31, 2008	$1,225		$342,378	$ (346,426)	$ -	$(2,823)
Comprehensive (loss) income:						
Net income				118,350		118,350
Unrealized gain (loss) on investment					445	445
Comprehensive (loss) income						118,795
Issuance of 292,745 shares of common stock for warrant exercises	29		3,462	-	-	3,491
Issuance of 325,314 shares of common stock upon issuance of restricted stock awards	33		1,396	-	-	1,429
Issuance of 53,365 shares of common stock upon exercise of stock options	5		575	-	-	580
Issuance of 99,985 shares of common stock upon conversion of notes	10		1,285			1,295
Stock compensation expense	-		1,147	-	-	1,147
Balance at December 31, 2009	1,302		350,243	(228,076)	445	123,914
Comprehensive (loss) income:						
Net loss				(6,434)		(6,434)
Unrealized gain (loss) on investment					548	548
Comprehensive (loss) income						(5,886)
Issuance of 39,042 shares of common stock upon issuance of restricted stock awards	4		-	-	-	4
Issuance of 2,593,882 shares of common stock upon merger	259		18,160	-	-	18,419
Issuance of 9,174,589 shares of preferred stock upon merger		918	55,108	-	-	56,026
Stock compensation expense	-		366	-	-	366
Balance at December 31, 2010	1,565	918	423,877	(234,510)	993	192,843
Comprehensive (loss) income:						
Net loss				(59,664)		(59,664)
					(543)	(543)

Unrealized gain (loss) on investment						
Comprehensive (loss) income						(60,207)
1 for 10 reverse stock split	(2,235)		2,235			0
Issuance of 5,200 shares of common stock upon exercise of stock options	-		32	-	-	32
Conversion of 9,174,589 shares of preferred stock into common stock	918	(918)		-	-	-
Stock compensation expense	-		1,599	-	-	1,599
Balance at December 31, 2011	$248	$-	$427,743	$ (294,174)	$ 450	$134,267

See accompanying notes to audited consolidated financial statements

Index

INSMED INCORPORATED
Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,		
	2011	2010	2009
Operating activities			
Net (loss) income	$(59,664)	$(6,434)	$118,350
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:			
Depreciation and amortization	343	54	707
Stock based compensation expense	1,599	366	2,542
Gain on sale of asset, net	(1)	-	(127,474)
Impairment Loss	25,990	-	-
Changes in operating assets and liabilities:			
Accounts receivable	(286)	19	(123)
Income tax receivable	-	2,023	(2,023)
Prepaid expenses and other assets	(214)	(78)	-
Accounts payable	884	(2,750)	(85)
Accrued expenses	667	(1,126)	(874)
Accrued lease expenses	1,201	-	-
Accrued compensation	(322)	201	214
Deferred revenue	(402)	4	96
Restricted stock unit liability	-	-	(113)
Asset retirement obligation	-	-	(2,217)
Interest payable	-	(1)	(12)
Net cash (used in) provided by operating activities	(30,205)	(7,722)	(11,012)
Investing activities			
Cash consideration for merger, net of cash acquired	-	(6,733)	-
Cash received from asset sale	-	-	127,474
Purchase of fixed assets	(979)	-	-
Sales of short-term investments	36,500	115,153	-
Purchases of short-term investments	(1,161)	(102,462)	(108,744)
Net cash provided by (used in) investing activities	34,360	5,958	18,730
Financing activities			
Payments on capital lease obligations	(82)	(6)	-
Repayment of convertible notes	-	(231)	(1,246)
Proceeds from issuance of common stock	32	-	580
Warrants converted into shares	-	-	3,491
Other	-	4	52
Net cash (used in) provided by financing activities	(50)	(233)	2,877
Increase (decrease) in cash and cash equivalents	4,105	(1,997)	10,595
Cash and cash equivalents at beginning of period	10,743	12,740	2,145
Cash and cash equivalents at end of period	$14,848	$10,743	$12,740

Supplemental disclosures of cash flow information			
Cash paid for interest	$10	$-	$82
Cash paid (received) for taxes, net	$-	$(1,884)	$2,795
Supplemental disclosures of non-cash investing and financing activities			
Purchase of capital leases	$198	$-	$-
Unrealized (loss) gain on investments	$(543)	$548	$445
Accretion of beneficial conversion charge	$(9,175)	$-	$-

See accompanying notes to audited consolidated financial statements

Index

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of the Business and Summary of Significant Accounting Policies

Insmed® Incorporated is a development-stage biopharmaceutical company with expertise in proprietary, advanced liposomal technology designed specifically for inhalation lung delivery. We develop innovative inhaled treatments for serious lung infections. Our proprietary liposomal technology is designed specifically for delivery of pharmaceuticals to the lung, and we believe it 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 on orphan markets with high unmet medical needs, which we believe presents a significant opportunity, as their challenge 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 aeruginosa (hereafter referred to as Pseudomonas) lung infections in CF patients and patients with NTM lung infections.

Insmed is the result of a business combination completed on December 1, 2010, with Transave, Inc., a privately-held, NJ-based pharmaceutical company focused on the development of differentiated and innovative inhaled pharmaceuticals for the site-specific treatment of serious lung infections. Integration of the two companies was completed in 2011 including the relocation of corporate headquarters to Monmouth Junction, New Jersey, and cessation of operations at the Richmond, Virginia, location as of December 31, 2011. On March 2, 2011, we completed a conversion of all of our outstanding preferred stock to common stock and also we completed a one-for-ten reverse stock split of our common stock. Unless otherwise noted, the per share amounts in this 10-K give retroactive effect to the reverse stock split for all periods presented.

After giving effect to the Merger, former Transave stockholders had approximately a 46.7% equity interest in the combined Company (on an as-converted, fully diluted basis), and legacy Insmed Incorporated shareholders had a 53.3% equity interest. The shares retained by us pursuant to the Merger agreement (approximately 1.76 million shares of common stock after giving effect to the conversion of the Series B Conditional Preferred Stock and the one-for-ten reverse stock split of our common stock) will be delivered on June 12, 2012, subject to reduction for any claims and indemnification payments that are pending in accordance with the terms of the Merger agreement.

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 (Celtrix). All significant intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States (GAAP) requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company bases its estimates and judgments on historical experience and on various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company’s balance sheets and the amounts of revenue and expenses reported for each periods presented are effected by estimates and assumptions, which are used

for, but not limited to, the accounting for revenue recognition, stock-based compensation, income taxes, loss contingencies, impairment of intangibles and long lived assets and accounting for research and development costs. Actual results could differ from those estimates.

Index

Common Stock Reverse Split

On March 2, 2011, our shareholders approved a one-for-ten reverse stock split of the Company's outstanding common stock (see Note 6). Unless otherwise noted, the accompanying consolidated financial statements and notes give retroactive effect to the reverse stock split for all periods presented.

Cash, Cash Equivalents and Short-Term Investments

The Company considers cash equivalents to be investments with maturities of three months or less when purchased. Short-term investments are available for sale and consist primarily of short-term municipal bonds, U. S. treasuries and mutual funds. These securities are carried at fair value of the investment based on quoted market prices. The cost of the specific security sold is used to compute the gain or loss on the sale of marketable securities.

Fixed Assets

Fixed assets are recorded at cost and are depreciated on a straight-line basis over their estimated useful lives of the assets. Estimated useful lives of five to seven years are used for computer equipment, laboratory equipment, office equipment and furniture and fixtures. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the asset. Long-lived assets, such as lab equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, then an impairment charge is recognized for the amount by which the carrying value of the asset exceeds the fair value of the asset. As of December 31, 2011 and 2010, management believes that no revision of the remaining useful lives or write-down of long-lived assets is required.

Goodwill and Identified Intangible Assets

As part of the Merger, 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 (NDA) by the 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 the quarter ended September 30, 2011, the FDA placed a clinical hold on our Phase 3 clinical trials for ARIKACE for CF and NTM. The clinical hold for the NTM indication was subsequently lifted in January 2012. Our management

determined the clinical hold was an indicator of possible intangible asset impairment due to the associated additional costs and material delay in our development program and, therefore, interim impairment testing was performed as of September 30, 2011. The annual impairment review resulted in a non-cash charge of $26.0 million 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. No additional impairment losses were identified as of our December 31, 2011 impairment testing due primarily to the subsequent lifting of the clinical hold in the NTM indication and additional external market data which indicated that the NTM market may be larger than originally anticipated. In January 2012 the FDA lifted the clinical hold on ARIKACE in the NTM indication. In February 2012, the Company announced that it would be initiating the ARIKACE NTM trial as a Phase 2 trial, as well as the previously planned Phase 3 trial for ARIKACE in the CF indication in Europe.

Index

Fair Value of Financial Instruments

We consider the recorded cost of our financial assets and liabilities, which consist primarily of cash, cash equivalents and short-term investments, to approximate the fair value of the respective assets and liabilities at December 31, 2011 and 2010, due to the short-term maturities of these instruments. See Note 9 for further discussion on fair value of our cash and investments.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments. The Company places its cash equivalents with high credit-quality financial institutions and invests its short-term investments in U.S. treasury securities, mutual funds and government agency bonds. The Company has established guidelines relative to credit ratings and maturities that seek to maintain safety and liquidity.

The Company's drugs supplies are supplied from by a sole manufacturer. The inability of the manufacturer to fulfill supply requirements of the Company could materially impact future operating results. A change in the relationship with this manufacturer, or an adverse change in their business, could materially impact future operating results.

Beneficial Conversion Charge ("BCC")

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 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 6 for further information about the beneficial conversion feature.

Revenue Recognition and Collaboration Agreements

Revenue from our Expanded Access Program in Italy is recognized when the drugs have been provided to program patients and collectability is assured. Revenue from collaborations is recognized as license fees when milestones are achieved and payments are due. The Company analyzes each element of an agreement to determine if it shall be accounted for as a separate element or single unit of accounting. If an element shall be treated separately for revenue recognition purposes, the revenue recognition principles most appropriate for that element are applied to determine when revenue shall be recognized. If an element shall not be treated separately for revenue recognition purposes, the revenue recognition principles most appropriate for the bundled group of elements are applied to determine when revenue shall be recognized. Payments received in excess of revenues recognized are recorded as deferred revenue until such time as the revenue recognition criteria have been met.

Index

Research and Development

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

Stock-Based Compensation

In some instances, consultants received equity instruments of the Company or liabilities for services provided that are based on the fair value of our equity instruments or that may be settled by the issuance of such equity instruments. These share-based transactions are accounted for using a fair-value-based method to recognize non-cash compensation expense; this expense is recognized ratably over the requisite service period, which generally equals the vesting period of options, and is adjusted for expected forfeitures.

Income Taxes

Income taxes are accounted for in accordance with ASC 740, Income Taxes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The Company has no uncertain tax positions as of December 31, 2011 that qualify for either recognition or disclosure in the financial statements.

Valuation allowances are recorded if it is more likely than not that some portion of the deferred tax asset will not be realized. In evaluating the need for a valuation allowance, we take into account various factors, including the expected level of future taxable income and available tax planning strategies. If actual results differ from the assumptions made in the evaluation of our valuation allowance, we record a change in valuation allowance through income tax expense in the period such determination is made.

The Company follows the provisions of ASC 740, Accounting for Uncertainty in Income Taxes, which provides a financial statement recognition threshold and measurement attribute for a tax position taken or expected to be taken in a tax return. Under ASC 740, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based solely on the technical merits of the position. The tax benefits recognized in the financial statements from such a position should be measured based on the largest benefit that has a greater than 50% likelihood to be sustained upon ultimate settlement.

The Company’s policy for interest and penalties related to income tax exposures is to recognize interest and penalties as a component of the income taxes on continuing operations in the consolidated statements of operations.

Net (Loss) Income Per Share

Basic net (loss) income per share is computed based upon the weighted average number of common shares outstanding during the year. The following table sets forth the reconciliation of the weighted average number of shares attributable to common stockholders used to compute basic net (loss) income per share to those used to compute diluted net (loss) income per share for the years ended December 31, 2011, 2010 and 2009.

Index

	2011	2010	2009
Weighted average number of shares - basic	23,348	13,250	12,712
Add dilutive effect of shares - restricted stock units and options	-	-	15
Weighted average number of shares - diluted	23,348	13,250	12,727

The following potentially dilutive securities have been excluded from the computations of diluted weighted-average shares outstanding as of December 31, 2011, 2010 and 2009 as they would be anti-dilutive.

	2011	2010	2009
Shares underlying warrants to purchase outstanding common stock	158	158	519
Shares underlying options to purchase outstanding common stock	892	214	259
Shares underlying restricted stock units	487	-	-

Comprehensive (Loss) Income

Comprehensive (loss) income consists of net loss plus unrealized (losses) gains on short-term investments. Comprehensive (loss) income as of December 31, 2011, 2010 and 2009 is as follows:

	Year Ended December 31,		
	2011	2010	2009
Net (loss) income	$ (59,664)	$ (6,434)	$ 118,350
Unrealized (loss) gain on short-term investments	(543)	548	445
Total comprehensive (loss) income	$ (60,207)	$ (5,886)	$ 118,795

Segment Information

The Company currently operates in one business segment, which is the development and commercialization of pharmaceutical products. A single management team that reports to the Chief Executive Officer comprehensively manages the entire business. The Company does not operate separate lines of business with respect to its products or product candidates. Accordingly, the Company does not have separately reportable segments.

Recent Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 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 2009-13 is effective for revenue arrangements entered into in fiscal years beginning on or after June 15, 2010. We adopted ASU 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 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 ASC Topic 820, Fair Value Measurements and Disclosures, to require additional disclosures regarding fair value measurements. Specifically, ASU 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 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 2010-06 did not impact our consolidated financial statements.

Index

In April 2010, the FASB issued ASU 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 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 2010-17 effective January 1, 2011 and it did not have a material impact on our consolidated financial statements.

In May 2011, the FASB issued ASU 2011-04, Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS. The new guidance limits the highest-and-best-use measure to nonfinancial assets, permits certain financial assets and liabilities with offsetting positions in market or counterparty credit risks to be measured at a net basis, and provides guidance on the applicability of premiums and discounts. Additionally, the new guidance expands the disclosures on Level 3 inputs by requiring quantitative disclosure of the unobservable inputs and assumptions, as well as description of the valuation processes and the sensitivity of the fair value to changes in unobservable inputs. ASU 2011-04 is effective for years beginning after December 15, 2011 and is not expected to have a material impact on our consolidated financial statements.

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

In September 2011, the FASB issued ASU 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.

2. Risks and Uncertainties

For the period from inception to December 31, 2011, the Company has incurred recurring operating losses and has accumulated a deficit of $294.2 million. During 2011, the Company recognized a net loss of $59.7 million. Our net cash used in operations for 2011 was $30.2 million. While we currently have sufficient funds to meet our financial needs for 2012, 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.

3. Business Combination

We entered into an Agreement and Plan of Merger with Transave, Inc. on December 1, 2010. The Merger has been accounted for using the acquisition method of accounting and, accordingly, the tangible and intangible assets acquired and liabilities assumed were recorded at their estimated fair values as of the date of the acquisition. Transaction costs related to the Merger were $6.0 million of which $4.8 million is expensed in 2010 and $1.2 million is expensed in 2009 and is included in general and administrative expenses in the statement of operations. Our evaluation of the estimate of the fair value of the assets acquired and the liabilities assumed from Transave and the related allocations of purchase price are shown in the tables below (on a pre-reverse stock-split basis). Both of these evaluations are “Level 3” as defined in Note 9.

Index

The following table summarizes the purchase price allocation for the Merger, based on the Company's fair market evaluation of assets acquired and liabilities assumed.

Computation of Purchase Price:	
Cash consideration paid	$8,544
Fair value of common stock consideration (2,593,892 shares issued)	18,416
Fair value of preferred series B stock consideration (9,174,589 shares issued)	56,020
Purchase price of acquired assets	82,980
Fair value of liabilities assumed	
Accounts payable	-
Accrued expenses	-
Current liablities	4,515
Long-term liabilities	87
Total fair value of liabilities assumed	4,602
Total purchase price to be allocated to assets acquired	$87,582
Allocation of Purchase Price:	
Fair value of net assets acquired	
Current assets	$2,170
Fixed assets	1,131
Other assets	91
In-process research and development	77,900
Goodwill	6,290
Total fair value of assets acquired	$87,582

Goodwill typically results through expected synergies from combining operations of an acquiree and an acquirer as well as from intangible assets that do not qualify for separate recognition. The goodwill recognized as a result of this Merger results from the synergies expected to result from the combination of Insmed and Transave. No portion of this goodwill will be deductible for tax purposes.

The fair value of the common stock (on a pre-reverse stock-split basis) was the Company's closing stock price on December 1, 2010, which was $0.71 per share. Based on a review of its features, the conditional convertible series B preferred stock was considered economically equivalent to the common stock. Accordingly, the fair value 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. This discount for lack of marketability via a protective put analysis and the fair value of the series B preferred stock was estimated at $0.61 per share at December 1, 2010.

The following unaudited pro forma financial information combines the consolidated results of operations as if the Merger had occurred as of the beginning of the periods presented.

Index

INSMED INCORPORATED
Proforma Statement of Operations (Unaudited)
(in thousands)

	2010
Revenues	7,654
Operating loss	(20,266)
Net income (loss) after income taxes	(25,873)

4. Identified Intangible Assets and Goodwill

In August 2011, we announced that in separate actions the FDA had placed a clinical hold on our Phase 3 clinical trials for ARIKACE in CF patients with Pseudomonas lung infections and for patients with NTM lung infections. Since the clinical programs were being conducted under separate INDs, we received separate notifications for CF and NTM. A clinical hold is a notification issued by the FDA to the sponsor to delay the commencement of a proposed clinical trial or suspend an ongoing clinical trial. The FDA informed us that this decision was based on an initial review of the results of a long-term rat inhalation carcinogenicity study with ARIKACE. In this study, rats received daily doses of ARIKACE by inhalation for up to two years. The FDA requested additional information on ARIKACE and data from the rat study. As a result of the clinical hold, we suspended initiation of the ARIKACE Phase 3 clinical trial programs, including the recruitment and enrollment of patients.

We provided the requested information to the FDA in August and were informed by the FDA that, based on its review of the information provided to date, including the rat inhalation carcinogenicity study results, the FDA had insufficient information to assess the risks for ARIKACE in CF patients. In October 2011, the FDA notified us that the FDA was continuing the clinical hold previously placed on our Phase 3 clinical trial for ARIKACE in CF patients with Pseudomonas lung infections and in patients with NTM lung infections. Regarding the clinical hold for CF patients with Pseudomonas lung infections, the FDA requested additional information from us, including that we conduct a nine-month dog inhalation toxicity study of ARIKACE to determine if the findings of the rat inhalation carcinogenicity study are also observed in a non-rodent model and to propose a CF patient population/disease state in which the risk-benefit profile of ARIKACE may be more favorable. We were informed during further dialogue with the FDA that if we chose to proceed, the required nine-month dog inhalation toxicity study of ARIKACE could be conducted in parallel with the CF Phase 3 clinical trials in human subjects. Regarding the clinical hold for patients with NTM lung infections, the FDA requested we conduct a Phase 2 clinical trial in adult (age 18 and older) NTM patients to provide proof-of-concept efficacy and safety data for ARIKACE in NTM 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 the income approach the impairment analysis compared the fair value of the in-process research and development intangible assets with their respective carrying amounts. This approach calculates fair value by estimating future cash flows attributable to the assets and then discounting these cash flows to a present value using a risk-adjusted discount rate. A market based valuation approach was not considered given a lack of revenues and profits for the Company. This approach requires significant management judgment with respect to unobservable inputs such as future volume, revenue and expense growth rates, changes in working capital use, appropriate discount rates and other assumptions and estimates. The estimates and assumptions used are consistent with the Company's business plans. Additionally, 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. The non-cash charge of $26.0 million was

recorded as an impairment loss and classified as an operating expense in the Consolidated Statements of Operations.

Index

In January 2012, the FDA lifted the clinical hold on ARIKACE in patients with NTM lung infections. We intend to conduct, as requested by the FDA, a Phase 2 clinical trial in adult NTM patients to provide proof-of-concept efficacy and safety data for ARIKACE in NTM patients. We expect to begin enrolling patients in the Phase 2 clinical trial in mid-2012. We have also begun the work required to allow the Company to initiate the nine-month dog inhalation toxicity study in the second quarter of 2012.

In February 2012, the company announced that it would be initiating the ARIKACE NTM trial as a Phase 2 trial, as well as the previously planned Phase 3 trial for ARIKACE in the CF indication in Europe. Also in February 2012, we filed our complete response to the FDA clinical hold on the U.S. study of ARIKACE in CF patients with Pseudomonas infection. We will continue discussions with the FDA to pursue removal of the clinical hold on ARIKACE in U.S. for the treatment of CF patients with Pseudomonas lung infections.

As a result of these events, the Company believes that the no additional impairment of in-process research and development intangible assets exists as of December 31, 2011.

5. Fixed Assets, net

Fixed assets are stated at cost and depreciated or amortized when available by applying the straight-line method, based on useful lives as follows:

Asset Description	Estimated Useful Life (years)	2011	2010
Lab equipment	7	$ 3,072	$ 2,595
Furniture and fixtures	7	56	54
Computer hardware and software	5	469	405
Office equipment	7	115	48
Leasehold improvements	lease term	577	979
		4,289	4,081
Less accumulated depreciation		(2,352)	(2,979)
Fixed assets, net		$ 1,937	$ 1,102

Depreciation expense was $0.3 million, $0.1 million and $0.7 million for the years ended December 31, 2011, 2010 and 2009, respectively. Depreciation expense includes depreciation for equipment under capital lease obligations.

Fixed assets include equipment held under capital lease obligations with an approximate net carrying value of $0.4 million and $0.1 million as of December 31, 2011 and 2010, respectively.

6. 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.

82

Index

Common and Preferred Stock

On December 1, 2010, we entered into an Agreement and Plan of Merger (the Merger) 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
Preferred series B stock converted into common stock on March 1, 2011	91,746
Total shares outstanding prior to reverse stock split	248,283
1 for 10 reverse stock split	1:10
Approximate number of common shares outstanding March 2, 2011	24,828

As a result of the conversion of the Series B Preferred Stock, we recorded a non-cash charge for the beneficial conversion feature of the Series B Preferred Stock in the amount of $9.2 million, which reduced net income available to holders of our common shares and, in turn, reduced our earnings per common share on a basic and diluted basis by $0.40 for year ended December 31, 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.

7. Stock Based Compensation

Stock Warrants

The following table summarizes warrant activity for the years ended December 31, 2011, 2010 and 2009 as follows:

	Number of Warants	Weighted Average Exercise Price

Outstanding at January 1, 2009	1,095,026	$	13.20
Exercised	(292,745)		11.90
Expired	(283,195)		17.00
Outstanding at December 31, 2009	519,086		11.80
Expired	(361,532)		12.20
Outstanding at December 31, 2010	157,554		11.00
Outstanding at December 31, 2011	157,554	$	11.00

Index

All warrants have an expiration date of May 2012.

Stock Options

As of December 31, 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 December 31, 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.

The following table summarizes stock option activity for the years ended December 31, 2011, 2010 and 2009 as follows:

Index

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Options outstanding at January 1, 2009	428,224	$ 21.00		
Granted	-	-		
Exercised	(53,365)	10.90		
Forfeited	(34,254)	15.46		
Cancelled	(81,330)	23.48		
Options outstanding at December 31, 2009	259,275	$ 23.00	1.99	$45,620
Vested and expected to vest at December 31, 2009	258,953	$ 23.06	1.99	$45,511
Exercisable at December 31, 2009	237,000	$ 23.90	1.93	$39,371
Options outstanding at December 31, 2009	259,275	$ 23.00		
Granted	-	-		
Exercised	-	-		
Cancelled	(45,000)	48.04		
Options outstanding at December 31, 2010	214,275	$ 18.43	1.34	$9,880
Vested and expected to vest at December 31, 2010	214,275	$ 18.43	1.34	$9,880
Exercisable at December 31, 2010	214,275	$ 18.43	1.34	$9,880
Options outstanding at December 31, 2010	214,275	$ 18.43		
Granted	766,000	3.77		
Exercised	(5,200)	6.16		
Cancelled	(83,324)	26.57		
Options outstanding at December 31, 2011	891,751	5.15	8.48	$11,352
Vested and expected to vest at December 31, 2011	816,414	5.30	8.36	$10,114
Exercisable at December 31, 2011	125,751	13.54	0.83	$-

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 year ended December 31, 2011.

	2011
Volatility	111.6%
Risk-free interest rate	0.9%
Dividend yield	0.0%
Expected option term (in years)	6.25

For the year ended December 31, 2011, the volatility factor was based on the Company's historical volatility since the closing of the Merger on December 1, 2010. The expected life was determined using the simplified method as described in ASC Topic 718, "Accounting for Stock Compensation", which is the midpoint between the vesting date and the end of the contractual term. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant. Forfeitures are based on actual percentage of option forfeitures since the closing of the Business Combination on December 1, 2010, and is the basis for future forfeiture expectations.

85

Index

For the years ended December 31, 2010 and 2009 the Company did not grant stock options and therefore used the calculated 2008 Black-Scholes-Merton valuation model. The weighted-average grant-date fair value of stock options awarded was estimated on the date of grant using the following assumptions in 2008: risk-free interest rate of 2.42%, no dividends, volatility of 107% and an expected life of 4.07 years. The volatility factor was estimated based on the Company's historical volatility. The Company also used historical data to derive the option's expected life and employee forfeiture rates within the valuation model. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant. The dividend yield is predicated on the current annualized dividend payment.

The Company recognized stock-based compensation expense related to stock options of approximately $0.3 million, $0.4 million $0.2 million for the years ended December 31, 2011, 2010 and 2009, respectively. General and administrative expenses include $0.2 million, $0.03 million and $0.1 million and research and development expenses include $0.1 million, $0.01 million and $0.1 million of stock-based compensation expense in the consolidated statement of operations for the years December 31, 2011, 2010 and 2009, respectively. As of December 31, 2011, there was $2.2 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 3.74 years. As of December 31, 2010, there were zero unvested shares.

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 as 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.

The following table summarizes RS and RSU activity for the years ended December 31, 2011, 2010 and 2009 as follows:

	Number of RS	Weighted Average Grant Price	Number of RSU's	Weighted Average Grant Price
Outstanding at January 1, 2009	315,553	$6.04	184,661	$6.04
Granted	149,204	17.10	36,823	17.10
Exercised	(455,985)	9.58	(221,484)	7.88
Outstanding at December 31, 2009	8,772	17.10	-	-
Granted	30,270	8.80	-	-
Exercised	(39,042)	10.72	-	-
Outstanding at December 31, 2010	-	-	-	-
Granted	-	-	491,255	6.36
Forfeited	-	-	(4,230)	5.13
Outstanding at December 31, 2011	-	$-	487,025	$6.37
Expected to Vest			447,839	6.36

The Company recognized stock-based compensation expense related to RS and RSU's of approximately $1.3 million, $0.3 million and $2.3 million for 2011, 2010 and 2009, respectively. General and administrative expenses include

$0.9 million, $0.2 million and $1.2 million and research and development expenses include $0.4 million, $0.1 million and $1.1 million of stock-based compensation expense in the consolidated statement of operations for the years ended December 31, 2011, 2010 and 2009, respectively. As of December 31, 2011, there was $2.8 million of unrecognized compensation expense related to unvested RSUs, which is expected to be recognized over a weighted average period of 2.0 years. As of December 31, 2011 there were zero vested RSU's.

Index

A total of approximately 2.1 million shares of common stock were reserved for issuance at December 31, 2011, in connection with restricted stock, restricted stock units, stock options, stock warrants and the 2000 employee stock purchase plan.

8. Income Taxes

The Company is subject to U.S. federal and state income taxes. The statute of limitations for tax audit is generally open for the years 2008 and later. However, except in 2009, the Company has incurred net operating losses since inception. Such loss carryforwards would be subject to audit in any tax year in which those losses are utilized, notwithstanding the year of origin. The Company's policy is to recognize interest accrued related to unrecognized tax benefits and penalties in income tax expense. The Company has recorded no such expense. The Company obtained additional loss carryforwards from the Merger. As of December 31, 2011 and 2010, the Company has recorded no reserves for unrecognized income tax benefits. The Company does not anticipate any material changes in the amount of unrecognized tax positions over the next twelve months.

The net deferred tax assets of approximately $110 million and $94 million at December 31, 2011 and 2010, respectively, arise primarily due to net operating loss carryforwards for income tax purposes. Due to the Company's anticipated future losses, these amounts have been entirely offset by increasing the valuation allowance $16.4 million to $110 million at December 31, 2011.

At December 31, 2011 and 2010, the Company had net operating loss carryforwards for income tax purposes of approximately $330 million and $310 million, respectively, expiring in various years beginning in 2012. Utilization of these carryforwards will likely be significantly limited due to changes in the ownership of the Company's common stock.

The Company does not believe there are any positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will increase or decrease significantly within the next twelve months. As of December 31, 2011, the Company has not accrued interest or penalties related to uncertain tax positions. The Company has never been audited by the Internal Revenue Service, and the tax returns for the years ended December 31, 2008 through December 31, 2011 are still subject to examination by major tax jurisdictions.

Deferred tax assets (liabilities) consist of the following at December 31:

Deferred tax assets	2011	2010
	(in thousands)	
General business credits	10,324	7,708
AMT credit	418	418
Other	1,791	3,064
NOL carryforwards	120,473	112,721
Total deferred tax assets	133,006	123,911
Deferred tax liabilities		
In-process research and development	(22,093)	(29,609)
Other	(170)	(377)
Total deferred tax liabilities	(22,263)	(29,986)

Tax deferred asset	110,743	93,925
Valuation allowance	(110,743)	(93,925)
Net deferred tax asset	-	-

Index

The differences between the U.S. federal statutory tax rate and the Company's effective tax rate are as follows:

	2011		2010		2009	
Statutory federal tax rate	34	%	34	%	34	%
Permanent items	(4	)%	(9	)%	0	%
State income taxes net of federal benefit	4	%	1	%	4	%
Research and development credit	5	%	0	%	0	%
Expired net operating loss carryforwards	(10	)%	0	%	0	%
Alternative minimum tax	0	%	1	%	0	%
Change in valuation allowance	(28	)%	(28	)%	(38	)%
Other	(1	)%	0	%	0	%
Total Expense	0	%	(1	)%	0	%

9. Investments and Fair Value Measurements

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

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

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

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

Each major category of financial assets and liabilities measured at fair value on a recurring basis are categorized in the tables below based upon the lowest level of significant input to the valuations. The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

Financial instruments in Level 1 generally include U.S. treasuries and mutual funds listed in active markets. Financial instruments in Level 2 generally include municipal bonds listed in secondary markets.

The following table presents assets and liabilities measured at fair value as of December 31, 2011 and December 31, 2010.

Index

	Total	Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Quoted Prices in Inactive Markets for Identical Assets (Level 2)	Significant Unobservable Inputs (Level 3)
As of December 31, 2011:				
Assets:				
Cash and cash equivalents	$14,848	$ 14,848	$ -	$ -
Mutual funds	56,163	56,163	-	-
Government agency bonds	5,261	-	5,261	-
Certificate of deposit (a)	2,085	2,085	-	-
	$78,357	$ 73,096	$ 5,261	$ -
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.

The Company's cash and cash equivalents and short-term investments, excluding government agency bonds, permit daily redemption and the fair values of these investments are based upon the quoted prices in active markets provided by the holding financial institutions. The Company's investment in government agency bonds permit daily redemption and the fair values of these investments are based upon the quoted prices in inactive markets by the holding financial institutions. The cash equivalents consist of liquid investments with a maturity of three months or less and the short-term investments consist of instruments with maturities greater than three months. The certificate of deposit matures in fiscal 2013.

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The Company’s in-process research and development asset is fair valued using the income approach. This approach calculates fair value by estimating future cash flows attributable to the assets and then discounting these cash flows to a present value using a risk-adjusted discount rate. A market based valuation approach was not considered given a lack of revenues and profits for the Company. This approach requires significant management judgment with respect to future volume, revenue and expense growth rates, changes in working capital use, appropriate discount rates and other assumptions and estimates. The estimates and assumptions used are consistent with our business plans.

We recognize transfers between levels within the fair value hierarchy, if any, at the end of each quarter. During 2011, approximately $27 million was transferred from Level 2 assets into Level 1 to be utilized in the Company’s operating activities. There were no significant transfers in or out of Level 1, Level 2 or Level 3 during 2010.

As of December 31, 2011, we held two securities that were in an unrealized loss position with a total estimated fair value of $12.6 million and gross unrealized loss of approximately $0.2 million. This security has not been in a

continuous unrealized loss position for greater than one year. The net unrealized gain of $0.5 million is reported in accumulated other comprehensive income in the stockholder's equity section of our balance sheet. Unrealized gains and losses for 2011 are as follows (in thousands):

Index

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

At December 31, 2010, we held nine securities that 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 nine securities, none had been in a continuous unrealized loss position for greater than one year. The following table summarizes unrealized gains and losses for 2010.

	December 31, 2010			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
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.

10. Employee Benefit Plans

The Company also maintains a tax-qualified employee savings and retirement plan (the" 401(k) plan") for eligible employees. Participating employees may defer up to the lesser of 25% of W-2 compensation or the maximum amount permitted by the Internal Revenue Code, as amended. The 401(k) plan permits the Company to make matching contributions on behalf of all participants who have elected to make deferrals. To date, the Company has not made any contributions to the plan.

11. License and Collaborative Agreements

Muscular Dystrophy Association

On December 12, 2007, we announced that we were awarded a grant of $2.1 million from the Muscular Dystrophy Association for our Phase 3 enabling clinical trial of IPLEX in the Myotonic Muscular Dystrophy indication. We received half of the $2.1 million milestone payments in 2008 and the remaining half in 2009.

NAPO

In 2007, we entered into an agreement with NAPO Pharmaceuticals, whereby NAPO will license from us the technology surrounding INSM-18 also known as Masoprocal. The license gives NAPO the right to develop,

manufacture and commercialize Masoprocal products for any indications relating specifically to diabetes, cardiac disease, vascular disease, metabolic disease and Syndrome X. The agreement calls for payments from NAPO to us upon the achievement of certain milestones which have not yet been met.

Index

Cystic Fibrosis Foundation Therapeutics, Inc.

In 2009 and 2005, the Company entered into a research funding agreements with Cystic Fibrosis Foundation Therapeutics, Inc. (CFFT) where the Company received $2.2 million and $1.7 million for each respective agreement in research funding for the development of its ARIKACE product. If ARIKACE becomes an approved product in the United States, the Company will owe a “royalty payment” to CFFT of up to $13.4 million that is payable over a three-year period after approval as a commercialized drug in the United States. Furthermore, if certain sales milestones are meet within 5 years of the drug commercialization approval in the United States, the Company would owe an additional $3.9 million in additional “royalty payment.” Since there is significant development risk associated with ARIKACE, the Company has not accrued the royalty obligations.

TriAct

On December 20, 2010, we entered into an agreement with TriAct Therapeutics Inc. (“TriAct”) TriAct obtained an exclusive license from Insmed for INS-18 also known as Masoprocal. The license gives TriAct the right to develop, manufacture and commercialize Masoprocal products for any indications relating specifically to Oncology. The agreement calls for the issue of TriAct common stock to Insmed upon the achievement of certain milestones. To date, no common stock has been received nor milestones achieved.

Eleison

On February 1, 2011, we entered into an agreement with Eleison Pharmaceuticals whereby Eleison obtained an exclusive license from Insmed for Inhaled CISPLATIN Lipid Complex. The license gives Eleison the right to develop, manufacture and commercialize inhaled CISPLATIN Lipid Complex for cancers affecting the lung. Payments were received in 2011 and are recorded in license fees.

PARI Pharma GmbH

In April 2008, we entered into a licensing agreement with PARI Pharma GmbH for use of the optimized, investigational eFlow Nebulizer System for delivery of ARIKACE in treating patients with CF, bronchiectasis, and non-tuberculosis mycobacterial infections. Insmed has rights to several U.S. and foreign issued patents, and there are future patent applications involving improvements to the optimized, investigational eFlow Nebulizer System. In consideration of this agreement, PARI shall receive payments either in cash, qualified stock or a combination of both, at PARI’s discretion, based on achievement of certain milestone events including Phase 3 trial initiation, NDA acceptance and regulatory approval of ARIKACE together with royalty payments on commercial sales of ARIKACE.

12. 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. From September 2011 through December 2011 we subleased the new facility from the existing lessor, a large pharmaceutical company that has vacated the facility. Following expiration of the sublease on December 31, 2011 the lease for the same building commenced 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 also retained approximately 1,350 sq. ft. of lab space at 11 Deer Park Drive under a lease which also expires in December 2014. The additional space at 11 Deer Park Drive will be utilized to support the manufacture of ARIKACE for our clinical programs. Total financial obligations through the term of the new facility lease are approximately $2.1 million. We

determined that the larger facility is required for our growing clinical, regulatory and development efforts in support of our ARIKACE programs in CF and NTM. The Richmond Office lease runs through October 2016 and we are actively seeking to sublet this facility. Commitments for the Richmond office lease through October 2016 term are approximately $2.3 million. At December 31, 2011, we have recorded a net present value charge of $1.2 million in general and administrative expenses associated with the vacant Richmond facility.

Index

Rent expense charged to operations was $1.0 million, $0.5 million and $0.5 million for the years ended December 31, 2011, 2010 and 2009, respectively. Future minimum rental payments required under operating leases are as follows.

Years ending December 31,	
2012	$ 1,183
2013	1,189
2014	1,201
2015	498
2016	425
	$ 4,496

Legal Proceedings

Cacchillo v. Insmed

On October 6, 2010, a complaint was filed against us by Angeline Cacchillo (“Plaintiff”) in the U.S. District Court for the Northern District of New York (the “Court”), captioned Cacchillo v. Insmed, Inc., No. 1:10-cv-0199, seeking monetary damages and a court order requiring Insmed 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”). 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 U.S. Court of Appeals for the Second Circuit, which affirmed the trial court’s order denying the Plaintiff’s motion for a preliminary injunction.

We filed a motion with the Court to dismiss all of the outstanding claims, and on June 29, 2011, the Court dismissed six of Plaintiff’s claims, leaving outstanding the claims for (i) fraudulent inducement, (ii) negligent misrepresentation, and (iii) breach of contract. We filed an answer and affirmative defenses with the Court on July 12, 2011. Plaintiff’s claim for monetary damages with respect to these claims remains outstanding. The Court has scheduled a trial date in October 2012.

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. Insmed

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. Insmed 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 Insmed Incorporated, River Acquisition Co., Transave, LLC, Transave and TVM V Life Science Ventures GmbH & Co. KG, in its capacity as stockholders' agent (the "Merger Agreement"). 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 Merger. In addition, pursuant to the terms of the settlement, we agreed to pay plaintiff's legal fees and expenses.

Index

Pilkiewicz v. Transave LLC

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

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

Under the terms of the Merger Agreement, certain of the former stockholders of Transave are obligated to indemnify us for certain liabilities in connection with the appraisal action. We believe that the allegations contained in the amended petition are without merit and we intend to continue to vigorously defend this action. It is not possible at this time to estimate the amount of loss or range of possible loss, if any, that might result from an adverse resolution of this action.

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

Index

13. Quarterly Financial Data (Unaudited)

The following table summarizes unaudited quarterly financial data for the years ended December 31, 2011 and 2010.

INSMED INCORPORATED
Quarterly Financial Data
(in thousands)

	2011				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Revenues	$1,601	$978	$435	$1,403	$4,417
Operating loss	(7,415)	(10,473)	(34,960)	(8,871)	(61,719)
Net loss after income taxes	(6,894)	(10,017)	(34,591)	(8,162)	(59,664)
Basic and diluted net loss attributable to common stockholders per common share	$(0.85)	$(0.40)	$(1.39)	$(0.33)	$(2.95)

	2010				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Revenues	$1,929	$1,864	$1,807	$1,321	$6,921
Operating loss	(251)	(913)	(598)	(6,330)	(8,092)
Net income (loss)after income taxes	118	(378)	(330)	(5,844)	(6,434)
Basic and diluted net income (loss) attributable to common stockholders per common share	$0.01	$(0.03)	$(0.03)	$(0.42)	$(0.49)

14. Subsequent Events

The Company completed an evaluation of the impact of any subsequent events and determined there were no other subsequent events requiring disclosure in or adjustment to these financial statements.

Index

EXHIBIT INDEX

2.1	Asset Purchase Agreement, dated February 12, 2009, between Protein Transaction LLC (a wholly owned subsidiary of Merck & Co. Inc.) Insmed Incorporated and Merck & Co., Inc. (previously filed as Exhibit 10.1 to Insmed Incorporated's Current Report on Form 8-K filed on February 13, 2009 and incorporated herein by reference).
2.2	Agreement and Plan of Merger, dated December 1, 2010, among Insmed Incorporated, River Acquisition Co., Transave, LLC Transave, Inc. and TVM V Life Science Ventures GmbH & Co. KG (previously filed as Exhibit 2.1 to Insmed Incorporated's Current Report on Form 8-K filed on December 2, 2010 and incorporated herein by reference).
3.1	Articles of Incorporation of Insmed Incorporated, as amended (previously filed as Annex H to the Joint Proxy Statement/Prospectus contained in Part I of Insmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).
3.2	Amended and Restated Bylaws of Insmed Incorporated (previously filed as Annex I to the Joint Proxy Statement/Prospectus contained in Part I of Insmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).
3.3	Form of Articles of Amendment to Insmed 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 Insmed Incorporated and First Union National Bank, as Rights Agent, filed as Exhibit 4.4 to Insmed Incorporated's Registration Statement on Form 8-A filed on May, 17, 2001, and incorporated herein by reference).
3.4	Articles of Amendment to Insmed Incorporated's Articles of Incorporation, as amended, for Reverse Split (previously filed as Exhibit 3.4 to Insmed Incorporated's Annual Report on Form 10-K for the year ended December 31, 2002, and incorporated herein by reference).
3.5	Articles of Amendment to Insmed Incorporated's Articles of Incorporation, as amended, to create a new series of Preferred Stock designated as Series B Conditional Convertible Preferred Stock (previously field as Exhibit 3.1 to Insmed Incorporated's Current Report on Form 8-K filed on December 2, 2010, and incorporated herein by reference).
3.6	Articles of Amendment to Insmed Incorporated's Articles of Incorporation, as amended, for one-for-ten reverse stock split (previously filed as Exhibit 3.1 to Insmed Incorporated's Current Report on Form 8-K filed on March 2, 2011, and incorporated herein by reference).
3.7	Our Amended and Restated Bylaws (previously filed as Exhibit 3.1 to Insmed Incorporated's Current Report on Form 8-K filed on March 9, 2012, and incorporated herein by reference).
4.1	Specimen stock certificate representing common stock, $.01 par value per share, of the Registrant (previously filed as Exhibit 4.2 to Insmed Incorporated's Registration Statement on Form S-4/A (Registration No. 333-30098) and incorporated herein by reference).
4.2	Rights Agreement, dated as of May 16, 2001, between Insmed Incorporated and First Union National Bank, as Rights Agent (which includes as (i) Exhibit A the form of Articles of Amendment to Insmed Incorporated's Articles of Incorporation, as amended, (ii) Exhibit B the form of Rights

	Certificate, and (iii) Exhibit C the Summary of the Rights to Purchase Preferred Stock) (previously filed as Exhibit 4.4 to Insmed Incorporated's Registration Statement on Form 8-A filed with the Securities and Exchange Commission on May 17, 2001 and incorporated herein by reference)

Index

4.3	Form of Rights Certificate (previously filed as Exhibit 4.1 to Insmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).
4.4	Form of Rights Stock and Warrant Purchase Agreement by and between Insmed Incorporated and each of the investors in the July 2003 private placement of common stock and warrants to purchase common stock (previously filed as Exhibit 4.6 to Insmed Incorporated's Registration Statement on Form S-3 (Registration No. 333-107308) on July 24, 2003, and incorporated herein by reference).
4.5	Form of Warrant issued by Insmed Incorporated to each of the investors in July 2003 private placement of common stock and warrants to purchase common stock (previously filed as Exhibit 4.7 to Insmed Incorporated's Registration Statement on Form S-3 (Registration No. 333-107308) on July 24, 2003 and incorporated herein by reference).
4.6	Form of Stock and Warrant Purchase Agreement by and between Insmed Incorporated and each of the investors in the November 2004 private placement of common stock and warrants to purchase common stock (previously filed as Exhibit 10.1 to Insmed Incorporated's Current Report on Form 8-K filed on November 10, 2004, and incorporated herein by reference).
4.7	Form of Warrant issued by Insmed Incorporated to each of the investors in November 2004 private placement of common stock and warrants to purchase common stock (previously filed as Exhibit B to the Form of Stock and Warrant Purchase Agreement by and between Insmed Incorporated and each of the investors previously filed as Exhibit 10.1 to Insmed Incorporated's Current Report on Form 8-K filed on November 10, 2004 and incorporated herein by reference).
4.8	Form of Purchase Agreement dated March 15, 2005, between Insmed Incorporated and each of the investors in the March 2005 private placement of notes and warrants to purchase common stock (previously filed as Exhibit 4.1 to Insmed Incorporated's Current Report on Form 8-K filed on March 16, 2005 and incorporated herein by reference).
4.9	Form of 5.5% Note Due 2008-2010 dated March 15, 2005, between Insmed Incorporated and each of the investors in the March 2005 private placement of notes and warrants to purchase common stock (previously filed as Exhibit 4.2 to Insmed Incorporated's Current Report on Form 8-K filed on March 16, 2005, and incorporated herein by reference).
4.10	Form of Warrant dated March 15, 2005, between Insmed Incorporated and each of the investors in the March 2005 private placement of notes and warrants to purchase common stock (previously filed as Exhibit 4.1 to Insmed Incorporated's Current Report on Form 8-K filed on March 16, 2005, and incorporated herein by reference).
4.11	Form of Registration Rights Agreement dated March 15, 2005, between Insmed Incorporated and each of the investors in the March 2005 private placement of notes and warrants to purchase common stock (previously filed as Exhibit 4.4 to Insmed Incorporated's Current Report on Form 8-K filed on March 16, 2005, and incorporated herein by reference).

Index

4.12	Amendment No. 1 to Rights Agreement dated March 15, 2005, between Insmed Incorporated and Wachovia Bank, N.A. (f/k/a First Union National Bank) (previously filed as Exhibit 4.5 to Insmed Incorporated's Current Report on Form 8-K filed on March 16, 2005 and incorporated herein by reference).
4.13	Form of Warrant dated May 3, 2007, between Insmed Incorporated and each of the investors in the May 2010 private placement of common stock and warrants to purchase common stock (previously filed as Exhibit 4.1 to Insmed Incorporated's Current Report on Form 8-K filed on May 4, 2007, and incorporated herein by reference).
4.14	Shareholders Agreement, dated December 1, 2010, among Insmed Incorporated and each of the listed shareholders (previously filed as Exhibit 4.1 to Insmed Incorporated's Current Report on Form 8-K filed on December 2, 2010, and incorporated herein by reference).
4.15	Registration Rights Agreement, dated December 1, 2010, among Insmed Incorporated and each of the listed shareholders (previously filed as Exhibit 4.2 to Insmed Incorporated's Current Report on Form 8-K filed on December 2, 2010, and incorporated herein by reference).
10.1**	Insmed Incorporated 2000 Stock Purchase Plan (previously filed as Exhibit 10.1 to Insmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).
10.2**	Insmed Incorporated 2000 Stock Incentive Plan (previously filed as Exhibit 10.2 to Insmed Incorporated's Registration Statement on Form S-4/A (Registration No. 333-30098) and incorporated herein by reference).
10.3	Amended and Restated License Agreement between Insmed Pharmaceuticals, Inc. and the University of Virginia Patent Foundation (previously filed as Exhibit 10.3 to Insmed Incorporated's Registration Statement on Form S-4/A (Registration No. 333-30098) and incorporated herein by reference)
10.4+	Subscription, Joint Development and Operating Agreement by and among Celtrix Pharmaceuticals, Inc., Élan Corporation, plc, Élan International Services, Ltd., and Celtrix Newco Ltd. dated as of April 21, 1999, (previously filed as Exhibit 10.8 to Insmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).
10.5+	License Agreement by and between Celtrix Newco Ltd. and Celtrix Pharmaceuticals, Inc. dated as of April 21, 1999, (previously filed as Exhibit 10.9 to Insmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).

Index

10.6+	License Agreement by and between Celtrix Newco Ltd. and Élan Pharmaceutical Technologies, a division of Élan Corporation, plc, dated as of April 21, 1999, (previously filed as Exhibit 10.10 to Insmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).
10.7	License Agreement, dated as of April 1, 1993, between Genentech, Inc. and Celtrix Pharmaceuticals, Inc. (previously filed as Exhibit 10.11 to Insmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).
10.8	Purchase Agreement among Insmed, Inc., Insmed Pharmaceuticals, Inc. and certain investors named therein dated January 13, 2000 (previously filed as Exhibit 10.12 to Insmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).
10.9	Form of Warrant of Insmed to be issued pursuant to Purchase Agreement among Insmed Incorporated, Insmed Pharmaceuticals, Inc. and certain investors dated January 13, 2000 (previously filed as Exhibit 10.13 to Insmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).
10.10	Form of Registration Rights Agreement among Insmed Incorporated, Insmed Pharmaceuticals, Inc. and certain investors party to the Purchase Agreement among Insmed Incorporated, Insmed Pharmaceuticals, Inc. and certain investors dated January 13, 2000 (previously filed as Exhibit 10.14 to Insmed Incorporated's Registration Statement on From S-4 (Registration No. 333-30098) and incorporated herein by reference).
10.11	Sublease, dated March 30, 2001, between Rhodia Inc. and Insmed Incorporated (previously filed as Exhibit 10.15 to Insmed Incorporated's Quarterly Report on form 10-Q for the quarter ended March 31, 2001, and incorporated herein by reference.
10.12	Consent to Sublease, dated as of April 12, 2001, among A & W Virginia Corporation, as Landlord, Rhodia Inc., as Tenant, and Insmed Incorporated, as Subtenant (previously filed as Exhibit 10.16 to Insmed Incorporated's Quarterly Report on form 10-Q for the quarter ended March 31, 2001, and incorporated herein by reference).
10.13+	License and Supply Agreement, dated as of August 28, 2003, between Insmed Incorporated and Pharmacia AB (previously filed as Exhibit 10.16 to Insmed Incorporated's Annual Report on form 10-K for the year ended December 31, 2003 and incorporated herein by reference).
10.14**	Agreement, dated as of March 3, 2004, between Insmed Incorporated and Geoffrey Allan, Ph.D. (previously filed as Exhibit 10.17 to the Insmed Incorporated's Annual Report on form 10-K for the year ended December 31, 2003, and incorporated herein by reference).
10.15*	License Agreement, dated as of January 19, 2004, between Insmed Incorporated and Fujisawa Pharmaceutical Co., Ltd. (previously filed as Exhibit 10.18 to the Insmed Incorporated's Annual Report on Form 10-K for the year ended December 31, 2003, and incorporated herein by reference).
10.16**	Form of Change of Control Agreement entered into between Insmed Incorporated and certain of its executive officers (previously filed as Exhibit 10.19 to Insmed Incorporated's Annual Report on Form 10-K for the year ended December 31, 2004, and incorporated herein by reference).

10.17**	Form of Executive Stock Option Grant (previously filed as Exhibit 10.1 to Insmed Incorporated's Annual Report on Form 10-K for the year ended December 31, 2004, and incorporated herein by reference).

Index

10.18	Lease between 2545 Central, LLC and Insmed Incorporated made December 14, 2005, (previously filed as Exhibit 10.21 on Insmed's Annual Report on Form 10-K for the year ended December 31, 2005, and incorporated herein by reference).
10.19	First Amendment to Lease dated February 6, 2009, to original December 14, 2005, Lease for 5797 Central Avenue, Boulder Co. (previously filed as Exhibit 10.2 to Insmed's Current Report on Form 8-K filed on February 13, 2009, and incorporated herein by reference).
10.20**	Change in Control Agreement entered into between Insmed Incorporated and Geoffrey Allan, Ph.D. (previously filed as Exhibit 10.19 to Insmed Incorporated's Annual Report on Form 10-K for the year ended December 31, 2006, and incorporated herein by reference).
10.21**	Change in Control Agreement entered into between Insmed Incorporated and Ronald Gunn (previously filed as Exhibit 10.20 to Insmed Incorporated's Annual Report on Form 10-K for the year ended December 31, 2006, and incorporated herein by reference).
10.22**	Form of Change in Control Agreement entered into between Insmed Incorporated and Kevin Tully and Doug Farrar (previously filed as Exhibit 10.21 to Insmed Incorporated's Annual Report on Form 10-K for the year ended December 31, 2006, and incorporated herein by reference).
10.23**	Amended and Restated 2000 Employee Stock Purchase Plan (previously filed as Exhibit 10.22 to Insmed Incorporated's Annual Report on Form 10-K for the year ended December 31, 2006 and incorporated herein by reference).
10.24	Form of Subscription Agreement entered into between Insmed Incorporated and each of the investors the May 2007 private placement of common stock and warrants to purchase common stock (previously filed as Exhibit 10.1 to Insmed's Current Report on Form 8-K filed on May 4, 2007, and incorporated herein by reference).
10.25*	Settlement, license and development agreement, dated March 5, 2007, between Insmed Incorporated, Insmed Therapeutic Proteins, Inc., Celtrix Pharmaceuticals, Tercica Inc., and Genentech, Inc. (previously filed as Exhibit 10.1 to Insmed's Quarterly Report on 10-Q filed on May 10, 2007, and incorporated herein by reference).
10.26**	Form of Award Agreement (Restricted Stock Units) pursuant to Insmed's Amended and Restated 2000 Stock Incentive Plan (previously filed as Exhibit 10.1 to Insmed Incorporated's Current Report on Form 8-K filed on May 30, 2009).
10.27**	Form of Award Agreement (Restricted Stock Units) pursuant to Insmed's Amended and Restated 2000 Stock Incentive Plan (previously filed as Exhibit 10.1 to Insmed Incorporated's Current Report on Form 8-K filed on May 30, 2008).
10.28**	Separation Agreement and General Release, dated July 2, 2009 between Insmed Incorporated and Geoffrey Allan, Ph.D. (previously filed as Exhibit 10.1 to Insmed Incorporated's Current Report on Form 8-K filed on July 2, 2009 and incorporated herein by reference).
10.29**	Separation and Release Agreement, dated December 3, 2010, between Insmed Incorporated and Steve Glover (previously filed as Exhibit 10.1 to Insmed Incorporated's Current Report on Form 8-K filed on December 13, 2010, and incorporated herein by reference).

99

Index

10.30**	Employment Agreement, dated December 2, 2010, between Insmed Incorporated and Timothy Whitten (previously filed as Exhibit 10.1 to Insmed Incorporated's Current Report on Form 8-K filed on February 1, 2011 and incorporated herein by reference).
10.31**	Employment Agreement, dated December 2, 2010, between Insmed Incorporated and Kevin P. Tully (previously filed as Exhibit 10.2 to Insmed Incorporated's Current Report on Form 8-K filed on February 1, 2011, and incorporated herein by reference).
10.32**	Employment Agreement, dated December 2, 2010, between Insmed Incorporated and Nicholas Labella, Jr. (previously filed as Exhibit 10.3 to Insmed Incorporated's Current Report on Form 8-K filed on February 1, 2011, and incorporated herein by reference).
10.33**	Employment Agreement, dated December 2, 2010, between Insmed Incorporated and Dr. Renu Gupta (previously filed as Exhibit 10.4 to Insmed Incorporated's Current Report on Form 8-K filed on February 1, 2011, and incorporated herein by reference).
10.34**	Employment Agreement, effective as of July 18, 2011, between Insmed Incorporated and Andrea Holtzman Drucker (previously filed as Exhibit 10.1 to Insmed Incorporated's Current Report on Form 8-K filed on July 18, 2011, and incorporated herein by reference).
21.1	Subsidiaries of Insmed Incorporated
23.1	Consent of Ernst & Young LLP.
31.1	Certification of Timothy Whitten, Chief Executive Officer of Insmed Incorporated, pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes Oxley Act of 2003.
31.2	Certification of Timothy Whitten, Chief Executive Officer of Insmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2003.
32.1	Certification of Kevin P. Tully, Executive vice President and Chief Financial Officer (Principal Financial and Accounting Officer) of Insmed Incorporated, pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes Oxley Act of 2003.
32.2	Certification of Kevin P. Tully, Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer) of Insmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2003.

+ The Securities and Exchange Commission has granted confidential treatment with respect to certain information in these exhibits. The confidential portions of these exhibits have been omitted and filed separately with the Securities and Exchange Commission.

* Confidential treatment has been requested for certain portions of this exhibit. The confidential portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission.

** Management contract or compensatory plan or arrangement of the Company required to be filed as an exhibit.

100