INSMED INC
Form 10-K
March 16, 2011

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

FORM 10-K

(Mark One)

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

For the fiscal year ended: December 31, 2010

OR

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

For the transition period from _____ to _____

Commission File Number 0-30739

INSMED INCORPORATED
(Exact name of registrant as specified in its charter)

Virginia	54-1972729
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer identification no.)
11 Deer Park Drive, Suite 117 Monmouth Junction, NJ 08852	(732) 438-9434
(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/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 [ ] No []

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 [ ] No []

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

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

Indicate by check mark 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. []

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant on June 30, 2010 was $87,298,199 (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 10, 2011, there were 24,828,101 shares of the registrant's common stock, $.01 par value, outstanding.

Portions of the registrant's definitive Proxy Statement to be filed with the Securities and Exchange Commission no later than 120 days, or April 30, 2011, after the registrant's fiscal year ended December 31, 2010, and to be delivered to shareholders in connection with the 2011 Annual Meeting of Shareholders, are herein incorporated by reference in Part III.

INSMED INCORPORATED

INDEX

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. 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.

PART I

We may from time to time make written or oral "forward-looking statements", including statements contained in our filings with the Securities and Exchange Commission (including this Annual Report on Form 10-K and the Exhibits hereto and thereto), in our reports to stockholders and in other communications. Such statements give our current expectations or forecasts of future events; they do not relate strictly to historical or current facts. One can identify these forward-looking statements by use of words such as "may," "could," "should," "would," "believe," "anticipate," "estima "expect," "intend," "plan," "projects," "outlook" or similar expressions. In particular, these include statements relating to our beliefs, plans, objectives, goals, future actions, prospective products or product approvals, future performance or results of current and anticipated products, the outcome of contingencies, such as legal proceedings and financial results. These statements are based upon the current beliefs and expectations of management and are subject to significant risks and uncertainties. Our actual results may differ materially from those set forth in the forward-looking statements. Forward-looking statements involve certain risks and uncertainties that are subject to change based on various factors (many of which are beyond our control). Factors that could cause or contribute to differences in our actual results include those discussed in Item 1A under the section entitled "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 undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosures we make on related subjects in our 10-Q and 8-K reports to the Securities and Exchange Commission.

ITEM 1. BUSINESS

BUSINESS OVERVIEW

On December 1, 2010, we completed a business combination with Transave, Inc. (referred to as "Merger" throughout this document), 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. Under the terms of the merger agreement, Insmed paid off all of Transave's $7.8 million debt, and issued (on a pre-reverse stock-split basis) approximately 25.9 million shares of Insmed common stock, and approximately 91.7 million shares of Insmed Series B Conditional Convertible Preferred Stock and cash consideration of $561,280 in exchange for all of the outstanding capital stock of Transave. Of the 91.7 million shares of Series B Conditional Convertible Preferred Stock, 17.6 million shares were retained by us as security for any indemnification payments required pursuant to the merger agreement. On March 1, 2011, all of our shares of Series B Conditional Convertible Preferred Stock were converted into shares of our Common Stock, on a one for one basis, following the approval of such conversion by our shareholders at a special meeting of our shareholders held on March 1, 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 have approximately a 46.7% equity interest in the combined Company (on an as-converted, fully diluted basis), and legacy Insmed Incorporated shareholders have 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 10 reverse stock split of our common stock) will be delivered on June 12, 2012, subject to reduction for any indemnification payments being made under the merger agreement.

We are a pharmaceutical Company and following the December 1, 2010 merger, have expertise in proprietary, advanced liposomal technology designed specifically for inhalation lung delivery. Our proprietary liposomal technology is designed specifically for delivery of pharmaceuticals to the lung and 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 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 mycobacteria (NTM) lung infections.

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. Although ARIKACE is considered a New Chemical Entity (NCE) by the U.S. Food and Drug Administration (FDA) due to its patented liposomal technology, the key active ingredient, amikacin, is an FDA approved antibiotic with proven efficacy in the treatment of gram-negative infections. Arikace is in the aminoglycoside class of antibiotics.

We believe that ARIKACE has potential usage in at least two orphan indications (CF patients who have pseudomonas lung infections and patients who have NTM lung infections) both with a high unmet-need. We estimate the global market potential for these two orphan indications to be over $1 billion combined.

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 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 cystic fibrosis and could potentially be the first inhaled antibiotic to be approved for once-daily administration.

The Company has orphan drug designation for CF patients that have Pseudomonas lung infections in both the United States and the European Union.

For NTM lung infections, the Company filed an investigational new drug (“IND”) application with the FDA for initiating Phase 3 clinical trials in the first quarter of 2011. In addition, the Company plans to file for orphan drug designation for NTM lung infections in both the United States and the European Union by the end of 2011.

Our current priority is to conduct Phase 3 studies beginning in 2011 for ARIKACE in the treatment of CF patients with Pseudomonas lung infections and patients with NTM lung infections. We believe we have the financial resources and the clinical and regulatory expertise to advance ARIKACE through Phase 3 development and approval for these two current target indications.

In addition to the ARIKACE program, we have a secondary proprietary program, IPLEX™. Under the proprietary IPLEX protein platform, while drug supplies last, we plan to maintain an expanded access program for amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease. In July 2009, due to the sale of our IPLEX manufacturing facility in March of that year, we announced that Insmed would cease the supply of IPLEX to any new patients to conserve inventory for existing ALS patients and that the Company would not initiate further clinical trials with IPLEX in the near term. We also have provided IPLEX for an early stage research program investigating retinopathy of prematurity (ROP) through an IPLEX Material Transfer Agreement with Premacure in Sweden. Sufficient quantity of IPLEX has been supplied to Premacure to complete a Phase 2 trial, which they are conducting. The Company intends to analyze the ongoing data collected for these indications, and assess the overall viability of

the IPLEX development program in 2011. We currently expect that our supply of IPLEX will be exhausted in the third quarter of 2011.

ARIKACE – Our Lead Product Candidate

We believe that 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 minimize the serum levels of amikacin compared to IV administration, which may reduce the potential to cause side effects, such as ototoxicity and nephrotoxicity. In addition, ARIKACE may be more convenient to administer, as it is delivered once daily compared to the currently marketed inhaled antibiotics, which require administration two to three times daily.

We believe that ARIKACE has the potential to be further differentiated because the liposomal delivery technology may allow ARIKACE to reach the site of the lung infection better than other aminoglycoside antibiotics. For treating pseudomonas lung infections in CF patients, ARIKACE has been shown, in vitro, to penetrate the bacterial biofilm, a protective barrier produced by pseudomonas, whereas the other aminoglycoside antibiotics have not been shown to penetrate the biofilm effectively. This means that ARIKACE may reach the site of the Pseudomonas infection in the lung better than the other aminoglycoside antibiotics. For NTM lung infections, ARIKACE has been shown to be potentially preferentially taken up by the macrophages. Since NTM is an intracellular pathogen, this may allow Arikace to reach the site of the NTM lung infection better than other aminoglycoside antibiotics.

In phase 2 studies in CF patients with Pseudomonas lung infections ARIKACE has been shown to provide sustained improvement in lung function, including improving lung function both during and between treatment periods in patients with cystic fibrosis and could potentially be the first approved inhaled antibiotic to be administered once-daily.

The data from our completed randomized, placebo-controlled Phase 2 clinical trial program in CF patients with Pseudomonas lung infections indicated that ARIKACE, delivered at a dose of 560 mg once daily via an optimized, investigational eFlow® Nebulizer System for 28 consecutive days, demonstrated superior clinical benefit compared to placebo as measured by significant and sustained improvement in lung function and reduction in Pseudomonas density. This benefit was sustained over multiple cycles as observed in a long-term, multi-cycle, open-label study. 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.

Our primary focus is to advance ARIKACE through Phase 3 clinical studies for CF patients with Pseudomonas lung infections and patients with NTM lung infections.

We plan to commence patient accrual to Phase 3 studies of ARIKACE for CF patients with Pseudomonas lung infections during the second half of 2011 to support potential approvals in the United States and the European Union. In the United States, the main primary efficacy study (Phase 3 clinical trial) will consist of a randomized, double-blind trial in which ARIKACE will be compared to placebo for one 28-day treatment period plus a 56 day off treatment period in approximately 300 subjects. The primary endpoint is time to pulmonary exacerbation over the 84 days. In the European Union, there will be a randomized, double-blind Phase 3 trial comparing ARIKACE to an approved competitive product, inhaled tobramycin solution (TOBI®), in approximately 300 subjects. The primary endpoint will be change in pulmonary function (FEV-1) measured at the end of the off period following the third treatment cycle (about six months) after three 28 day on treatment and three 28 day off treatment cycles. Patients from both of the primary efficacy studies will then be consented to receive ARIKACE in an open label safety and tolerability study for a total of at least six cycles (about one year) of treatment. Some patients may receive Arikace for up to two years in an open label manner. The key elements of these study designs and regulatory paths have been agreed to with the FDA and the European Medicines Agency (EMA). We plan to conduct each of the Phase 3 trials in multiple countries.

In the NTM indication we filed an IND application to enter Phase 3 in patients with NTM lung infections during the first quarter of 2011. Assuming we achieve agreement with FDA, we intend to initiate patient accrual to a Phase 3, placebo controlled trial in the second half of 2011. We anticipate the trial design having a primary endpoint related to the reduction in the NTM pathogen with trial duration of three months of treatment in approximately 100 subjects followed by an open label trial of three months.

The overall product profile that we are working to develop for ARIKACE may potentially lead to a differentiated inhaled antibiotic treatment which could result in: (1) improved efficacy resulting from sustained deposition of drug in the lung, penetration of Pseudomonas biofilm and facilitated drug release (virulence factors), and for NTM, enhanced uptake into macrophages, where NTM often grows; (2) decreased side effects and improved tolerability; (3) reduced dosing frequency; and (4) decreased administration time.

According to the Cystic Fibrosis Foundation, CF affects roughly 30,000 children and adults in the United States and roughly 70,000 children and adults worldwide. According to the Company's sponsored analysis conducted by SDI Healthcare, more than 30,000 patients visited physician offices suffering with NTM lung disease in the United States during 2008.

In addition to CF and NTM, we believe that ARIKACE has potential to be used for treating other types of conditions, such as non-CF bronchiectasis characterized by Pseudomonas aeruginosa lung infections, for which we also have orphan drug status in the United States.

We believe the Company has the financial resources and the clinical and regulatory expertise to advance ARIKACE through Phase 3 development and approval for our two current target indications. Our initial intention is to retain marketing rights for ARIKACE in the United States and retain marketing or co-marketing rights in Europe although we have the option of seeking a licensing partner for commercialization if we choose to do so. Because of the highly concentrated nature of the prescribing population, we believe ARIKACE™ will require limited commercial infrastructure (e.g. less than 50 sales representatives in the United States) which may enable the Company to achieve profitability sooner after market launch than an indication that requires a large internal commercial infrastructure.

Market Opportunity: Cystic Fibrosis Patients with Pseudomonas aeruginosa Lung Infections

Cystic fibrosis (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 United States and roughly 70,000 children and adults worldwide (The Company has orphan drug designation for CF patients that have Pseudomonas lung infections in both the United States and the European Union.) 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.

Despite extensive treatment with multiple antibiotics, improved nutrition, and other treatments, life expectancy of a CF patient is only about 36 years. 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. (Liou et al, Journal of Cystic Fibrosis 9 (2010) 250–256)

According to the Cystic Fibrosis Foundation (Patient Registry, 2009), over half of all CF patients have 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 to 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 they become chronically infected in spite of all currently available antibiotic treatments.

CF therapy significantly impacts patients' quality of life. Some patients with CF presently spend up to 3 hours per day taking medications and other treatments, including inhaled antibiotics. The current most commonly used inhaled antibiotic in the U.S. is administered twice daily over 30-40 minutes per day for 28 days followed by a 28 day period "off drug". 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 days off the drug. Any inhaled treatment that reduces the treatment burden of a CF patient could represent a significant breakthrough in improving the patient's quality of life. A once daily shorter treatment could lead to better compliance and potentially better efficacy.

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 month with the goal of better maintaining lung function. It is anticipated that aminoglycosides including ARIKACE if approved will continue to be recommended as core therapy in the on-month due to their established effectiveness against Pseudomonas.

The global CF market for inhaled antibiotics is expected to experience significant growth in the next five years from about $400 million today. Expected growth in the market is due to:

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

Physicians initiating inhaled antibiotics at earlier stages;

CF patients living longer; and

Standard of care in the rest of the world continuing to advance closer to that of the EU and US.

As mentioned above, 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 a barrier protecting the bacteria from direct attack by antibiotics. Current belief is that this biofilm barrier is charge negative and since conventional aminoglycosides antibiotics are charge positive, it is believed that they are attracted to the surface of the biofilm, and therefore have limited ability to penetrate it, preventing effective dose levels of the drug from getting to the bacteria. In addition, many studies have shown that marketed drugs delivered via inhalation often have a very short residence time in the lung and are cleared rapidly into the blood stream.

We believe that 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 Pseudomonas 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 encased within. We have conducted in vitro experiments, which demonstrate that ARIKACE liposomes penetrate into both human CF sputum and the biofilm of Pseudomonas macro-colonies. We believe getting the FDA approved antibiotic, amikacin, in close proximity 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 bacteria participate in their own potential destruction. (Meers et al, Journal of Antimicrobial Chemotherapy (2008) 61, 859–868)

Evidence to date leads us to believe that the sustained levels of drug in the lung reduces dosing frequency, thereby easing a patient's treatment burden and potentially improving patient compliance. Maintenance of the antibiotic above

the therapeutic level (minimal level of drug needed to kill Pseudomonas) between doses may also increase efficacy and decrease the potential for the development of resistant strains of bacteria. In preclinical animal studies, the residence time of drug in the lungs from inhalation of ARIKACE was significantly longer than that from inhalation of amikacin solution or tobramycin solution; the half-life of antibiotic in the lung was increased by more than 100 times with the use of ARIKACE.

The second part of our delivery technology, supporting the Company's patented liposomal formulation, is the state of the art nebulizer, which we believe represents a competitive advantage over the nebulizer that was approved for use by the current inhaled antibiotic market leader. ARIKACE will be administered once daily via inhalation using an optimized, investigational eFlow® Nebulizer System developed by PARI Pharma GmbH. 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 eFlow Nebulizer System uses eFlow Technology to enable highly efficient aerosolization of medication including liposomal formulations via a vibrating, perforated membrane which includes thousands of specially designed laser drilled holes, which aids the delivery of ARIKACE to the lung. We believe that compared to other nebulizer systems, eFlow Technology is significantly more efficient by delivering a very high density of active drug, a precisely defined and controlled droplet size, and 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 use, we believe eFlow Technology reduces the burden of taking daily, inhaled treatments.

Insmed plans to commence patient accrual to Phase 3 studies of ARIKACE for CF patients with Pseudomonas lung infections during the second half of 2011 to support potential approvals in the United States and the European Union.

Market Opportunity: Non-tuberculous Mycobacteria Lung Infections

Non-tuberculous mycobacteria (NTM) lung infections can cause severe pulmonary disease for which there are currently limited effective treatments. NTM may be considered to be a cousin of tuberculosis (TB), but not contagious. NTM is found in the environment, e.g., soil and water, and can lead to serious infections, the most common of which occur in the lung. 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 bodies 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 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.

According to a Company sponsored analysis conducted by SDI Healthcare, more than 30,000 patients visited physician offices suffering with NTM lung disease in the United States 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. About two-thirds of the NTM patients received at least one antibiotic and of those receiving an antibiotic, they received between 7 and 8 courses in 2008.

We believe the unmet need for new therapies is extremely 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. Few clinical trials are under way to identify treatment recommendations, and no new antibiotics have been assessed for treating NTM lung infections in multi-center, randomized clinical trials for many years.

Amikacin, in the currently approved formulation, does not have an FDA approved indication 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. Since 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 (ear) and renal toxicity (kidney).

We believe that ARIKACE has an attractive profile in treating patients with NTM because of the ability of ARIKACE to be taken up inside lung macrophages which harbor invading organisms such as NTM. 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 oto and renal toxicity.

The Company filed an IND with the FDA for NTM lung infections to initiate Phase 3 clinical trials in the first quarter of 2011. In addition, the Company plans to file for orphan drug designation for NTM lung infections both the United States and the European Union by the end of 2011.

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

Although CF and NTM are the current primary indications for ARIKACE, we believe Non-CF bronchiectasis offers another potential market opportunity. 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 about 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.

ARIKACE randomized, placebo-controlled Phase 2 clinical trial results in which the drug was administered once daily for 28 days demonstrated an improvement in time to pulmonary exacerbations/reduced need for anti-Pseudomonas rescue treatment, a decrease in Pseudomonas Log CFU's and a decrease in frequency of cough with expectoration. The study also revealed that ARIKACE was well-tolerated with adverse events consistent with underlying chronic lung disease in bronchiectasis patients. Patients in the 560 mg cohort had a slightly higher frequency of dry cough than those in the 280 mg cohort, but the cough was of short duration, was self-limiting, and did not result in any physician choosing to discontinue a patient from the trial.

The Company has orphan drug designation in the United States for non-CF bronchiectasis patients that have Pseudomonas lung infections.

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 the Phase 3 studies for the first two indications, CF patients with Pseudomonas lung infections and NTM lung infections.

IPLEX

Our other proprietary protein product, IPLEX (mecasermin rinfabate, recombinant DNA origin, injection), which is a complex of recombinant human IGF-1 and its binding protein IGFBP-3 (rhIGF-1/rhIGFBP-3), has been studied as a treatment for several serious medical conditions.

IPLEX is typically administered as a once-daily subcutaneous injection, which can restore and maintain IGF-1 at physiologically relevant levels. The binding protein, rhIGFBP-3, extends the residence time of IGF-1 in the blood. In the bound state, we believe IGF-1 is inactive and remains so until delivered to target tissues in the body where it is released and becomes biologically active.

We continue to evaluate IPLEX as a treatment for Retinopathy Of Prematurity ("ROP") and Amyotrophic Lateral Sclerosis ("ALS"), but are not conducting clinical trials or spending on research and development. In the ALS indication we are working with patients in the U.S. and Europe as part of our Expanded Access Program (EAP). In the ROP indication, we have supplied IPLEX to Premacure AB is located in Sweden. Premacure has initiated, under their control and at their cost, a Phase 2 multicenter trial for IPLEX in the ROP indication using the IPLEX already supplied to them, which they believe is sufficient to complete the Phase 2 trial. We have been informed by Premacure that five infants have been recruited into the trial to date. They plan to accrue up to 95 patients in order to get 80 evaluable patients.

Expanded Access Program 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. The progressive degeneration of the motor neurons in ALS patients eventually leads to death. When the motor neurons die, the ability of the brain to initiate and control muscle movement is lost. With voluntary muscle action progressively affected, patients in the later stages of the disease may become totally paralyzed. IGF-1 has been shown to be highly neurotrophic and normally circulates in the body bound with its natural chaperone, BP3. It is believed that IPLEX, which is a complex of IGF-1 and BP3, increases the half life of IGF-1 in the bloodstream, allowing it to circulate in the body longer and affording a greater opportunity for IGF-1 to cross the blood-brain barrier and utilize its neurotrophic qualities in the area where it could prove most effective.

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. The request came as a result of several Italian Court rulings ordering the Italian National Health System to provide IPLEX to specific ALS patients who have petitioned the Court. Through an agreement with Cephalon, which holds patent rights in the European Union 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. and Ipsen Inc., we were allowed to develop IPLEX 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 are gathering uncontrolled data on ALS through our ongoing Expanded Access Program.

IPLEX and 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 3 / 4 pounds, or 1250 grams, or less that 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 visual loss in childhood and can lead to lifelong vision impairment and blindness.

Today, with advances in neonatal care, smaller and more premature infants are being saved. There are approximately 3.9 million infants born in the U.S. each year; of those, about 28,000 weigh 2 3 / 4 pounds or less. It is estimated that 14,000–16,000 of these infants are affected by some degree of ROP. Of these, 1,100–1,500 infants annually develop ROP that is severe enough to require medical treatment and 400–600 infants each year in the US become legally blind from ROP.

The most effective proven treatments for ROP are laser therapy or cryotherapy. Laser therapy "burns away" the periphery of the retina, which has no normal blood vessels. With cryotherapy, physicians use an instrument that generates freezing temperatures to briefly touch spots on the surface of the eye that overlie the periphery of the retina. Both laser treatment and cryotherapy destroy the peripheral areas of the retina, slowing or reversing the abnormal growth of blood vessels but destroying some side vision. Both laser treatments and cryotherapy are performed only on

infants with advanced ROP and both treatments are considered invasive surgeries on the eye, and doctors don't know the long-term side effects of each.

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 AB which is located in Sweden. Premacure has initiated, under their control and at their cost, a Phase 2 multicenter trial for IPLEX in the ROP indication using the IPLEX already supplied to them, which they believe is sufficient to complete the Phase 2 trial. We have been informed by Premacure that five infants have been recruited into the trial to date. They plan to accrue up to 95 patients in order to get 80 evaluable patients.

IPLEX and Short-Stature Market

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. As a result of our settlement agreement with Tercica, Inc. and Genentech, Inc., discussed below, we have withdrawn IPLEX from this market.

In December 2004, Tercica (now Ipsen) 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. In these cases, Tercica and Genentech alleged that production and use of IPLEX infringed claims in certain U.S. and European patents, owned by Genentech and licensed to Tercica, directed to methods of using rhIGF-1/rhIGFBP-3 and methods of producing rhIGF-1 and IGFBP-3. In June 2006, Tercica also filed an unfair competition suit against us in the U.S. District Court of the Eastern District of Virginia, claiming that we disseminated misleading statements to the market in connection with our marketing of IPLEX.

On December 6, 2006, a jury in the U.S. District Court for the Northern District of California found that we infringed patents held by Tercica and Genentech and awarded damages of $7.5 million as an upfront payment and a royalty of 15% on past sales of IPLEX below $100 million and 20% for past sales of IPLEX above $100 million.

On March 5, 2007, we reached a settlement agreement ending all litigation with Tercica and Genentech. Pursuant to the agreement, we agreed to cease sales and marketing of IPLEX in the United States and agreed to withdraw our European Marketing Authorization Application for IPLEX. We continue to provide IPLEX to named patients with ALS in Italy and the rest of Europe under our Expanded Access Program. 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. These indications include severe insulin resistance and myotonic muscular dystrophy, among others. The development partnership includes provisions that give us 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. In addition, as part of the settlement agreement, Tercica and Genentech waived the damages awarded by the jury in the patent infringement suit from the U.S. District Court for the Northern District of California. The settlement agreement prevents us from actively pursuing worldwide development activities for this indication.

INSM-18 and rhIGFBP-3 - Oncology Programs

INSM-18 and rhIGFBP-3 are two additional development candidates of Insmed and could be primarily investigated for the treatment of cancer. We believe both INSM-18 and rhIGFBP-3 are promising potential novel treatments for a variety of cancer types. Preclinical models demonstrate that both treatments 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 outlicensed the rights of INSM-18 to Napo Pharmaceuticals for diabetes and to TriAct Inc. for other INSM -18 indications. Due to the high cost of trials in the oncology area, we would need to identify a partner to co-develop rhIGFBP-3.

CISPLATIN Lipid Complex

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. It is in pre-clinical development and we are not actively pursuing development at this time. We have recently out-licensed the rights to Eleison Pharmaceuticals, a privately-held Company focused on developing compounds for orphan indications.

RESEARCH AND DEVELOPMENT

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. The development plan includes the treatment of Pseudomonas and Burkholderia cepacia (B. cepacia) infection of the lungs in patients with CF, and patients with NTM lung disease. The Company 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 commercial product with the potential for enhanced safety, efficacy and convenience for patients. Pre-clinical development of ARIKACE was initiated in 2006 and was the basis of the US 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.

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. The principal neutral lipid in pulmonary surfactant is cholesterol. The ARIKACE liposomes are comprised of two lipids, DPPC and cholesterol. The lipids used in the liposomes of ARIKACE are the same as those found in the surfactant layer of the lungs and are therefore biocompatible, and unlikely to be associated with significant adverse effects.

The electrically charge neutral liposomes of ARIKACE shield the entrapped cationic amikacin thereby minimizing electrostatic interaction of the drug with the negatively charged sputum/biofilm within the lung of CF patients. This electrostatic binding accounts for an approximately 50% decrease in bioavailability of inhaled tobramycin (Hunt et al., 1995). The liposome particles of ARIKACE were found to be small enough to penetrate and diffuse through sputum into the bacterial biofilm deep in the lung, and deposit drug in close proximity to the bacterial colonies thus improving the bioavailability of amikacin. In addition, there are Pseudomonas derived virulence factors (rhamnolipids) which release amikacin from liposomes. Through these mechanisms, it is believed that relatively high concentrations of drug can accumulate locally at the bacterial macro-colony environment, and thus enhance bacterial killing. (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 United States, in 2008, the median predicted age of survival rose in 2009 to about 36 years, up from 32 years in 2000 (Cystic Fibrosis Patient Registry, 2009). 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 in 2008. The Eurocare CF Registry has confirmed approximately 29,000 CF patients, with an estimated 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 US are infected. Pseudomonas grows in macrocolonies with biofilm-like characteristics in the hypoxic environment of the inspissated (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.

Therapies for Cystic Fibrosis

Pseudomonas is susceptible to several wide spectrum antibiotics, notably aminoglycosides. 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. Ototoxicity and nephrotoxicity are common adverse events (AE) 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®). Inhaled tobramycin, 300 mg, administered twice a day for cycles of 28 days followed by 28 days off drug 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 15-20 minute inhalation sessions per dose.

There are two main obstacles to effective and safe treatment. First, high-level multi-drug antibiotic resistance complicates eradication of such strains from the bronchial secretions of CF patients and second, there is limited penetration of anti-infectives 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 cornerstones of CF therapy; 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 (Schentag et al., 1978; Smith et al., 1978).

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 to decrease the frequency of administration, reduce the administration time, and to improve quality of life.

We have been granted orphan drug designation in the US and EU for ARIKACE in CF.

Non-Tuberculous Mycobacterial Lung Disease

The 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 spread. It appears that the prevalence of human disease attributable to these organisms over the past 2 decades is increasing. Pulmonary disease due to NTM was traditionally reported as primarily upper lobe fibrocavitary disease occurring in male smokers with emphysema. More recently, certain disease and demographic populations seem to be particularly susceptible to nodular bronchiectatic pulmonary disease with predominant infection of the anterior aspect of the mid-lung. In CF, the prevalence of NTM (~75% Mycobacterium avium complex [MAC], 20% M. abscessus) in the lower airways is 13%, and increases with age. Elderly, caucasian women without apparent predisposing conditions have been reported with increasing frequency to have pulmonary disease associated with MAC, and one community pulmonary practice reported this to be 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. These conditions include chronic obstructive airway disease associated with smoking, bronchiectasis, previous mycobacterial diseases, CF, and pneumoconiosis. (Olivier et al 2003. Am J Resp Crit Care Med 167(6): p828-34)

Treatment guidelines for patients with MAC lung disease in the recently published ATS/Infectious Diseases Society of America (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 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; the guidelines list drugs which 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 expensive and poorly tolerated It is clear from single-site studies that more effective, less-toxic therapeutic options are needed.

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 with neither significant systemic absorption nor the associated systemic toxicities. Disadvantages of aerosolized aminoglycoside solutions include rapid clearance from lung tissue, which 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. Thus, liposomal amikacin for inhalation (ARIKACE) was developed to overcome these limitations. We are planning to file for orphan drug designation for this indication.

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 which can enhance the release drug in vivo. Other in vitro studies showed that the supernatant obtained from a culture of Pseudomonas originating from a CF patient released ~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 locally to the bacterial macrocolony environment are the basis for 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, (5) ARIKACE has in vitro activity that is superior to amikacin solution against different strains of NTM, and (6) data from evaluation of ARIKACE in toxicology studies suggest that there should not be any important safety issues in patients administered ARIKACE at 560 mg daily for up to three months consecutively, and possibly longer. Also, neither ARIKACE nor its predecessor formulation (SLIT™ Amikacin) showed evidence of toxicity in the standard battery of genetic toxicity studies. A carcinogenicity study with ARIKACE is ongoing.

ARIKACE Clinical Program

Liposomal amikacin for inhalation has been evaluated in a series of Phase 1 healthy volunteers, and CF patients (The predecessor SLIT™ Amikacin formulation), and ARIKACE ™ in Phase 2 clinical studies, in Cystic Fibrosis (CF) and Bronchiectasis (BR) patients.

Cystic Fibrosis Program

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

Both studies were conducted in CF patients > 6 years of age 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 (AE) and there were no differences between the groups in overall rates of AEs. The AEs 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 ARIKACE demonstrated superior clinical benefit vs. 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 FEV1 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 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 study to include a long term safety and efficacy follow-up of six repeat 28 day cycles of 560mg ARIKACE and 56 days off study drug. The study was completed in November 2010, and final data analysis is underway. 49 patients have been enrolled and 43 patients completed 6 cycles (18 months). Interim data from 41 patients who had completed 5 cycles was presented at the October 2010 North American Cystic Fibrosis ("NACF") Conference. Overall, ARIKACE 560 mg administered once daily for 5 cycles was well tolerated and demonstrated adverse effects that were consistent with those expected in a population of CF patients. At the end of the treatment period of the fifth cycle, FEV1 was increased by 12.0% above baseline ($p=0.0002$). The improvement in lung function was sustained at the end of two months off study drug, as shown by an increase in FEV1 of 5.5% ($p=0.018$).

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, and there is evidence of clinical and microbiologic benefit, particularly at the 560 mg dose. This is the bases for the launch of the Phase 3 program for global registration of ARIKACE in the treatment of Pseudomonas infections in CF patients.

Non-Tuberculous Lung Disease 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 have received a response to our Pre-IND application for ARIKACE in the treatment of NTM Lung Disease and have since submitted an IND to launch a Phase 3 study of ARIKACE in CF and non-CF patients with non-tuberculous mycobacterial lung disease.

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 lung disease and infection with micro-organisms susceptible to amikacin.

We are launching a Phase 3 program for treatment of NTM lung disease in CF and non-CF patients.

Bronchiectasis Program

In addition to the CF trials summarized above, ARIKACE has also been studied in patients with Non-CF Bronchiectasis (BR) and chronic infection with Pseudomonas. This study was completed in May 2009. Study subjects received ARIKACE 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 BR.

ARIKACE 280 mg and 560 mg, administered once daily for 28 days was safe and well tolerated. The AEs were consistent with underlying chronic lung disease in BR patients. There was no evidence of renal- 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 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. ARIKACE group (2.3%). Patients receiving ARIKACE demonstrated sustained superior clinical benefit vs. 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 initiate further clinical studies until we have completed the Phase 3 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 organization using the technology developed and optimized within Insmed. The contract organization is familiar with complex formulations such as ARIKACE, and has the facilities and equipment to support the further development and commercialization of the product. The facilities meet cGMP requirements for the sterile manufacturing of the finished product. An active program is underway which evaluates the facility requirements for commercial production.

IPLEX

We previously manufactured our own supply of IPLEX and rhIGFBP-3 at the Boulder, Colorado, manufacturing facility. The transfer of the Boulder facility to Merck removed our internal IPLEX production capability. We believe, however, that we have sufficient inventory of IPLEX to support subjects currently receiving IPLEX in the U.S. and Europe into approximately the third quarter of 2011. 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 12 to 18 months once an acceptable third party is identified.

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. Lastly, 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. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach.

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 United States.

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.

The patent positions of companies like ours are generally uncertain and involve complex legal, technical, scientific and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in promptly filing patent applications on new discoveries, and in obtaining effective claims and enforcing those claims once granted. 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. 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. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, narrowed, invalidated or circumvented or be found to be invalid or unenforceable, which could limit our ability to stop competitors from marketing related products and reduce the term of patent protection that we may have for our products. Neither we nor our licensors can be certain that we were the first to invent the inventions claimed in our owned or licensed patents or patent applications. In addition, our competitors may independently develop similar technologies or duplicate any technology developed by us and the rights granted under any issued patents may not provide us with any meaningful competitive advantages against these competitors. 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 several issued patents and pending patent applications in the U.S. and to several foreign applications, which are foreign counterparts of many of our U.S. patents. Our patent portfolio includes patents and patent applications with claims relating to compositions and methods of treating lung infections. The patent positions for ARIKACE (liposomal amikacin for inhalation), our product candidate for treatment of lung infections, and IPLEX, our product candidate for treatment of retinopathy of prematurity (ROP) and amyotrophic lateral sclerosis (ALS), 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 eFlow® Nebulizer System.

- 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 European Union, Canada and Japan.

- We also own pending U.S. and foreign patent applications that cover the composition and use of our cisplatin-lipid-complex technology.

As part of the development of ARIKACE and IPLEX we have filed or may file patent applications related to new production methods, improved formulations, new medical uses and new dosing regimens in the United States and in many of the major international pharmaceutical markets. As with any pending patent application, there can be no assurance that any of these applications will issue in the United States, European Union, Canada, Japan or in any other country where we decide to file for protection. There also can be no assurance that a subsequent U.S. or foreign patent will later be held valid and enforceable.

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 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. In addition, 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) prohibits approval of generic copies of an orphan drug (an orphan drug is a drug for a rare disease or condition) (both new drug and biologics), and delays approval of a second Company’s version of the orphan drug even if the second Company submits a full NDA containing a new set of safety and effectiveness investigations to the FDA for that drug, for seven years. The seven year period reflects the time it will take to recover the cost of developing an orphan drug from sales of such drug in the United States. 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.

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. The agreements that we have entered into are subject to early termination upon material breach by us. Our ability to maintain licensure under these agreements is dependent on our ability to meet the obligations defined in these agreements and although we take steps to ensure compliance with the provisions of these agreements, we cannot assure that the licensors will not take dispute with our actions and will seek to terminate the agreements.

We currently have a licensing agreement with PARI Pharma GmbH for use of the optimized eFlow® Nebulizer System for delivery of ARIKACE in treating patients with cystic fibrosis, bronchiectasis, and non-tuberculosis mycobacteria infections. Insmed has rights to several U.S. and foreign issued patents, and there are future patent applications involving improvements to the eFlow® Nebulizer System. In consideration of this agreement, PARI shall receive payments either in cash, qualified stock or a combination of both totaling approximately $4.5 million 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 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 United States and foreign territories, as discussed earlier in this section;

- In April 2005, we were granted a non-exclusive license to certain proprietary manufacturing technology from Avecia Limited;

- 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.; and

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

We have also entered into an out-licensing agreement with Eleison Pharmaceuticals granting Eleison exclusive rights to patent applications covering our cisplatin-lipid-complex technology.

Third Party Patents

Third parties hold U.S. and foreign patents that may be construed as being directed to a composition, production and use of inhaled antibiotics and rhIGF-1, rhIGFBP-3, IPLEX and recombinant proteins generally. We are not aware of any patents that would pose an obstacle to our potential commercialization plans for ARIKACE, IPLEX or rhIGFBP-3, should we decide to do so. We can provide no assurance, however, that a third party would not assert a contrary position in the future, for instance in the context of an infringement action. Likewise, we cannot predict with certainty the outcome of such a proceeding. 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 triple damages and the other party's attorneys' fees, which may be substantial;

- cease the development, manufacture, marketing and sale of products that infringe the proprietary rights of others;

- expend significant resources to redesign our product so that it does not infringe the proprietary rights of others;
- develop or acquire non-infringing proprietary rights, which may not be possible and would require additional clinical trials and regulatory approvals;
- redesign our product to avoid infringing on third party proprietary rights, which may result in significant regulatory delays associated with conducting additional clinical trials or other steps to obtain regulatory approval; and
- obtain one or more licenses 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 our attention.

In 2007, we settled patent infringement litigation brought against us by Tercica and Genentech. As part of the settlement agreement, we entered into a Consent Judgment and Permanent Injunction in the United States District Court for the Northern District of California. If our settlement agreement with Tercica and Genentech is terminated, the Consent Judgment and Permanent Injunction against us will survive termination, which could have a material adverse effect on our business, financial condition and results of operations.

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, all of the U.S. trademark applications for these marks have been either registered or approved by the U.S. Patent and Trademark Office and Notices of Allowances and have been issued. 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.

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, less expensive, or that have better tolerability or convenience. We may also face generic competitors where third party payers 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 mainly based in the U.S. that have approved therapies or therapies in development for the treatment of chronic lung infections. Most of these competitors are focused on the Cystic Fibrosis 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. We are not aware of any other companies currently developing an inhaled antibiotic

for non-tuberculous mycobacteria lung infections.

Inhaled tobramycin (TOBI®) was the first inhaled antibiotic solution to be approved by the FDA and has been sold in the US 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. Additionally, specialty pharmacies in the United States compound generic tobramycin originally formulated for I.V. use and sell it for inhalation purposes.

Forest Laboratories markets inhaled colistin (Colomycin®) in Europe including the U.K. and Ireland. Colomycin is used in Europe primarily as an adjunct therapy and in some cases as a primary therapy. Colistin is not approved for inhaled treatment in the U.S., but it is frequently used off label 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 United States that same year with less convenient three times per day dosing 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 limited to adult patients.

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

Competitor	Indication	Product	Class of Product	2010 Global Sales (in millions)	
Novartis	CF Patients with Pseudomonas Lung Infections	TOBI® (Tobramycin Inhalation Solution)	Aminoglycoside	Marketed	$279
Gilead	CF Patients with Pseudomonas Lung Infections	Cayston® (Aztreonam for Inhalation Solution)	Monobactam	Marketed	$48
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	Not Reported

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

While our product will have to compete with several of these products that have current sales and histories of effective and safe use and may have to compete with other products that are in development, we believe that our formulation technology, significantly higher efficiency and patient convenience of the optimized eFlow Nebulizer System, respiratory expertise, together with our experience and knowledge in our specific areas of focus provide us with an

important competitive advantage for our lead product candidate, ARIKACE. We intend to compete by developing ARIKACE to be a differentiated inhaled antibiotic treatment with the potential for (1) improved efficacy resulting from sustained deposition of drug in the lung, penetration of Pseudomonas biofilm and facilitated drug release (virulence factors), and enhanced uptake into macrophages, where NTM often grows; (2) decreased side effects and improved tolerability; (3) reduced dosing frequency; (4) decreased administration time; and (5) approval to include treating CF patients with mild lung disease (FEV-1 % Predicted of >75%) where currently approved products are not approved for this use.

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 a 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 preclinical 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.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not commented on or questioned the IND 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 or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes 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 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 agency'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 also refer applications for novel drug products or drug products which 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 2 or 6 months depending on the type of information included.

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 which 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.

In June 2007, we received clearance from the FDA for our IND for liposomal amikacin for inhalation, for the treatment of Pseudomonas aeruginosa infection in patients with cystic fibrosis.

In the first quarter of 2011 we submitted our IND for NTM to the FDA.

In August 2008, we received clearance from the FDA to initiate clinical trial of our liposomal amikacin for inhalation in the treatment of Pseudomonas aeruginosa lung infection in patients with non- cystic fibrosis Bronchiectasis.

The Hatch-Waxman Act

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application (ANDA). An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. ANDA applicants are not required to conduct or submit results of preclinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (2) the listed patent has expired; (2i) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid is called a Paragraph 4 certification. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA applicant has provided a Paragraph 4 certification to the FDA, the applicant must also send notice of the Paragraph 4 certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph 4 certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph 4 certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired (New Chemical Entity Market Exclusivity). Federal law provides a period of five years following approval of a drug containing no previously approved active ingredients, during which ANDAs for generic versions of those drugs cannot be submitted unless the submission contains a Paragraph 4 challenge to a listed patent, in which case the submission may be made four years following the original product approval. Federal law provides for a period of three years of exclusivity following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials conducted by or for the sponsor, during which FDA cannot grant effective approval of an ANDA based on that listed drug for the same new dosage form, route of administration or combination, or new use.

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, or 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 agency 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 an orphan drug designation in the U.S. for ARIKACE for the treatment of Pseudomonas aeruginosa lung infection in patients with Cystic Fibrosis. We have also obtained orphan drug designation in the US for the treatment of lung infections in patients with non-CF Bronchiectasis. We anticipate filing for orphan drug designation for ARIKACE for the treatment of Non-tuberculous Mycobacterial Lung Disease by the end of 2011. 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.

We have obtained an orphan medicinal product designation in the EU from the EMA for ARIKACE for the treatment of Pseudomonas aeruginosa lung infection in patients with Cystic Fibrosis. We anticipate filing for orphan medicinal product designation from the EMA for ARIKACE for the treatment of Non-tuberculous Mycobacterial Lung Disease.

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.

As described in the section entitled “ARIKACE for Cystic Fibrosis”, we believe that the orphan designation of TOBI® in the EU will not prevent us from obtaining marketing approval of ARIKACE in the EU for the treatment of Pseudomonas aeruginosa infection in patients with cystic Fibrosis because ARIKACE may provide significant benefits over TOBI®.

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 approval process varies 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.

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.

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 device must be approved by FDA before ARIKACE can be commercialized.

Based on the risks and benefits of this 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 device before clearance to the US 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 device, as well as its substantial equivalence to previously cleared devices, in order for FDA to clear the subject device to the US 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 device. Whether or not we obtain FDA approval for a product and the device that will be used with ARIKACE, we must obtain approval of a product and the device by the comparable regulatory authorities of countries outside the U.S. before we can commence marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval.

Varying harmonization of Medical Device approval/clearance regulations outside the U.S. allows for fast-tracking of market clearance in some countries, using U.S. clearance as a baseline. 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 US.

EMPLOYEES

At December 31, 2010, we had a total of 40 employees, including 24 in regulatory and clinical, 9 in finance and administration, 4 temporarily involved in the transition and 3 in IPLEX distribution.

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.

AVAILABLE INFORMATION

We file electronically with the U.S. Securities and Exchange Commission, or 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.

ITEM 1A. RISK FACTORS

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

You should consider carefully the following risk factors, together with all of the other information included in this annual report on Form 10–K. Each of these risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock.

We have a history of operating losses and an expectation that we will generate operating losses for the foreseeable future, we may not achieve profitability for some time, if at all.

We are a pharmaceutical 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 until 2009 with the sale of 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 testing and clinical trials as well as regulatory approvals for commercialization and marketing before we are allowed to begin product sales. In addition, commercialization of our drug candidates 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, 2010, our accumulated deficit was $235 million. For the year ended December 31, 2010 our consolidated net loss was $6.4 million.

If we fail to meet the continued listing requirements of the NASDAQ Capital Market by June 13, 2011, 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.

We have been granted an additional 180-day compliance period, or until June 13, 2011, by the NASDAQ Listing Qualification Staff (the “Staff”) to regain compliance with the $1.00 per share minimum bid price rule for continued listing on The NASDAQ Capital Market, which requires us, among other things, to maintain a daily closing bid price per share of $1.00. We were previously notified by the Staff that we did not meet the minimum bid price rule required

for continued listing and we were initially provided until December 15, 2010 to achieve compliance. In order to assist us in regaining compliance with the minimum bid price requirement of the NASDAQ Capital- Market we have implemented a one-for-10 reverse stock split, which became effective on March 3, 2011 after receiving shareholder approval. While the reverse stock split could bring us back into compliance, there can be no assurance that the market price of the common stock will rise in proportion to the reduction in the number of outstanding shares resulting from the reverse stock split or any increase in the market price for our common stock resulting from a reverse stock split, would be sustainable since there are numerous factors and contingencies that would effect such price, including the market conditions for our common stock at the time, our reported results of operations in future periods and general economic, geopolitical, stock market and industry conditions. Accordingly, the total market capitalization of our common stock after a reverse stock split may be lower than the total market capitalization before such reverse stock split and, in the future, the market price of our common stock may not exceed or remain higher than the market price prior to such reverse stock split. While a higher share price may help generate investor interest in our common stock, there can be no assurance that a reverse stock split would result in a per share market price that attracts institutional investors or investment funds, or that such price would satisfy the investing guidelines of institutional investors or investment funds.

Our business combination with Transave is expected to result in benefits to the combined Company, but the combined Company may not realize those benefits due to challenges associated with integrating the companies or other factors.

We have recently completed a business combination with Transave. The success of the business combination will depend in part on the success of management of the combined Company in integrating the operations, technologies and personnel of the two companies. The inability of the combined Company to meet the challenges involved in integrating successfully our operations or to otherwise realize any of the anticipated benefits of the business combination could seriously harm the combined Company’s results of operations. In addition, the overall integration of the two companies may result in unanticipated operations problems, expenses, liabilities and diversion of management’s attention. The challenges involved in integration include:

- integrating the two Company’s operations, technologies and products;
- coordinating and integrating research and development;
- assimilating the personnel of both companies and integrating the business cultures of both companies;
- consolidating corporate and administrative infrastructures and eliminating duplicative operations; and
- maintaining employee morale and motivation.

We may not be able to successfully integrate our operations in a timely manner, or at all, and the combined Company may not realize the anticipated benefits of the business combination, including synergies or growth opportunities, to the extent or in the time frame anticipated. The anticipated benefits and synergies of the business combination are based on assumptions and current expectations, not actual experience, and assume a successful integration. In addition to the potential integration challenges discussed above, the combined Company’s ability to realize the benefits and synergies of the business combination could be adversely impacted to the extent that our relationships with existing or potential customers, suppliers or strategic partners is adversely affected as a consequence of the business combination, or by practical or legal constraints on its ability to combine operations. Furthermore, financial projections based on these assumptions relating to integration may not be correct if the underlying assumptions prove to be incorrect.

The ongoing integration of Insmed and Transave management following the recent business combination may present significant challenges.

Our business combination with Transave was only recently completed and we may face significant challenges in combining our management and internal control and disclosure systems in a timely and efficient manner. This integration will be complex and time-consuming because, among other things, our executive officers are currently located in separate Virginia and New Jersey offices. If we are unable to integrate our management and internal systems successfully, we might not achieve the anticipated potential benefits of the business combination.

We have not completed the research and development stage of any of our product candidates. If we are unable to successfully commercialize our products, it will materially adversely affect our business, financial condition and results of operations.

Our long-term viability and growth depend on the successful commercialization of products which lead to revenue and profits. Pharmaceutical product development is an expensive, high risk, lengthy, complicated, resource intensive process. In order to succeed, among other things, we must be able to:

- 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.

In order to conduct the development programs for our products we must, among other things, be able to successfully:

To generate any growth, we also would need to commercialize more than one product, which we currently have no plans to do. Failure to successfully commercialize our products will adversely affect our business, financial condition and results of operations.

We depend heavily on the success of our most advanced product candidate, ARIKACE. Clinical trials of ARIKACE may not be successful. If we are unable to commercialize ARIKACE, or experience significant delays in doing so, our business will be materially harmed.

We are investing a significant portion of our efforts and financial resources in the development of ARIKACE. Our ability to generate product revenue, which we do not expect will occur for at least the next several years, if ever, will depend heavily on the successful development and commercialization of ARIKACE. The successful commercialization of our product candidate will depend on several factors, including the following:

We currently plan to conduct Phase 3 clinical trials in 2011 for ARIKACE™ in the treatment of CF patients with pseudomonas lung infections and patients with NTM lung infections. 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 early-stage development. Accordingly, the results of the completed clinical trials for ARIKACE™ may not be predictive of the results we may obtain in later stage trials. We do not expect any of our drug candidates to be commercially available for at least several years, if at all.

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

Before obtaining regulatory approval for the sale of our product candidates, we must conduct, at our own expense, extensive preclinical tests to demonstrate the safety of our product candidates in animals, and clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Preclinical and clinical testing is expensive, difficult to design and implement and can take many years to complete. A failure of one or more of our preclinical studies or clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent our ability to obtain regulatory approval or commercialize our product candidates, including:

- our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials or we may abandon projects that we expect to be promising;

- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- conditions imposed on us by the FDA or any non-U.S. regulatory authority regarding the scope or design of our clinical trials may require us to resubmit our clinical trial protocols to institutional review boards for re-inspection due to changes in the regulatory environment;

- the number of patients required for our clinical trials may be larger than we anticipate or participants may drop out of our clinical trials at a higher rate than we anticipate;

- our third party contractors or clinical investigators may fail to comply with regulatory requirements or fail to meet their contractual obligations to us in a timely manner;

- we might have to suspend or terminate one or more of our clinical trials if we, the regulators or the institutional review boards determine that the participants are being exposed to unacceptable health risks;

- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;

- the cost of our clinical trials may be greater than we anticipate;

- the supply or quality of our product candidates or other materials necessary to conduct our clinical trials may be insufficient or inadequate or we may not be able to reach agreements on acceptable terms with prospective clinical research organizations; and

- the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

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

- be delayed in obtaining, or may not be able to obtain, marketing approval for one or more of our product candidates;

- obtain approval for indications that are not as broad as intended or entirely different than those indications for which we sought approval; or

- have the product removed from the market after obtaining marketing approval.

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

If we cannot enroll enough patients to complete our clinical trials, such failure may adversely affect our business, financial condition and results of operations.

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;

- competition from other companies' clinical studies for the same patient population; and

- ability to obtain comparator drug/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. Such delays could materially

adversely affect our business, financial condition and results of operations.

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. Except for IPLEX, which we do not currently market, we have not obtained regulatory approval nor commercialized any of our product candidates. We will conduct a Phase III clinical trial for ARIKACE in the near future but have not yet completed a Phase III clinical trial for any of our product candidates. 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 be unable to obtain an adequate supply of nebulizer devices for timely completion of our clinical studies. The failure to obtain these devices and any resulting delays in clinical programs may materially adversely affect our business, financial condition and results of operation.

We are dependent upon PARI Respiratory Equipment and PARI Pharma GmbH for the production and supply of nebulizer devices. We may encounter delays in the delivery of devices to us due to manufacturing delays, regulatory actions directed against the manufacturer, or issues in the shipping of devices. Such delays may affect the enrollment and treatment schedules of patients and delay the receipt of evaluative clinical data. We may be delayed 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.

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.

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.

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.

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

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

Data submitted to the regulators is subject to varying interpretations that could delay, limit or prevent regulatory agency approval. We may also encounter delays or rejections based on changes in regulatory agency policies during the period in which we develop a product and the period required for review of any application for regulatory agency approval of a particular product. Delays in obtaining regulatory agency approvals could adversely affect the development and marketing of any drugs that we or our collaborative partners develop. Such delays could impose costly procedures on our collaborative partners' or our activities, diminish any competitive advantages that our collaborative partners or we may attain and adversely affect our ability to receive royalties, any of which could materially adversely affect our business, financial condition and results of operations.

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

We will need regulatory approval for both the product and the medical device (nebulizer) that will be used to administer our lead product ARIKACE. Without these regulatory approvals, we will not be able to market or commercialize our lead product candidate.

Our lead product candidate, ARIKACE is administered via a nebulizer, which is a medical device that will require regulatory approval. We are dependent upon PARI Pharma GmbH to apply and receive the appropriate regulatory approvals in parallel to the product candidate regulatory applications and approvals. Failure to obtain the regulatory approval for the device could delay, limit or eliminate the ability of Insmed to commercialize the product.

We estimate that our supply of IPLEX, our material source of operating revenues, will be exhausted in the third quarter of 2011, which could adversely affect our financial condition and results of operation.

Our supply of IPLEX is currently forecast to be exhausted in approximately the third quarter of 2011. At that time, our revenues from the Expanded Access Program, or EAP, in Italy for cost recovery will end and, unless we execute an income generating transaction, we will have no material sources of operating revenue.

The Italian Health Authority may refuse to pay for IPLEX used by patients in Italy under EAP, which could have an adverse effect on our business, financial condition and results of operations.

At present the Italian Health Authority approves all drug payments for IPLEX used by Italian patients with ALS in Italy as part of the EAP. Should the Italian Health Authority decide to stop approving IPLEX for ALS it would impact our ongoing cash position.

We may not have or be able to obtain sufficient quantities of our products to meet our supply and clinical studies obligations and our business, financial condition and results of operation may be adversely affected.

We do not have an in-house manufacturing capability and depend completely on a small number of third-party manufacturers and active pharmaceutical ingredient formulators for the manufacture of our products. We do not have long-term agreements with any of these third parties, and if they are unable or unwilling to perform for any reason, we may not be able to locate alternative acceptable manufacturers or formulators or enter into favorable agreements with them. Any inability to acquire sufficient quantities of our products in a timely manner from these third parties could delay clinical trials and prevent us from developing our products in a cost-effective manner or on a timely basis. In addition, manufacturers of our products are 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 demands of our clinical supplies. 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. We believe however, that we have a good relationship with our suppliers, and have worked to establish timelines and schedules to meet our continued needs. Commercial manufacturing and supply agreements have not been established. Issues arising from scale-up, environmental controls, equipment requirements, or other factors, may have an adverse impact on our ability to manufacture the product. The transfer of the Boulder facility to Merck in connection with the sale of our FOB platform eliminated our internal IPLEX production capability. We believe, however, that we have sufficient inventory of IPLEX to support our ongoing ALS EAP in the U.S. and Europe into approximately the third quarter of 2011. Any requirements for IPLEX beyond that or any significant increase in demand beyond our current commitments in the ALS fields will require that we identify a Contract Manufacturing Organization or CMO to produce the necessary IPLEX to meet the demand. We are not pursuing any third party manufacturing arrangement at this time, but if we chose to do so, we estimate that the technical transfer of our IPLEX production process could require significant investment and take 12 to 18 months once a CMO has been identified.

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

We depend highly on the principal members of our scientific and management staff, the loss of whose services might significantly delay or prevent the achievement of research, development or business objectives and would materially adversely affect our business, financial condition and results of operations. 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. We face intense competition for such personnel and relationships. We cannot assure that we will attract and retain such persons or maintain such relationships.

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. We expect these demands will require an increase in management and scientific personnel and the development of additional expertise by existing management personnel. The failure to attract and retain such personnel or to develop such expertise could materially adversely

affect our business, financial condition and results of operations.

We rely on collaborative relationships for our success. If we are unable to form these relationships it could materially adversely impact our business, financial condition and results of operations.

We currently rely and may 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 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 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.

Given these risks, 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 and results of operations.

Our growth depends on technologies that may not be available or, if available and licensed, might not improve our business, financial condition or results of operations.

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 could conduct proprietary development programs with collaborators, and any conflicts with them could harm our business, financial condition and results of operations. We could enter into collaborative relationships that would involve our collaborators conducting proprietary development programs. Any conflict with our collaborators could reduce our ability to obtain future collaboration agreements and negatively influence our relationship with existing collaborators, which could have an adverse effect on our business, financial condition and results of operations. Moreover, disagreements with our collaborators could develop over rights to our intellectual property.

Certain of our collaborators could also be or become competitors. Our collaborators could harm our product development 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.

We may need additional funds in the future to continue our operations, but we face uncertainties with respect to our access to capital that could materially adversely impact our business, financial condition and results of operations.

We may require additional future capital in order to conduct Phase III clinical trials and commercialize ARIKACE and continue our research and development activities, or to acquire complementary technology. As of December 31, 2010, we had $110 million of cash and investments on hand. That amount may not be sufficient to meet the capital requirements of any business activity that we may generate. Our future capital requirements will depend on many factors, including factors associated with:

- Phase III clinical trials and commercialization of ARIKACE;
- research and development, including, among other items, preclinical testing and clinical studies,
- process development and scale up;
- obtaining marketing, sales and distribution capabilities;
- obtaining regulatory approvals;
- retaining employees and consultants;
- filing and prosecuting patent applications and enforcing patent claims;
- establishing strategic alliances;
- manufacturing; and
- potential future litigation.

We may also need to spend more money 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 satisfy our capital requirements. The failure to satisfy our capital requirements will adversely affect our business, financial condition and results of operations.

We may seek additional funding through strategic alliances, private or public sales of our securities 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. There can be no assurance, however, that we can obtain additional funding on

reasonable terms, or at all. If we cannot obtain adequate funds, we may need to significantly curtail our product development programs and relinquish rights to our technologies or drug candidates. This may adversely affect our business, financial condition and results of operations.

We may not accurately predict the protection afforded by our patents and proprietary technology and if our predictions are wrong, this may materially adversely affect our business, financial condition and results of operations.

Our success will depend in part on our ability 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.

Our patent positions are highly uncertain, and any future patents we receive for our potential products will be subject to this uncertainty, which may adversely affect our business, financial condition and results of operations. We intend to actively pursue patent protection for products resulting from our research and development activities that have significant potential commercial value. Nevertheless, it is possible that, in the patent application process, certain claims may be rejected or achieve such limited allowance that the value of the patents would be diminished. Further, there can be no assurance that any patents obtained will afford us adequate protection. In addition, any patents we procure may require cooperation with companies holding related patents. We may have difficulty forming a successful relationship with these 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 and results of operation. 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, 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.

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 an interference or other proceeding in a court or patent office could materially adversely affect our business, financial condition and results of operations.

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 pursue FOB product candidates will be significantly limited.

We operate in a highly competitive environment and if we are unable to adapt to our environment, we may be unable to compete successfully, which will materially adversely affect our business, financial condition and results of operations.

Biotechnology and related pharmaceutical technology have undergone and should 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. 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 and results of operations.

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 or rhIGF-1 which could adversely affect our competitive position in all indications where we are currently developing products developing ARIKACE™ or IPLEX™.

In the event there are other Amikacin or rhIGF-1 products approved by the FDA to treat indications other than those covered by ARIKACE and IPLEX, physicians may elect to prescribe a competitor's product containing Amikacin or rhIGF-1 to treat the indications for which ARIKACE or IPLEX has received and may receive approval. This 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 or rhIGF-1 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 or rhIGF-1 to treat such

diseases.

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. This may materially adversely affect our business, financial condition and results of operations.

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 United States. 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.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information. Disclosure of such information may materially adversely affect our business, financial condition and results of operations.

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 competitive business, financial condition and results of operations.

Our research, development and manufacturing activities at our former Boulder Facility and those used in the production of ARIKACE involved 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 involved the controlled use of hazardous materials, and chemicals. Our contract manufacture has the facilities and equipment for the appropriate handling of such material. However, if any liability arises, we could be liable for any losses incurred by the contract manufacturer and our results of operations and financial conditions could be materially adversely affected.

Our research, development and manufacturing activities at our former Boulder Facility involved the controlled use of hazardous materials, including hazardous chemicals and radioactive materials. Under the terms and conditions of our agreement with Merck for the sale of our FOB assets, we retained our obligations and liabilities under any environmental law relating to activities conducted before March 31, 2009 but which arise at any time during the two-year period beginning on March 31, 2009. If any such obligation or liability arises, we could be subject to an obligation to indemnify Merck for the losses incurred by Merck which could materially adversely affect our results of operations and financial condition.

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. This could have a material adverse effect on our business, financial condition and results of operations.

If our settlement agreement with Tercica and Genentech (now Ipsen and Roche) is terminated, the consent order from the court would be reinstated, which would have a material adverse effect on our business, financial condition and results of operations.

As part of our settlement agreement with Genentech and Tercica, we entered into a Consent Judgment and Permanent Injunction in the United States 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, which would have a material adverse effect on our business, financial condition and results of operations as we would no longer have a license to manufacture IPLEX using the present process without incurring significant penalties and royalties.

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

As of March 10, 2011, the warrants issued by us in May 2007 were exercisable for up to approximately 160,000 shares of our common stock.

As of March 10, 2011, our outstanding restricted stock, restricted stock units and stock options to our employees, officers, directors and consultants were exercisable for up to 750,000 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.

We may be unable to use our net operating losses.

We have substantial tax loss carryforwards for U.S. federal income tax purposes. Our ability to use such carryforwards 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 in connection with the business combination with Transave, may further limit or eliminate our ability to use our net operating losses.

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.

Our common stock is listed on the Nasdaq Capital Market under the ticker symbol “INSM.” Beginning March 2, 2011 we are temporarily trading under the symbol “INSMD” following the reverse stock split for a period of approximately 20 days. The market price of our stock has been and may continue to be highly volatile, and announcements by us or

by third parties may have a significant impact on our stock price. These announcements 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;
- 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;
- changes in the position of securities analysts with respect to our stock; and
- operating results below the expectations of public market analysts and investors.

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.

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. Certain former Transave stockholders holding 40% of our shares of common stock entered into lock-up arrangements with us in connection with the merger, which provide that these shareholders may only dispose of their shares beginning 180 days following the closing date of the merger (or May 30, 2011). Thereafter, these shareholders can 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. 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 proceeds from the sale of our FOB assets to Merck will be primarily used for the Phase 3 trials and commercialization efforts of ARIKACE.

Certain provisions of Virginia law, our articles of incorporation and our amended and restated bylaws, and our Rights Plan 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:

- 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, in May 2001, our board of directors approved the adoption of a Rights Plan under which shareholders received rights to purchase new shares of preferred stock if a person or group acquires 15% or more of our common stock. These provisions are intended to discourage acquisitions of 15% or more of our common stock without negotiations with the board. The rights trade with our common stock, unless and until they are separated upon the occurrence of certain future events. Our board of directors may redeem the rights at a price of $0.01 per right prior to the time a person acquires 15% or more of our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

On December 1, 2010, in connection with the merger, we obtained the lease for our clinical, regulatory, laboratory and administrations facility located in Monmouth Junction, New Jersey. We plan to use this site in New Jersey as our principal corporate office, where we occupy approximately 22,000 square feet dedicated to cGCP research of our clinical drug ARIKACE and additional laboratory and research and development operations and administrative functions. The annual cash costs for this facility including utilities and services in 2010 were approximately $1.0 million under an operating lease which expires in November 2011.

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 is presently being closed down 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 2010 was approximately $0.4 million.

We believe that our existing NJ facilities are adequate for our current needs and that suitable additional or alternate space will be available on commercially reasonable terms when our leases expire or when we need additional space. Prior to our lease expiration in November 2011, we are currently seeking alternative facilities in order to meet the ongoing needs of our business

ITEM 3. LEGAL PROCEEDINGS

Cacchillo vs. Insmed

On October 6, 2010, a complaint was filed against us by Angeline Cacchillo (Plaintiff) in the United States District Court for the Northern District of New York (Court) seeking money 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"). The data from this trial did not provide sufficient evidence that IPLEX was effective to treat MMD. As a result, we decided not to proceed to a phase III trial.

In the complaint, Plaintiff alleges (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) intentional infliction of emotional distress by refusing to support Plaintiff's compassionate use application after providing IPLEX, (v) violation of an assumed duty of care to Plaintiff, (vi) breach of fiduciary duty to Plaintiff, (vii) negligence and (viii) 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 8, 2010, the Court issued an Order to Show Cause requiring us to respond to Plaintiff's motion. On October 13, 2010, we filed an opposition to Plaintiff's motion for the preliminary injunction and on October 15, 2010, an oral argument was held before the Court on the Plaintiff's motion.

On October 22, 2010, the Court denied Plaintiff's motion for the preliminary injunction concluding that the Court lacked subject matter jurisdiction with respect to her claim for a preliminary injunction. Plaintiff appealed the Court's denial of her motion for a preliminary injunction to the United States Court of Appeals for the Second Circuit. The matter has been fully briefed and oral argument has been scheduled for March 15, 2011. Plaintiff's claim for monetary damages remains outstanding. 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 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, 2001, by and among Insmed Incorporated, River Acquisition Co., Transave, LLC, Transave, Inc. and TVM V Life Science Ventures GmbH & Co. KG, in its capacity as stockholders' agent. We intend 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.

ITEM 4. (REMOVED AND RESERVED)

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER REPURCHASES 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 as a result of a decision by the Panel in response to our appeal of the Staff Determination.

Our trading symbol is "INSM." Beginning March 2, 2011 we are temporarily trading under the symbol "INSMD" 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 2010 and fiscal 2009 adjusted for the 1 for 10 reverse stock split:

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
Fiscal Year 2009		
Fourth Quarter	8.50	7.00
Third Quarter	10.90	7.70
Second Quarter	25.70	8.70
First Quarter	11.30	4.00

On March 10, 2011, the last reported sale price for our common stock on the Nasdaq Capital Market was $4.98 per share. As of March 10, 2011, there were approximately 540 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.

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, 2010. The financial statements for each of the five fiscal years ended December 31, 2010, 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, 2010 and 2009 and for the years ended December 31, 2010, 2009 and 2008 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."

	Year Ended December 31,				
	2006	2007	2008	2009	2010
Historical Statement of Operations Data:					
Revenues	$1,025	$7,581	$11,699	$10,373	$6,921
Operating expenses:					
Cost of goods sold	1,490	576	-	-	-
Asset Impairment	7,103	-	-	-	-
Research and development	21,123	19,198	21,047	9,207	4,757
General and administrative	25,682	8,246	5,063	9,840	10,256
Total operating expenses	55,398	28,020	26,110	19,047	15,013
Operating loss	(54,373)	(20,439)	(14,411)	(8,674)	(8,092)
Loss on investments	-	-	(500)	-	-
Gain on sale of asset, net	-	-	-	127,474	-
Interest income	1,937	1,159	500	808	1,845
Interest expense	(3,703)	(682)	(1,256)	(781)	(109)
Income or (loss) before income taxes	(56,139)	(19,962)	(15,667)	118,827	(6,356)
Income tax expense	-	-	-	(477)	(78)
Net income or (loss)	$(56,139)	$(19,962)	$(15,667)	$118,350	$(6,434)
Basic net income (loss) per share	$(5.89)	$(1.74)	$(1.28)	$9.31	$(0.49)
Weighted average shares	9,532	11,468	12,213	12,712	13,250
Diluted net income (loss) per share	$(5.89)	$(1.74)	$(1.28)	$9.31	$(0.49)
Weighted average shares	9,532	11,468	12,213	12,727	13,250
Historical Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$24,112	$16,479	$2,397	$122,181	$108,049
Certificate of deposit	2,205	2,085	2,085	2,085	2,176
Total assets	28,348	19,500	4,758	126,695	196,265
Long-term debt, net	3,161	2,113	487	-	-
Net Stockholders' equity (deficit)	13,880	11,488	(2,823)	123,914	192,843

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

On December 1, 2010, we completed a business combination with Transave, Inc., a privately-held, NJ-based pharmaceutical Company focused on the development of differentiated, innovative inhaled pharmaceuticals for the site-specific treatment of serious lung infections. Under the terms of the merger agreement, Insmed paid off all of Transave's $7.8 million debt, and issued approximately 25.9 million shares of Insmed common stock, and approximately 91.7 million shares of Insmed Series B Conditional Convertible Preferred Stock and cash consideration of $561,280 in exchange for all of the outstanding capital stock of Transave. Of the 91.7 million shares of Series B Conditional Convertible Preferred Stock, 17.6 million shares were retained by us as security for any indemnification payments required pursuant to the merger agreement. On March 1, 2011 at a special meeting of our shareholders, all of our shares of Series B Conditional Convertible Preferred Stock were converted into shares of our Common Stock, on a one for one basis. Also at this meeting, our shareholders approved a one for ten reverse stock split of our common stock, which became effective at 5:00 pm EST on March 2, 2011.

After giving effect to the merger and following conversion of the preferred stock into common stock, former Transave stockholders have approximately a 47% equity interest in the combined Company, and Insmed Incorporated shareholders have a 53% interest on a fully diluted, as exercised, basis. The shares retained by us pursuant to the merger agreement (approximately 1.76 million shares of common stock after giving effect to the conversion of the Series B Conditional Preferred Stock and the one for 10 reverse stock split of our common stock) will be delivered on June 12, 2012, subject to reduction for any indemnification payments being made under the merger agreement.

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

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

Research and Development Activities

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 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. Our focus is now principally on our proprietary, advanced liposomal technology designed specifically for inhalation lung delivery. Our initial priority is to conduct Phase 3 studies with patient accrual beginning in the second half of 2011 for ARIKACE in treating CF patients with Pseudomonas lung infections and patients with NTM lung infections

All of our research and development expenditures, whether conducted by our own staff or by external scientists on our behalf and at our expense, are recorded as expenses as incurred. Research and development expenses consist primarily of salaries and related expenses, costs to develop and manufacture products and amounts paid to contract research organizations, hospitals and laboratories for the provision of services and materials for drug development and clinical trials.

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. A significant finding in any one drug for a particular indication may provide benefits to our efforts across all of these products. 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 R&D 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 research and development effort for 2011.

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

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

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

Results of Operations

Fiscal 2010 compared to Fiscal 2009

On March 1, 2011, at a special meeting, our shareholders approved a one for 10 reverse stock split of our common stock, which became effective at 5:00 pm EST on March 2, 2011. This reverse stock split is reflected in the shares outstanding and earnings per share calculations throughout this 10-K.

For the year-ended December 31, 2010, revenues totaled $6.9 million, as compared to $10.4 million for the year-ended December 31, 2009. The reduction was primarily due to a year-over-year decrease of $2.3 million in cost recovery from Insmed's 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. The causes of the fourth quarter revenue variance were also responsible for the full-year differences in revenue between 2010 and 2009.
Net loss for the 12-months ended December 31, 2010 was $6.4 million, or $0.49 per share, compared to a net income of $118.4 million, or $9.31 per share, for the corresponding 12-months of 2009. This $124.8 million variance was due to the $127.0 million after tax gain on the sale of the Company's FOB assets to Merck in 2009, combined with a $3.5 million decrease in total revenues. These were partially offset by a $4.0 million reduction in total expenses, a $1.0 million increase in investment returns and a $0.7 million decrease in interest expense.

The $4.0 million decrease in total expenses was due to a $4.4 million reduction in R&D Expenses, which was partially offset by a $0.4 million increase in SG&A Expenses. The $4.4 million reduction in R&D Expenses was due primarily to a decrease in manufacturing expenses following the sale of Insmed's FOB assets in March 2009, and was partially offset by the ARIKACE-related R&D Expenses incurred in December 2010. The $0.4 million increase in SG&A Expenses was due largely to the increased finance, legal and consulting fees related to the strategic review and the business combination with Transave on December 1, 2010. The improved return on investments reflected the increased cash position and higher yield rates, while the lower interest expense was due to the elimination of the debt discount amortization.

As of December 31, 2010, Insmed had total cash, cash equivalents, short-term investments, and certificate of deposits on hand of $110.2 million, consisting of $108.0 million in cash and short-term investments and $2.2 million in a certificate of deposit, as compared to $124.3 million of cash on hand as of December 31, 2009. The $14.1 million decrease in total cash was due to the $8.0 million full payment of Transave debt at the time of the merger, together with the payment of approximately $6.1 million in costs primarily related to the strategic review during 2010 and the business combination with Transave.

Fiscal 2009 compared to Fiscal 2008

For the 12-months ended December 31, 2009, revenues totaled $10.4 million, as compared to $11.7 million in the 12-months of 2008. Consistent with fourth quarter results, the decrease was primarily attributable to a year-over-year decrease of $1.3 million in cost recovery from our IPLEX EAP in Europe.

Net income for the 12-months ended December 31, 2009 was $118.4 million, or $0.93 per share, compared to a net loss of $15.7 million, or $0.13 per share, for the corresponding 12-months of 2008. This $134.0 million improvement was primarily due to the $127.0 million after tax gain on sale of our FOB assets to Merck, combined with a $7.1 million decrease in total expenses, a $0.3 million improvement in investment returns, a $0.5 million decrease in interest expense, and a $0.5 million reduction in the realized loss on investments, which were partially offset by a $1.3 million reduction in net revenue.

The $7.1 million decrease in total expenses was due to an $11.8 million reduction in R&D expenses, which was partially offset by a $4.7 million increase in SG&A expenses.

The $11.8 million reduction in R&D expenses was due primarily to a decrease in manufacturing expenses following the sale of our FOB assets in March 2009. The $4.7 million increase in SG&A expenses was due largely to a combination of the recognition of stock compensation expense for the restricted stock and restricted stock units that vested on March 31, 2009, and the award of bonuses, together with the increased finance, legal and consulting fees related to the ongoing strategic review. The improved return on investments reflected the increased cash position, the lower interest expense was again due to the reduction in debt discount amortization and the $0.5 million reduction in investment loss was due to the write-off of the NAPO investment, which occurred in 2008.

As of December 31, 2009, Insmed had total cash, cash equivalents, short-term investments, and certificate of deposits on hand totaling $124.3 million, consisting of $122.2 million in cash and short term investments and $2.1 million in a certificate of deposit, as compared to $2.4 million of cash on hand as of December 31, 2008. The $121.9 million increase in total cash was due to the $127.5 million in before tax proceeds from the sale of Insmed's FOB assets to Merck, $4.1 million from the conversion of warrants and options into common stock, the release of a $2.1 million previously restricted certificate of deposit, and a $0.4 million increase in unrealized gains on investments, which was partially offset by $11.0 million utilized to fund operations and $1.2 million for the partial repayment of the Company's 2005 convertible notes.

Liquidity and Capital Resources

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

We have funded our operations to date through public and private placements of debt and equity securities and the proceeds from the sale of our FOB platform to Merck. We will continue to incur losses to the extent we expand our research and development and do not expect material revenues for at least the next several years. Furthermore, revenues from our EAP in Italy associated with cost recovery will be eliminated by approximately the third quarter of 2011, when our current IPLEXTM inventory is depleted. At December 31, 2010, our cash and investments were approximately $110.2 million, and were invested in money market instruments, treasuries, municipal bonds and mutual funds. This is a decrease of $14.0 million from December 31, 2009, primarily as a result of debt payment and transaction expenses associated with merger with Transave, Inc.

Expenditures in fiscal 2010 were principally related in support of our EAP, our ongoing Strategic Review Process and the Merger. Planned expenditures in 2011 include the funding of our Phase 3 trials of ARIKACE, other ongoing research and development activity and general and administrative support costs.

On March 31, 2009, we completed the sale of our FOB platform for an aggregate price of $130 million. After fees, taxes and other costs related to the transaction, we received net after tax proceeds of approximately $127 million as a result of this transaction.

Even though we currently have sufficient funds to meet our financial needs for the upcoming year, our business strategy in the future may require us to raise additional capital either through licensing, debt or equity sales. In the future, we may require additional funds for the continued development of our potential product candidates or to pursue the license of complementary technologies. There can be no assurance that adequate funds will be available when we need them or on favorable terms. If at any time we are unable to obtain sufficient additional funds, we will be required to delay, restrict or eliminate some or all of our research or development programs, dispose of assets or

technology or cease operations.

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

We do not have any off-balance sheet arrangements 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.

Contractual Obligations

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

	Payments Due by Years (in thousands)					
	Total	2011	2012	2013	2014	2015 & Beyond
Operating lease obligations	$3,231	$1,017	$437	$445	$458	$874

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 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 (now Ipsen) and Genentech (now 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 Expanded Access Program 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 Expanded Access Program revenue. License income is recognized as revenue when the milestones are achieved and payments are due. Grant revenue is recognized once payment has been received.

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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We invest excess cash in investment grade, interest-bearing securities and, at December 31, 2010, had $110.2 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, 2010, 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 2010, 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 58 – 80.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of certain members of our management, including our Chief 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, 2010, 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.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2010 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, 2010, our internal control over financial reporting was effective.

Management's assessment of the effectiveness of internal control over financial reporting excludes the evaluation of internal controls over financial reporting of the Transave Inc. business combination, which merged with the Company on December 1, 2010. The aggregated total assets and total operating expenses of these operations represent approximately 1% and 17%, respectively, of the consolidated financial statements as of and for the year ended December 31, 2010.

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, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

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 2010 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 2011 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 2011 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 2011 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 2011 annual meeting of stockholders to be filed with the Securities and Exchange Commission.

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 (Deficit)

(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, 10.19, 10.20, 10.21, 10.22, 10.26, 10.27 and 10.28 constitute management contracts or compensatory plans or arrangements required to be filed as exhibits hereto.

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 in the City of Richmond, Commonwealth of Virginia, on the 16th day of March, 2011.

Insmed Incorporated
a Virginia corporation
(Registrant)

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

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 16th day of March, 2011.

Signature	Title
/s/ Donald Hayden, Jr. Donald Hayden, Jr.	Chairman of the Board
/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

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, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2010. 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, 2010 and 2009, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2010, 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, 2010, 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 16, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Richmond, Virginia
March 16, 2011

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, 2010, 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 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.

As indicated in the accompanying Management's Annual Report on Internal Control over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of the Transave, Inc. acquisition which is included in the 2010 consolidated financial statements of Insmed Incorporated. The aggregated total assets and total operating expenses of these operations represent approximately 1% and 17%, respectively, of the consolidated financial statements as of and for the year ended December 31, 2010. Our audit of internal control over financial reporting of Insmed Incorporated also did not include an evaluation of the internal control over financial reporting of the Transave, Inc. acquisition.

In our opinion, Insmed Incorporated maintained, in all material respects, effective internal control over financial reporting as of December 31, 2010, 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, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the

period ended December 31, 2010 and our report dated March 16, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Richmond, Virginia
March 16, 2011

INSMED INCORPORATED
CONSOLIDATED BALANCE SHEETS
(in thousands, except per share data)

	December 31, 2010	December 31, 2009
Assets		
Current assets:		
Cash and cash equivalents	$10,743	$12,740
Short-term investments	97,306	109,441
Income tax receivable	-	2,023
Accounts receivable, net	471	245
Prepaid expenses	277	159
Total current assets	108,797	124,608
Long-term assets:		
Certificate of deposit	2,176	2,085
In-process research and development	77,900	-
Goodwill	6,290	-
Fixed assets, net	1,102	-
Deferred financing costs, net	-	2
Total long-term assets	87,468	2,087
Total assets	$196,265	$126,695
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$1,450	$312
Accrued project costs & other	139	1,150
Payroll liabilities	1,117	580
Interest payable	-	1
Deferred rent	150	132
Capital lease obligations, current	81	-
Deferred revenue	402	398
Convertible debt	-	231
Debt discount	-	(23)
Net convertible debt	-	208
Total current liabilities	3,339	2,781
Long-term liabilities:		
Capital lease obligations, long-term	83	-
Total liabilities	3,422	2,781
Stockholders' equity:		

Common stock; $.01 par value; authorized shares 500,000,000; issued and outstanding shares, 15,653,734 in 2010 and 13,020,810 in 2009	1,565	1,302
Preferred stock; $.01 par value; authorized shares 200,000,000; issued and outstanding shares, 9,174,589 in 2010 and zero in 2009	918	-
Additional paid-in capital	423,877	350,243
Accumulated deficit	(234,510)	(228,076)
Accumulated other comprehensive income:		
Unrealized gain on investments	993	445
Net stockholders' equity	192,843	123,914
Total liabilities and stockholders' equity	$196,265	$126,695

See accompanying notes.

INSMED INCORPORATED
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Twelve Months Ended December 31,		
	2010	2009	2008
Royalties	$4	$129	$144
Grant revenue	-	1,044	1,044
Other expanded access program income, net	6,917	9,200	10,511
Total revenues	6,921	10,373	11,699
Operating expenses:			
Research and development	4,757	9,207	21,047
Selling, general and administrative	10,256	9,840	5,063
Total expenses	15,013	19,047	26,110
Operating loss	(8,092)	(8,674)	(14,411)
Investment income	1,845	808	500
Realized loss on investment	-	-	(500)
Interest expense	(109)	(781)	(1,256)
Gain on sale of asset, net	-	127,474	-
Income (loss) before taxes	(6,356)	118,827	(15,667)
Income tax expense	78	477	-
Net (loss) income	$(6,434)	$118,350	$(15,667)
Basic net (loss) income per share	$(0.49)	$9.31	$(1.28)
Shares used in computing basic net (loss) income per share	13,250	12,712	12,213
Diluted net (loss) income per share	$(0.49)	$9.30	$(1.28)
Shares used in computing diluted net (loss) income per share	13,250	12,727	12,213

See accompanying notes.

INSMED INCORPORATED
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
YEARS ENDED DECEMBER 31, 2010, 2009, AND 2008
(in thousands, except share amounts)

	Common Stock	Preferred Stock	Additional Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balance at December 31, 2007	1,219		341,270	(330,759)	(242)	11,488
Comprehensive earnings:						
Net loss				(15,667)		(15,667)
Realized gain on investment					242	242
Comprehensive loss	-		-			(15,425)
Issuance of 34,970 shares of common						
stock from Employee Stock Purchase Plan	4		117	-	-	121
Issuance of 24,000 shares of common						
stock for consulting services	2		141	-	-	143
Stock compensation expense	-		850	-	-	850
Balance at December 31, 2008	1,225		342,378	(346,426)	-	(2,823)
Comprehensive earnings:						
Net income				118,350		118,350
Unrealized gain on investment					445	445
Comprehensive 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						
	10		1,285			1,295

stock upon conversion of notes						
Stock compensation expense	-		1,147	-	-	1,147
Balance at December 31, 2009	1,302		350,243	(228,076)	445	123,914
Comprehensive earnings:						
Net loss				(6,434)		(6,434)
Unrealized gain on investment					548	548
Comprehensive loss						(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

See accompanying notes.

INSMED INCORPORATED
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Twelve Months Ended December 31,		
	2010	2009	2008
Operating activities			
Net income (loss)	$(6,434)	$118,350	$(15,667)
Adjustments to reconcile net income (loss) to net cash used in provided by operating activities:			
Depreciation and amortization	54	707	1,043
Stock based compensation expense	366	2,542	850
Gain on sale of asset, net	-	(127,474)	-
Change in trading securities	-	-	143
Realized loss on investments	-	-	500
Changes in operating assets and liabilities:			
Accounts receivable	19	(123)	-
Income tax receivable	2,023	(2,023)	128
Prepaid expenses	(78)	-	-
Accounts payable	(2,750)	(85)	170
Accrued project costs & other	(1,144)	(965)	373
Payroll liabilities	201	214	433
Income tax liability	-	127	(178)
Deferred rent	18	(36)	53
Deferred revenue	4	96	57
Restricted stock unit liability	-	(113)	113
Asset retirement obligation	-	(2,217)	-
Interest payable	(1)	(12)	(10)
Net cash used in operating activities	(7,722)	(11,012)	(11,992)
Investing activities			
Cash consideration for merger, net of cash acquired	(6,733)	-	-
Cash received from asset sale	-	127,474	-
Sales of short-term investments	115,153	-	12,673
Purchases of short-term investments	(102,462)	(108,744)	-
Net cash provided by investing activities	5,958	18,730	12,673
Financing activities			
Proceeds from issuance of common stock	-	580	-
Payments on capital lease obligations	(6)	-	-
Repayment of convertible notes	(231)	(1,246)	(2,211)
Certificate of deposits	-	10	-
Warrants converted into shares	-	3,491	-
Other	4	42	121
Net cash provided by (used in) financing activities	(233)	2,877	(2,090)
Increase (decrease) in cash and cash equivalents	(1,997)	10,595	(1,409)
Cash and cash equivalents at beginning of period	12,740	2,145	3,554

Cash and cash equivalents at end of period	$10,743	$12,740	$2,145
Supplemental information			
Cash paid for interest	$-	$82	$234
Cash paid (received) for taxes, net	(1,884)	2,795	-

See accompanying notes.

INSMED INCORPORATED

NOTES TO

CONSOLIDATED FINANCIAL STATEMENTS

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

On December 1, 2010, we completed a business combination with Transave, Inc., a privately-held, NJ-based pharmaceutical Company focused on the development of differentiated, innovative inhaled pharmaceuticals for the site-specific treatment of serious lung infections. Under the terms of the merger agreement, Insmed paid off all of Transave's $7.8 million debt, and issued (on a pre-reverse stock-split basis) approximately 25.9 million shares of Insmed common stock, and approximately 91.7 million shares of Insmed Series B Conditional Convertible Preferred Stock and cash consideration of $561,280 in exchange for all of the outstanding capital stock of Transave. On March 1, 2011 at a special meeting of our shareholders, all of our shares of Series B Conditional Convertible Preferred Stock were converted into shares of our Common Stock, on a one for one basis. Also at this meeting, our shareholders approved a one for ten reverse stock split of our common stock, which became effective at 5:00 pm EST on March 2, 2011 (see note 13).

After giving effect to the business combination and following conversion of the preferred stock into common stock, former Transave stockholders have approximately a 47% equity interest in the combined Company, and Insmed Incorporated shareholders have a 53% interest on a fully diluted, as exercised, basis.

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

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

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. Actual results could differ from those estimates.

Common Stock Reverse Split

On March 2, 2011, our shareholders approved a 1 for 10 reverse stock split of the Company's outstanding common stock (see note 13). 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 investments with maturities of three months or less when purchased to be cash equivalents. 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 market. The cost of the specific security sold is used to compute the gain or loss on the sale of marketable securities.

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, 2010 and 2009 due to the short-term maturities of these instruments. See Note 12 for further discussion on fair value of our cash and investments. We also hold an investment in NAPO Pharmaceuticals, Inc. ("NAPO"), which was previously classified as an "available-for-sale" security but was considered other than temporararily impaired as NAPO was de-listed from the London Stock Exchange in 2008. This impairment is reported as a loss on investments on our consolidated statement of operations for 2008.

Stock-Based Compensation

In some instances, we receive employee services in exchange for providing equity instruments of the Company or liabilities 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.

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 and Genentech 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 Expanded Access Program 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 Expanded Access Program revenue. License income is recognized as revenue when the milestones are achieved and payments are due. Grant revenue is recognized once payment has been received. Shipping and handling costs charged to customers are included in revenue and totaled $0.2 million, $0.2 million and $0.4 million for 2010, 2009 and 2008, respectively.

Research and Development

Research and development costs are expensed as incurred except for purchase in-process research and development (see below and note 3). Research and development expenses consist primarily of salaries and related expenses, cost to develop and manufacture drug candidates, patent protection costs, amounts paid to contract research organizations, hospitals and laboratories for the provision of services and materials for drug development and clinical trials. Our

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

Identified Intangible Assets

In conjunction with the recent Merger, we have recorded in-process research and development intangible assets as part of our recognition and measurement of assets acquired and liabilities assumed. Identifiable intangible assets are measured at their respective fair values as of the acquisition date and are not amortized until commercialization or unanticipated market events occur. Once commercialization occurs, these intangible assets will be amortized over the estimated useful lives. A discounted cash flow model was used in valuing these intangible assets, and these models require the use of significant estimates and assumptions in such areas as growth rates, profitability and the discount rate applied to the cash flows. 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 market events may occur which could affect the accuracy or validity of the estimates and assumptions.

Impairment of Goodwill and Indefinite Lived Intangible Assets

Goodwill and indefinite lived intangible assets are tested for impairment annually or more frequently when events occur or circumstances change that would more likely than not reduce the fair value of the asset below its carrying amount. Events or circumstances that may require an interim impairment assessment include negative clinical trial results, the non-approval of a new drug application by the FDA, or a sustained decline in market capitalization. The potential impairment of goodwill is determined by comparing the fair value (using income or market approaches) of the products with its carrying amount, including goodwill. No impairment was noted for 2010.

Income Taxes

Income taxes are accounted for in accordance with Accounting Standards Codification (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 carryforwards. 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.

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.

Net Income (Loss) Per Share

Basic net income /(loss) per share is computed based upon the weighted average number of common shares outstanding during the year. The following table sets forth the computation of basic and diluted (loss) earnings per share:

Twelve Months Ended December 31,

	2010	2009	2008
	(in thousands except per share data)		
Numerator:			
Net income (loss) for basic and diluted income (loss) per share	$(6,434)	$118,350	$(15,667)
Denominator:			
Weighted average shares for basic income (loss) per share	13,250	12,712	12,213
Effect of dilutive securities:			
Preferred stock	-	-	-
Stock options and restricted stock	-	16	-
Denominator for diluted income (loss) per share	13,250	12,727	12,213
Basic income (loss) per share	$(0.49)	$9.31	$(1.28)
Diluted income (loss) per share	$(0.49)	$9.30	$(1.28)

For the years ended 2010 and 2008, our diluted net loss per share was the same as our basic net loss per share because all stock options, warrants, and other potentially dilutive securities were antidilutive and, therefore, excluded from the calculation of diluted net loss per share. Shares excluded for 2010 and 2008 were 98,000 and zero, respectively. Also, our average stock price for the year ended December 31, 2009 was $9.80, therefore any warrant, option or convertible note that contained a strike price above this amount was excluded from diluted earnings per share for 2009.

Segment Information

The Company currently operates in one business segment, which is the development and commercialization of pharmaceutical products. The Company is managed and operated as one business. 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.

2. Risks and Uncertainties

For the period from inception to December 31, 2010, the Company has incurred recurring operating losses and has accumulated a deficit of $235 million. During 2010, the Company recognized a net loss of $6.4 million. Our net cash used in operations for 2010 was $7.7 million.

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 selling, 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 12.

	Total Purchase Consideration
Cash consideration paid	$8,544
Fair value of common stock consideration (25,938,818 shares issued)	18,416

Fair value of preferred series B stock consideration (91,745,892 shares issued)	56,020
Purchase price of acquired assets	$82,980

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 as December 1, 2010.

Purchase Price Allocation

Current assets	$2,170
Fixed assets	1,131
Other assets	91
In-process research and development	77,900
Goodwill	6,290
Current liabilities assumed	(4,515)
Long term liabilities assumed	(87)
Total assets	$82,980

A substantial portion of the assets acquired consisted of intangible assets related to in-process research and development and goodwill. Goodwill consists of the value of the remaining Company operations. With the assistance of an independent third party the Company used the income approach to estimate the value of Transave's two primary indications for its lead product. Through this approach, the fair value of these indications was determined by discounting to their present value the estimated cash flows associated with the indications as of the date of acquisition taking into consideration estimated probability of success. The estimated cash flows were based on forecast revenues for those indications net of operating expenses and other intangible assets that contribute to the projected cash flow from this product. The projected revenues were based on assumed revenue growth rates and patient uptake. Operating expenses were estimated based on the supporting infrastructure expected to sustain the assumed revenue growth rates. The discount rate was based on the risks associated with the respective cash flows taking into consideration the Company's weighted average cost of capital, which includes unobservable inputs. We expect to amortize the value of the in-process research and development over the remaining life of the patents for the product post commercialization. The purchase consideration amount in excess of the readily identifiable assets and in-process research and development was recorded as goodwill and will have an indefinite life and is not expected to be deductible for tax purposes. It will be tested annually for impairment.

Transave was a development stage Company prior to the Merger. As such it had not begun generating revenues. Transave's apportionment of the net loss for 2010 is $2.6 million which reflects the one month of activity as a combined entity. Transave's net loss for the twelve months ended December 31, 2010 would have been $22 million and was also $22 million for the twelve months ended December 31, 2009.

4. Debt and Stockholders' Equity

Common Stock, Preferred Stock & Convertible Debt

On December 1, 2010, we entered into a merger agreement with Transave, Inc. Under the terms of the agreement, the Transave stockholders received (on a pre-reverse stock-split basis) an aggregate of 25,938,818 newly issued shares of the common stock, par value $0.01 per share, of the Company and 91,745,892 shares of newly created Series B

Conditional Convertible Preferred Stock, par value $0.01 per share, of the Company (see Note 3). They also received an aggregate of approximately $561,280 in cash. Collectively, the shares of the Company common stock and the Company 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. In connection with the closing of the Merger the Company paid off Transave's existing debt facility totaling approximately $8 million (see Note 13 regarding the conversion of the preferred stock to common stock and the 1 for 10 reverse stock split, which occurred in March 2011).

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 $35,000,000, 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 payment to the remaining convertible note holders was paid. The 2005 Warrants expired on March 15, 2010.

Stock Warrants and Options

The following table summarizes the activity of the Company's warrants:

	Warrants for Shares of Common Stock	Weighted-Average Exercise Price
Outstanding at January 1, 2010	519,086	$ 11.80
Exercised	-	-
Expired	(361,532)	12.20
Outstanding at December 31, 2010	157,554	$ 11.00

As of December 31, 2010, 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. The 2000 Plan currently provides for the issuance of a maximum of 925,000 shares of common stock which has all been utilized. The Company plans to seek shareholder approval in 2011 for additional shares to be set aside for current and future use. 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 $25,000 per year. The 2000 ESPP provides for the issuance of a maximum of 150,000 shares of our common stock to participating

employees.

The Company issues stock options to attract and retain executive officers, key employees, non-employee directors and other non-employee advisors and service providers. The maximum number of shares issuable under the Company's stock plan is 925,000 which have all been utilized. There were 98,656 shares available to be issued at December 31, 2010. Options may be granted at the discretion of the board of directors, compensation committee or a delegate. There were no grants of stock options during 2010 or 2009. The weighted-average fair value of options granted during 2008 was $8.40. There were no stock options exercised during 2008 and 2010. The total fair value of shares vested for 2010, 2009, and 2008 was $0.1 million, $0.5 million and $0.5 million respectively. As of December 31, 2010 there were zero nonvested shares. A summary of stock option activity is as follows:

Description	2010	Average Exercise Price	Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Options outstanding at January 1, 2010	259,275	$23.00		
Granted	-	-		
Exercised	-	-		
Cancelled	(45,000)	48.04		
Options outstanding at December 31, 2010	214,275	18.43	2.00	$9,880
Exercisable at December 31, 2010	214,275	$18.43	2.00	$9,880

The Company valued stock options granted in 2008 using a Black-Scholes-Merton valuation model which necessitates the development of certain key assumptions. 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 weighted-average grant-date fair value of stock options awarded was estimated on the date of grant using the following assumptions: risk-free interest rate of 2.42% in 2008, no dividends, volatility of 107% in 2008, an expected life of 4.07 years in 2008 and a forfeiture rate of 33% in 2008.

The following table summarizes awards outstanding and available for issuance at December 31, 2010:

Plan Category (1)	Number of Securities to Be Issued upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans
Equity Compensation Plans Approved by Shareholders:			
Amended and Restated 2000 Stock Incentive Plan (2)	214,275	$ 18.43	210,439
Amended and Restated 2000 Employee Stock Purchase Plan	—	—	36,538
Total:	214,275	$ 18.43	246,977

Restricted Stock and Restricted Stock Units

In May 2008, under the 2000 Plan, we began granting Restricted Stock ("RS") and Restricted Stock Units ("RSU's") 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 are valued at the market price of our common stock on the date of grant and RSU's are valued based on the market price on the date of settlement. RSU's are classified as liabilities, as they may be settled with a cash payment for each unit vested, equal to the fair market value of our common stock on the vesting date if there are insufficient shares available in the pool. We recognize noncash compensation expense for the fair values of these RS and RSU's on a straight-line basis over the requisite service period of these awards, which is generally four years. Below is a table of RS activity for the twelve months ended December 31, 2010, all of which are vested.

Effective on the closing of the Merger transaction on December 1, 2010, all RS awards were fully vested. Due to the acceleration of the vesting schedule, the Company recognized $0.1 million in stock-based compensation expense related to RS awards. The weighted-average grant date fair value of RS granted during the year was $8.80.

	Number of Shares Restricted Stock
Outstanding at January 1, 2010	8,772
Granted	30,270
Vested	39,042
Outstanding at December 31, 2010	-

As of December 31, 2010, we had zero unrecognized stock-based compensation expense related to unvested RS and RSU's. Stock-based compensation expense related to RS was approximately $0.3 million for the twelve months ended December 31, 2010.

A total of 408,367 shares of common stock were reserved for issuance at December 31, 2010 in connection with restricted stock, stock options, stock warrants, and the employee stock purchase plan.

The Company recognized non-cash share-based compensation expense of approximately $0.3 million for 2010, $2.5 million for 2009 and $1.0 million for 2008. This expense was included on the "Selling, general and administrative" and "Research and development" lines of the consolidated statement of operations. As of December 31, 2010, there was zero unrecognized compensation cost related to stock awards.

5. 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 2000 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, 2010 and 2009, 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 $94 million and $74 million at December 31, 2010 and 2009, 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 a valuation allowance.

At December 31, 2010 and 2009, the Company had net operating loss carryforwards for income tax purposes of approximately $310 million and $172 million, respectively, expiring in various years beginning in 2010. Utilization of these carryforwards will likely be significantly limited due to changes in the ownership of the Company's common

stock. The Company has never been audited by the Internal Revenue Service.

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

Deferred tax assets	2010	2009
	(in thousands)	
General Business Credits	7,708	2,009
AMT Credit	418	470
Other	3,064	6,668
NOL Carryforwards	112,721	65,214
Total deferred tax assets	123,911	74,361
Deferred tax liabilities		
In-process research and development	(29,609)	-
Other	(377)	(169)
Total deferred tax liabilities	(29,986)	(169)
Tax deferred asset/(liability)	93,925	74,192
Valuation allowance	(93,925)	(74,192)
Net deferred tax asset/(liability)	-	-

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

	2010	2009	2008
Statutory federal tax rate	34 %	34 %	34 %
Permanent items	-9 %	0 %	-2 %
State income taxes net of federal benefit	1 %	4 %	4 %
Research and development credit	0 %	0 %	-7 %
Expired net operating loss carryforwards	0 %	0 %	-46 %
Alternative minimum tax	1 %	0 %	0 %
Change in valuation allowance	-28 %	-38 %	17 %
Total Expense	-1 %	0 %	0 %

6. Leases

The Company leases office space in Richmond, Virginia and office and lab space in Monmouth Junction, New Jersey. The Richmond, Virginia space is under an operating lease agreement expiring in October 2016 and provides for monthly rent of approximately $35,777 with a 3% escalation per year. The Monmouth Junction, New Jersey space is under an operating lease agreement expiring in November 2011 and provides for monthly rent of approximately $53,377. Lease expense is recognized on a straight-line basis. The Company also leases a vehicle and office equipment. Future minimum payments on all these leases at December 31, 2010 are presented in the table below. Rent expense for all operating leases approximated $0.5 million in 2010, $0.5 million in 2009 and $1.1

million in 2008.

	Payments Due by Years (in thousands)					
	Total	2011	2012	2013	2014	2015 & Beyond
Operating lease obligations	$3,231	$1,017	$437	$445	$458	$874

7. 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.

8. Fixed Assets

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	Fixed Assets, Net	Useful Life (years)
Lab equipment	$995	5 - 10
Furniture and fixtures	15	5 - 7
Computer hardware and software	92	3 - 7
Total	1,102	

Depreciation for 2010 totaled $23,000.

9. 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. In 2007 we received $1.5 million in milestone payments.

TriAct

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 calls for the issue of TriAct common stock to Insmed upon the achievement of certain milestones. To date, no common stock has been received.

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. The agreement calls for payments from Eleison to us upon the achievement of certain milestones.

10. Quarterly Financial Data (Unaudited)

INSMED INCORPORATED
Quarterly Financial Data
(in thousands)

	Fiscal Quarter							
	First		Second		Third		Fourth	
	2010	2009	2010	2009	2010	2009	2010	2009
Revenues	$1,929	$2,370	$1,864	$3,040	$1,807	$2,475	$1,321	$2,488
Operating Income (Loss)	(251)	(6,947)	(913)	(1,306)	(598)	(764)	(6,330)	343
Net Income (Loss)	118	117,795	(378)	(1,601)	(330)	(150)	(5,844)	2,306
Net Income (Loss) Per Share (Basic and Diluted)	$0.00	$9.40	$0.00	$(0.10)	$0.00	$(0.10)	$(0.42)	$0.18

11. Legal Proceedings

Cacchillo vs. Insmed

On October 6, 2010, a complaint was filed against us by Angeline Cacchillo (Plaintiff) in the United States District Court for the Northern District of New York (Court) seeking money 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 IPLEXTM sponsored by us evaluating the effectiveness of the investigational drug in patients with type 1 myotonic muscular dystrophy (“MMD”). The data from this trial did not provide sufficient evidence that IPLEX was effective to treat MMD. As a result, we decided not to proceed to a phase III trial.

In the complaint, Plaintiff alleges (i) the 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) intentional infliction of emotional distress by refusing to support Plaintiff’s compassionate use application after providing IPLEX, (v) violation of an assumed duty of care to Plaintiff, (vi) breach of fiduciary duty to Plaintiff, (vii) negligence and (viii) unjust enrichment. Plaintiff seeks compensatory

and punitive monetary damages and sought injunctive 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 8, 2010, the Court issued an Order to Show Cause requiring us to respond to Plaintiff's motion. On October 13, 2010, we filed an opposition to Plaintiff's motion for the preliminary injunction and on October 15, 2010, an oral argument was held before the Court on the Plaintiff's motion.

On October 22, 2010, the Court denied Plaintiff's motion for the preliminary injunction concluding that the Court lacked subject matter jurisdiction with respect to her claim for a preliminary injunction. Plaintiff appealed the Court's denial of her motion for a preliminary injunction to the United States Court of Appeals for the Second Circuit. The matter has been fully briefed and oral argument has been scheduled for March 15, 2011. Plaintiff's claim for monetary damages remains outstanding. 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.

Genentech/Tercica vs. Insmed

On December 6, 2006, a jury in the United States District Court for the Northern District of California found that we infringed patents held by Tercica and Genentech and awarded damages of $7.5 million as an upfront payment and a royalty of 15% on sales of IPLEX below $100 million and 20% for sales of IPLEX above $100 million.

On March 5, 2007, we reached a settlement agreement ending all litigation with Tercica and Genentech. Pursuant to the agreement, we agreed to cease sales and marketing of IPLEX for the treatment of short stature disorders in the United States and agreed to withdraw our European Marketing Authorization Application for IPLEX for treatment of short stature disorders. We continue to provide IPLEX to named patients with ALS in Italy under our Expanded Access Program. On November 8, 2009, Genentech and Ipsen/Tercica signed a letter of intent whereby they have consented to amend the agreement between Genentech, Tercica, Inc. and Insmed Incorporated to permit us to supply IPLEX in connection with named-patient ALS programs worldwide on a royalty-free basis effective October 1, 2009. We previously paid a 4% royalty under our agreement for all cost-recovery that we receive under the Expanded Access Program. 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. These indications include severe insulin resistance, MMD and HARS, among others. The development partnership includes provisions that give us 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. In addition, as part of the settlement agreement, Tercica and Genentech waived the damages awarded by the jury in the patent infringement suit from the U.S. District Court for the Northern District of California.

Mackinson et al. v. Insmed

On February 24,2011, an action was filed 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, 2001, by and among Insmed Incorporated, River Acquisition Co., Transave, LLC, Transave, Inc. and TVM V Life Science Ventures GmbH & Co. KG, in its capacity as stockholders' agent. We intend 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.

12. Investments and Fair Value Measurements

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

- Level 1 – Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.
- Level 2 – Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the assets or liability through correlation with market data at the measurement date and for the duration of the instrument's anticipated life.
- Level 3 – Inputs reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

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

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

Assets and liabilities measured at fair value are summarized below (in thousands):

		Fair Value Measurements at Reporting Date Using	
Description	December 31, 2010	Quoted Prices in Active Markets for Identical Assets (Level 1)	Quoted Prices in Inactive Markets for Identical Assets (Level 2)
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	2,176	2,176	
Total	$110,225	$77,963	$32,262

	Fair Value Measurements at Reporting Date Using

Description	December 31, 2009	Quoted Prices in Active Markets for Identical Assets (Level 1)	Quoted Prices in Inactive Markets for Identical Assets (Level 2)
Cash and Cash Equivalents	$12,740	$12,740	$-
U.S. Treasury securities	16,473	16,473	-
Mutual Funds	52,827	52,827	-
Municipal bonds	40,141	-	40,141
Certificate of deposit	2,085	2,085	
Total	$124,266	$84,125	$40,141

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

	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
Total	$96,313	$1,100	$(107)	$97,306

At December 31, 2009, we held 23 securities which were in an unrealized loss position with a total estimated fair value of $40.1 million and gross unrealized losses of approximately $88,557. Of the 23 securities, none had been in a continuous unrealized loss position for greater than one year. Below is a table which summarizes unrealized gains and losses for 2009. The net of our unrealized gains and losses, $445,000 is reported in accumulated other comprehensive income in the stockholder's equity section of our Balance Sheet.

	December 31, 2009			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. Treasury securities	$16,475	$-	$(2)	$16,473
Mutual Funds	52,293	534	-	52,827
Municipal bonds	40,228	-	(87)	40,141
Total	$108,996	$534	$(89)	$109,441

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. We have concluded that none of the available-for-sale securities with unrealized losses at December 31, 2010 has experience an other-than-temporary impairment.

We also hold an investment in NAPO Pharmaceuticals, Inc. ("NAPO") which is currently valued at $0. During the year ended December 31, 2009 we recorded an other than temporary impairment of this investment of $392,000. This amount is reported as a loss on investments in our statement of operations for 2009.

Relevant accounting literature requires the disclosure of the estimated fair value of financial instruments including those financial instruments for which the fair value option was not elected. The carrying amount reported in the balance sheet for convertible debt at December 31, 2009 approximates its fair value due to the short-term maturity of these instruments.

13. Subsequent Events

On January 12, 2011, we issued 30,469 restricted stock units to our Board of Directors. On January 31, 2011 we issued 198,400 incentive stock options and 325,500 restricted stock units to executive management.

On February 11, 2011 Insmed Incorporated entered into a master services agreement with Chiltern International Inc, Work a pharmaceutical development services provider. Under the terms of the Agreement, Chiltern will provide project management, clinical monitoring, data management and related services to Insmed in connection with the conduct of Phase III clinical studies of Arikace TM (liposomal amikacin for inhalation) for treatment of cystic fibrosis ("CF") and nontuberculous mycobacteria (" NTM "). On March 11, 2011 work orders were signed amounting to $17.5 million. Insmed may terminate the agreement or any work order at any time for any reason and without cause upon 30 days' prior written notice.

On March 1, 2011, we held a special meeting of our shareholders to consider proposals relating to the conversion of our Series B Conditional Convertible Preferred Stock and a one-for-10 reverse stock split of the common stock, par value $0.01 per share. At the special meeting of shareholders, shareholders approved all of the proposals, as follows:

1. Preferred Stock Proposal: a proposal to approve the conversion of the Preferred Stock and the issuance of shares of the Common Stock upon conversion of the Preferred Stock. Insmed's shareholders, exclusive of such holders who have received the shares of Common Stock in the business combination with Transave, Inc., voted.

2. Reverse Split Proposal: a proposal to approve an amendment to Insmed's Articles of Incorporation, as amended, to effect a one- for-10 reverse stock split of the issued and outstanding shares of the Common Stock.

3. Adjournment Proposal: a proposal to approve the adjournment of the special meeting to a later date or dates, if necessary, to permit further solicitation and vote of proxies.

As a result of the approval of the conversion of the Preferred Stock, the 91,745,892 shares of the Preferred Stock outstanding (on a pre-reverse stock-split basis) were automatically and immediately converted into 91,745,892 shares of Insmed Common Stock. In addition, we filed Articles of Amendment to our Articles of Incorporation, as amended, to effect a one-for-10 reverse stock split of the common stock, par value $0.01 per share, of Insmed. The Amendment became effective at 5:00 P.M., Eastern Standard Time, on March 2, 2011. As a result of the Amendment, each holder of 10 shares of Insmed Common Stock immediately prior to the effectiveness of the reverse stock split became the holder of one share of Insmed Common Stock. Shareholders will receive a cash payment in lieu of any fractional shares of Common Stock they are entitled to receive. Below is a table detailing the conversion of the preferred shares and the reverse stock split.

Common stock shares outstanding February 28, 2011	156,537,341

Preferred series B stock converted into common stock on March 1, 2011	91,745,892
Total shares outstanding prior to reverse stock split	248,283,233
1 for 10 reverse stock split	1:10
Approximate number of shares outstanding March 2, 2011	24,828,323

EXHIBIT INDEX

2.1	Asset Purchase Agreement, dated February 12, 2010, 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, 2010 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 1 for 10 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).
4.1	Amendment to Amended and Restated Bylaws of Insmed Incorporated (previously filed as Exhibit 3.2 to Insmed Incorporated's Current Report on Form 8-K filed on December 2, 2010, and incorporated herein by reference).
4.2	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 (Registration No. 333-30098) and incorporated herein by reference).
4.3	Rights Agreement, dated as of the Registrant (previously filed as Exhibit 4.2 to Insmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference). 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	Rights 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 4.4 to Insmed Incorporated's Registration Statement on Form S-3 (Registration No. 333-107308) on May 17, 2001 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 2010-2010 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).
4.1	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).
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 4, 2010 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, 2010 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 (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 (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).
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).
10.1	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).
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, 2010 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, 2010 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 4.1 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, 2009.
10.28**	Separation Agreement and General Release, dated July 2, 2010 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, 2010 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).
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).
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.