INSMED INC
Form 10-K
March 31, 2009

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, 2008

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.)
8720 Stony Point Parkway Richmond, Virginia 23235	(804) 565-3000
(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 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 III 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, 2008 was $48,922,254 (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 February 28, 2009, there were 122,494,010 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, 2009, after the registrant's fiscal year ended December 31, 2008, and to be delivered to shareholders in connection with the 2009 Annual Meeting of Shareholders, are herein incorporated by reference in Part III and a small section of Part II.

INSMED INCORPORATED

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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

We are a development stage company with expertise in recombinant protein drug development. Our corporate office is located in Richmond, Virginia.

On February 12, 2009 we announced that we had entered into a definitive agreement with Merck & Co., Inc. ("Merck") whereby Merck, through an affiliate, would purchase all assets related to our follow-on biologics platform. On March 31, 2009, we completed the sale of these assets for an aggregate purchase price of $130 million. After fees, taxes and other costs related to the transaction, we expect net proceeds of approximately $123 million as a result of this transaction.

As part of this transaction, Merck assumed the lease of our Boulder, Colorado-based manufacturing facility and acquired ownership of all the equipment in the building. In addition, upon closing of the transaction, Merck offered positions to employees of the Boulder facility. We retain our Richmond, VA corporate office, which houses our Clinical, Regulatory, Finance, and Administrative functions, in support of the continuing IPLEX™ program. The transfer of the Boulder facility to Merck takes away our internal IPLEX™ production capability. We believe, however, that we have sufficient inventory of IPLEX™ to support our ongoing Amyotrophic Lateral Sclerosis Expanded Access Program ("ALS EAP") in Italy through 2010 together with the IPLEX™ requirement for the clinical trial currently being planned with the FDA for ALS patients in the US. Any requirements for IPLEX™ beyond 2010 or any significant increase in demand beyond our current commitments either in the Myotonic Muscular Dystrophy ("MMD") or ALS fields will require that we identify a Contract Manufacturing Organization ("CMO") to produce the necessary IPLEX™ to meet the demand. We estimate that the tech transfer of our IPLEX™ production process could take 12 to 18 months once a CMO has been identified.

Until the sale of our follow-on biologics platform, we pursued a dual path strategy involving entry into the follow-on biologics arena (also known as biosimilars, biogenerics and biologics) and advancing our proprietary protein platform into niche markets with unmet needs. Following the sale of our follow-on biologics assets, we plan to continue to support our proprietary protein platform and our product, the FDA-approved IPLEX™, which is in various stages of development for a number of serious medical conditions including MMD,ALS, also known as Lou Gehrig's disease, and Retinopathy of Prematurity ("ROP").

We have also engaged the services of RBC to act as financial advisor in evaluating other options for use of these proceeds which could include acquisitions of complimentary businesses or technologies, product licensing, mergers, share repurchase and the distribution of a portion of the proceeds to shareholders.

PRODUCT PLATFORMS

PROPRIETARY PROTEIN PLATFORM

IPLEX™

Our 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), is being 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.

Following an external review of the markets for the various indications which could be served by IPLEX™ we have prioritized our targets and have selected MMD as our initial primary indication for IPLEX™ and results from our Phase II clinical trial in this indication are expected during the second quarter of 2009. We are also evaluating IPLEX™ as a treatment for ALS in Italy and Europe as part of our Expanded Access Program (EAP) and are in the process of working with the FDA to design and initiate a Phase II clinical trial for ALS patients in the US. In the Retinopathy of Prematurity ("ROP") indication we are working with Premacure AB in Sweden and are supplying IPLEX™ to Premacure who intend to initiate a Phase II multicenter trial for IPLEX™ in the ROP indication during the second quarter of 2009.

Development of IPLEX™ in Myotonic Muscular Dystrophy

MMD is the most common type of adult muscular dystrophy and affects approximately 1 in 8,000 individuals. MMD causes progressive muscle wasting and weakness in the hands, forearms, legs, neck and face. It often involves many other systemic effects, including endocrine abnormalities, neurological changes, cataracts, gastrointestinal problems, and cardiac rhythm abnormalities. In extreme cases, these patients can eventually become totally disabled, dying usually from respiratory or cardiac failure. At present, there is no treatment to reverse most of these symptoms. Previous preclinical and clinical studies have demonstrated that IGF-1 therapy may be an effective treatment for MMD.

Based on information published by the Muscular Dystrophy Association (the "MDA"), we believe that there are approximately 30,000 patients that suffer from MMD in the United States. At present, there is no approved treatment for this disease.

Ongoing Clinical Study

An advanced Phase II clinical trial investigating IPLEX™ as a treatment for MMD has been completed and the results from the trial are expected during the second quarter of 2009. This Phase III enabling trial was initiated, with the help of a $2.1 million grant from the MDA and was a 24 week, 69 patients, and 13 site placebo controlled trial in the US using a dose of 1.0 mg/kg/day of IPLEX™. This study is evaluating the effects of IPLEX™ on endurance, using the FDA approved six-minute walk test, as well as cognitive function, GI function, muscle function, lean body mass and insulin sensitivity.

Expanded Access Program for Patients in Italy 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 the muscles throughout the body. The progressive degeneration of the motor neurons in ALS eventually leads to their 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 Expanded Access Program 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 are 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 2008, 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. We have since entered into an agreement with IDIS to manage our IPLEX™ EAP for all countries outside of Italy and the US. IDIS is the world leader in the development and implementation of Named Patient Programs, also known as EAP's. We will continue to manage the IPLEX™ EAP in Italy internally and we are presently in discussions with the FDA to design and initiate a Phase II clinical trial for ALS patients in the US.

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 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, MMD and ROP, 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.

Oncology Programs - INSM-18 and rhIGFBP-3

INSM-18 and rhIGFBP-3 are in early clinical development and are primarily being 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.

INSM-18

INSM-18 is an orally available small molecule tyrosine kinase inhibitor that has demonstrated selective inhibition of IGF-1 and human epidermal growth factor receptor (Her2/Neu). It has demonstrated anti-tumor activity in preclinical studies of breast, lung, pancreatic and prostate tumors. Two single dose Phase I clinical studies in healthy volunteers have been previously completed with INSM-18. In both studies, INSM-18 was safe and well tolerated.

The American Cancer Society estimated that 232,000 new cases of prostate cancer occurred in the United States in 2005. It also estimated that 30,000 deaths occurred as a result of prostate cancer, making it the second leading cause of cancer death in men.

Completed Clinical Study

The University of California, San Francisco, has completed a dose-escalating Phase I/II clinical study designed to define the maximum tolerated dose of INSM-18 in patients with relapsed prostate cancer. The study consisted of a 28-day treatment period at each dose level to investigate the effect of INSM-18 on prostate-specific antigen levels. An analysis of the data collected from the study is currently being conducted. The results from this study will be used to design a potential Phase II clinical study which we plan to progress in collaboration with a suitable partner.

rhIGFBP-3

Although IGF-1 is critical for normal growth and metabolism, aberrant signaling through this pathway is closely linked to the abnormal and unregulated growth of a variety of tumors. Blocking tumor-associated IGF signaling has prevented tumor growth in a variety of preclinical models. rhIGFBP-3 has demonstrated preclinical efficacy in numerous cancer indications, including breast, prostate, liver, ovarian and colon. Additionally, several lines of recent evidence, from various cell systems, have suggested that rhIGFBP-3 may play a more active, IGF-1-independent role in growth regulation of cancer cells, binding specifically with high affinity to the surface of various cell types and directly inhibiting monolayer growth of these cells in an IGF-1-independent manner. Recent independent studies have demonstrated that when IGFBP-3 is used in combination with other cancer therapies it can accentuate and even synergize the efficacy of standard cancer therapies. Paclitaxel-induced apoptosis is accentuated by rhIGFBP-3, which has been shown to sensitize cells to apoptotic signals such as irradiation and ceramides. Due to the high cost of trials in the oncology area we plan to identify a partner to co-develop rhIGFBP-3.

FOLLOW-ON BIOLOGICS

We completed the sale of our follow-on biologics assets on to Merck on March 31, 2009. Following this sale we do not have a presence in the FOB arena.

Follow-on biologics (FOB), also known as “biogenerics” or “biosimilars,” are versions of drugs produced through biological processes. The biologics on which they are based differ from traditional “small molecule” drugs such as Aspirin®, and Lipitor®, and all other medicines typically taken in pill form – in several important ways. First, biologics are made up of complex molecules, such as proteins, that must be administered via direct injection because if they were administered orally, they would be broken down in the digestive tract and never reach their intended targets. Second, these drugs are produced not by merely combining chemicals but by the natural processes of living cells. In the manufacture of biologics, the DNA of cells is engineered such that the cells themselves produce the desired proteins. Third, the production of biologics is much more exacting than that of small-molecule drugs. Growing one type of genetically-engineered cell while excluding all other organisms from the mix is inherently more difficult than simply achieving sterile conditions (no living organisms at all) under which traditional drugs are manufactured.

In November 2007 we announced completion of development of two key follow-on biologics at the facilities in Boulder, Colorado, INS-19 (Granulocyte Colony Stimulating Factor or G-CSF) and INS-20 (Peg G-CSF). In July 2008 we announced that we demonstrated the bioequivalence of INS-19 compared to Neupogen® and in October 2008 we announced that we had received approval from the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) to initiate a Phase I clinical study for our second follow-on biologic product candidate, INS-20.

RESEARCH AND DEVELOPMENT

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 for metabolic and endocrine diseases. Until the sale of our FOB assets on March 31, 2009, our research and development efforts were principally focused on pursuing a dual path strategy involving entry into the follow-on biologics arena (also known as biosimilars, biogenerics and biologics) and advancing our proprietary protein platform into niche markets with unmet needs. Our research and development efforts will now focus on our proprietary protein platform. Our lead proprietary protein product, the FDA-approved IPLEX™, is being studied as a treatment for several serious medical conditions with our primary focus being on MMD and ALS. We conduct very little of our own preclinical laboratory research. We have outsourced several Phase II clinical studies with IPLEX™ and our other anti-cancer product candidates, INSM-18 and rhIGFBP-3, and plan on conducting additional clinical studies in the future.

Research and development expenses primarily include expenses incurred in preparing and obtaining necessary approvals from regulatory bodies, certain expenses involving the development of manufacturing processes and clinical studies. Our research and development expenses were approximately $21.1 million for the fiscal year ended December 31, 2006, $19.2 million for the fiscal year ended December 31, 2007 (“fiscal 2007”) and $21.0 million for the year ended December 31, 2008 (“fiscal 2008”).

MANUFACTURING

We have previously manufactured our own supply of IPLEX™ and rhIGFBP-3 at the Boulder, Colorado, FDA-approved manufacturing facility. The manufacturing process requires compliance with current good manufacturing practices, or cGMP, and other similar regulations. IPLEX™, a complex of two proteins, rhIGF-1 and its binding protein rhIGFBP-3, are manufactured using recombinant DNA technology. This manufacturing process is complicated and involves expression of the proteins by bacterial fermentation followed by purification and combination. We currently outsource to third-party contract manufacturers some of the analytical testing and the final fill, finish and labeling of IPLEX™. The transfer of the Boulder facility to Merck will take away our internal IPLEX™ production capability. We

believe, however, that we will have sufficient inventory of IPLEX™ at the time of the sale to support our ongoing ALS EAP in Italy through 2010 together with the IPLEX™ requirement for the clinical trial currently being planned with the FDA for ALS patients in the US. Any requirements for IPLEX™ beyond 2010 or any significant increase in demand beyond our current commitments either in the MMD or ALS fields will require that we identify a Contract Manufacturing Organization ("CMO") to produce the necessary IPLEX™ to meet the demand. It is estimated that the tech transfer of our IPLEX™ production process could take 12 to 18 months once a CMO has been identified

PATENTS AND PROPRIETARY RIGHTS

Patent Portfolio

Proprietary protection is important to our business, and our policy is to protect our technology by filing patent applications for technology that we consider important. We directly hold 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 the major pharmaceutical markets, such as the European Union, Canada and Japan. The various issued patents relate to IPLEX™ and rhIGFBP-3 compositions, methods of production and methods of treatment, and expire at various times during the years 2010 through 2019.

As part of the ongoing development of IPLEX™, INSM-18 and rhIGFBP-3 we have filed or intend to 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, and 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.

As part of our business strategy, we plan to license 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 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 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.

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. 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.

We note that there has been increasing litigation in the biopharmaceutical industry with respect to the manufacture and sale of new therapeutic compounds. The validity and breadth of claims in biotechnology patents may involve complex factual and legal issues, for which no consistent policy exists. In particular, the patent protection available for protein-based drugs, such as IPLEX™ and rhIGFBP-3, is highly uncertain and involves issues relating to the scope of protection of claims to gene sequences and the production of their corresponding proteins.

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.

Third Party Patents

Third parties hold U.S. and foreign patents possibly directed to the composition, production and use of rhIGF-1, rhIGFBP-3, IPLEX™ and recombinant proteins generally. We are not aware of any patents that would prevent us from pursuing our plans to commercialize IPLEX™ and rhIGFBP-3. We can provide no assurance, however, that a third party will 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 treble 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 management's attention.

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.

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

COMPETITION

We are engaged in an industry that is intensely competitive and characterized by rapid technological progress. For our product candidates, we face significant competition from biotechnology, large pharmaceutical and other companies, universities and research institutions. Most of these companies and institutions have substantially greater capital resources, research and development staffs, facilities and experience in conducting clinical studies and obtaining regulatory approvals. In addition, many of these companies have greater experience and expertise than we do in manufacturing and marketing pharmaceutical products.

We cannot predict the relative competitive position of our product candidates if they are approved for use. However, we expect that the following factors will determine our ability to compete effectively: safety, efficacy, product price, ease of administration and marketing and sales capability.

In the proprietary protein area, we are aware of several pharmaceutical companies that are developing drugs in various forms of muscular dystrophy including PTC Therapeutics, Asklepios Biopharmaceutical Inc., Wyeth and Schering-Plough/Key Pharmaceutical, AVI Biopharma, Cephalon and Transgene, however, we believe that IPLEX™ is the only drug that is in development for the treatment of MMD. We are also aware that rhIGF-1 has been shown in a small clinical study to have positive effects in patients with MMD and that Nifendipine, Coenzyme Q10, DHEA-S and low dose Metformin have all been investigated for the treatment of MMD, however we are unaware of any formal development programs to pursue this indication for these drugs.

Many companies are pursuing the development of products for the treatment of cancer. Our competitors include multinational pharmaceutical companies, specialized biotechnology firms, universities and other research institutions. Although we are unaware of any companies developing rhIGFBP-3 for cancer, we are aware of companies who are developing products that are intended to target the same IGF-1 pathway targeted by INSM-18 and rhIGFBP-3. These companies include ImClone, Amgen, OSI Pharmaceuticals, Bristol Meyers Squibb and Genentech.

It is possible that there are other companies with products currently in development or that exist on the market that may compete directly with IPLEX™, INSM-18 and rhIGFBP-3.

GOVERNMENT REGULATION

Government authorities in the United States and other countries extensively regulate the research, development, testing, manufacture, promotion, marketing and distribution of drug products. Drugs are subject to rigorous regulation by the FDA and similar regulatory bodies in other countries. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or allow us to manufacture or market our products, and we may be criminally prosecuted.

We and our manufacturers may also be subject to regulations under other federal, state, and local laws, including the Occupational Safety and Health Act, the Environmental Protection Act, the Clean Air Act and import, export and customs regulations.

PROPRIETARY PROTEIN PLATFORM

FDA Approval Process

The steps ordinarily required before a new drug may be marketed in the United States are similar to steps required in many other countries. The process required by the FDA before a new drug may be marketed in the United States generally involves the following: completion of preclinical laboratory testing, submission of an Investigational New Drug Application, or IND, which must become effective before human clinical studies may begin, performance of adequate and well-controlled human clinical studies to establish the safety and efficacy of the proposed drug for its intended use and submission and approval of a New Drug Application, or NDA, by the FDA.

Preclinical tests include laboratory evaluation of product chemistry and stability, as well as animal studies to evaluate toxicity before a drug is administered to human subjects. The results of preclinical testing are submitted to the FDA as part of an IND. The FDA requires a 30-day waiting period after the submission of each IND before beginning clinical tests in humans. At any time during this 30-day period or at any time thereafter, the FDA may order the partial, temporary or permanent discontinuation of a clinical trial or impose other sanctions if the FDA believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. Clinical studies must be conducted in accordance with the FDA's good clinical practices requirements. The IND process may become extremely costly and substantially delay development of our products. Moreover, positive results of preclinical tests are not necessarily indicative of similar results in clinical trials.

Clinical studies to support NDA approval are typically conducted in three sequential phases, but the phases may overlap. In Phase I clinical studies, the product is tested in a small number of patients or healthy volunteers, primarily for safety at one or more doses and to assess pharmacokinetics. In Phase II clinical studies, in addition to safety, the sponsor evaluates the efficacy of the product on targeted indications, identifies possible adverse effects and safety risks in a patient population, and assesses dose tolerance and optimal dose range. If a compound is found to be potentially effective and to have an acceptable safety profile in Phase II studies, Phase III studies, also referred to as "pivotal studies," are undertaken. Phase III clinical studies typically involve testing for safety and clinical efficacy in an expanded patient population at geographically-dispersed study sites.

After completion of the required clinical testing, an NDA is submitted. An NDA contains the results of the preclinical and clinical studies, together with, among other things, detailed information on the manufacture and composition of the product and proposed labeling, including payment of a user fee. The FDA may request additional information before accepting an NDA for filing, in which case the application must be resubmitted with the additional information. During its review of an NDA, the FDA may refer the application to an appropriate advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee.

Under the policies agreed to by the FDA under the Prescription Drug User Fee Act, or the PDUFA, the FDA has ten months in which to complete its initial review of a standard NDA and respond to the applicant, and six months to initially review and respond to a priority NDA. Standard NDA status or priority NDA status are based on several factors identified by the FDA including for example, whether the drug product, if approved, would be a significant improvement compared to marketed products in the treatment, diagnosis, or prevention of a disease. The review process and the PDUFA goal date may be extended by three months if the FDA requests, or the NDA sponsor otherwise submits, a major amendment containing additional information or clarification regarding information already provided in the submission within the last three months of the PDUFA goal date.

If the FDA's evaluations of the NDA and the clinical and manufacturing procedures and facilities are favorable, the FDA may issue either an approval letter or an approvable letter, which contains the conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug for certain approved indications. In addition, an approval letter may contain various post-marketing commitments or agreements, which are often referred to as Phase IV studies. If the FDA's evaluation of the NDA submission and the clinical and manufacturing procedures

and facilities is not favorable, the FDA may refuse to approve the NDA and issue a not approvable letter.

The manufacturers of approved products and their manufacturing facilities are subject to continual review and periodic inspections. Because we intend to contract with third parties for manufacturing of these products, our control of compliance with FDA requirements may be incomplete. In addition, identification of certain side effects or the occurrence of manufacturing problems after any of our drugs are on the market could cause subsequent product recall, discontinuance, or withdrawal of approval, reformulation of the drug, additional preclinical testing or clinical studies and labeling changes.

The FDA's policies may change, and additional government regulations may be enacted that could prevent or delay regulatory approval for our products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

The Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Act, amended the Federal Food, Drug, and Cosmetic Act (the "FDCA"). Under the Hatch-Waxman Act, newly-approved drugs and indications may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, meaning that the FDA has not previously approved any other new drug containing the same active moiety. However, in the case of a combination drug containing a new chemical entity and a non-new chemical entity, five year exclusivity does not attach to the new chemical entity. The Hatch-Waxman Act prohibits the submission of an Abbreviated NDA, or ANDA, for a generic drug, or a Section 505(b)(2) NDA for another version of such drug during the five year exclusive period. However, the submission of an ANDA or Section 505(b)(2) NDA containing a paragraph IV certification claiming that a patent listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or Orange Book, for the drug is invalid or will not be infringed by the manufacture, use or sale of the new product is permitted after four years. The submission of a paragraph IV certification may trigger a 30-month stay of approval of the ANDA or Section 505(b)(2) NDA. Protection under Hatch-Waxman will not prevent the submission or approval of another full NDA; however, the applicant would be required to conduct its own preclinical and adequate and well-controlled clinical studies to demonstrate safety and effectiveness. The Hatch-Waxman Act also provides three years of marketing exclusivity for the approval of new and supplemental NDAs, for, among other things, new indications, dosage forms, or strengths of an existing drug, if new clinical investigations that were conducted or sponsored by the applicant are essential to the approval of the application.

IPLEX™ is currently protected by a seven year period of orphan drug exclusivity for the treatment of severe primary IGF-1 deficiency, which prevents the FDA from approving another marketing application for the same drug for the same indication, except in the limited circumstances described below. In addition, the FDA's Orange Book publication lists two patents covering IPLEX™ to which a generic applicant must certify.

Orphan Drug Designation and Exclusivity

Some jurisdictions, including the European Union and the United States, may designate drugs for relatively small patient populations as orphan drugs. The FDA grants orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. In the United States, orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product that has orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of

seven years, except in limited circumstances, such as a showing of clinical superiority (superior efficacy, safety, or a major contribution to patient care) to the product with orphan drug exclusivity. Also, competitors may receive approval of different drugs or biologics for the indications for which the orphan drug has exclusivity.

We have received orphan designation for IPLEX™ for the treatment of MMD. We also intend to file for orphan drug designation IPLEX™ for other indications that meet the criteria for orphan drug designation and for which IPLEX™ appears to be a promising treatment. If the FDA designates the drug and approves our marketing application, or approves marketing applications under current designations, we will be granted seven years of orphan drug exclusivity for the drug for the designated indication. Obtaining FDA approval to market a product with orphan drug exclusivity may not provide us with a material commercial advantage.

Under European Union medicine laws, the criteria for designation as an "orphan medicine" are similar but somewhat different from those in the United States. A drug is designated as an orphan drug if the sponsor can establish that the drug is intended for a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the European Union or that is unlikely to be profitable, and if there is no approved satisfactory treatment or if the drug would be a significant benefit to those persons with the condition. Orphan medicines are entitled to ten years of market exclusivity, except under certain limited circumstances comparable to United States law. During this period of market exclusivity, no "similar" product, whether or not supported by full safety and efficacy data, will be approved unless a second applicant can establish that its product is safer, more effective or otherwise clinically superior. This period may be reduced to six years if the conditions that originally justified orphan drug designation change or the sponsor makes excessive profits. We have obtained orphan medicine designation in the European Union for IPLEX™ for the treatment of extreme insulin resistance.

Other Regulatory Requirements

We may also be subject to a number of post-approval regulatory requirements. If we seek to make certain changes to an approved product, such as promoting or labeling a product for a new indication, making certain manufacturing changes or product enhancements or adding labeling claims, we will need FDA review and approval before the change can be implemented. While physicians may use products for indications that have not been approved by the FDA, we may not label or promote the product for an indication that has not been approved. Securing FDA approval for new indications or product enhancements and, in some cases, for manufacturing and labeling claims, is generally a time-consuming and expensive process that may require us to conduct clinical studies under the FDA's IND regulations. Even if such studies are conducted, the FDA may not approve any change in a timely fashion, or at all. In addition, adverse experiences associated with use of the products must be reported to the FDA, and FDA rules govern how we can label, advertise or otherwise commercialize our products.

Outside the United States, our ability to market our products will also depend on receiving marketing authorizations from the appropriate regulatory authorities. The requirements governing the conduct of clinical studies and marketing authorization vary widely from country to country. The foreign regulatory approval process includes risks similar to those associated with FDA approval described above.

EMPLOYEES

At December 31, 2008, we had 97 employees, including 19 in research and development, 31 in regulatory, clinical and quality assurance, 29 in manufacturing, and 18 in finance and administration. After giving effect to the sale of our FOB assets on March 31, 2009, we had 18 employees as of that date, including 3 executives, 10 in regulatory and clinical and 5 in finance and administration.

Our continued success will depend in large measure on our ability to attract and retain 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 development stage company with expertise in protein recombinant drug development. We have incurred losses each year of operation and 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 requires us to establish a sales and marketing organization and contractual relationships to enable product manufacturing and other related activities. We expect that these activities, together with our general and administrative expenses, will result in substantial operating losses for the foreseeable future. As of December 31, 2008, our accumulated deficit was $346 million and for the year ended December 31, 2008 our consolidated net loss was $15.7 million.

The Italian Health Authority may refuse to pay for IPLEX™ used by patients in Italy under our Expanded Access Program, which could have a material 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 our Expanded Access Program. Should the Italian Health Authority decide to stop approving IPLEX™ for ALS it would significantly affect our cash position and could require us to raise funds sooner than anticipated, which may only be available to us on less than favorable terms.

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:

- raise sufficient money and pay for the development of the products
- attract and retain appropriate personnel; and
- develop relationships with other companies to perform various development activities that we are unable to perform.

Even if we are successful in developing and obtaining approval for our product candidates, there are numerous circumstances that could prevent the successful commercialization of the products such as:

- the regulatory approvals of our products are delayed or we are required to conduct further research and development of our products prior to receiving regulatory approval;
- we are unable to build a sales and marketing group to successfully launch and sell our products;
- we are unable to raise the additional funds needed to successfully develop and commercialize our products or acquire additional products for growth;
- we are required to allocate available funds to litigation matters;
- we are unable to manufacture the quantity of product needed in accordance with current good manufacturing practices to meet market demand, or at all;
-

our product is determined to be ineffective or unsafe following approval and is removed from the market or we are required to perform additional research and development to further prove the safety and effectiveness of the product before re-entry into the market;

- competition from other products or technologies prevents or reduces market acceptance of our products;

- we do not have and cannot obtain the intellectual property rights needed to manufacture or market our products without infringing on another company's patents;

- we are unsuccessful in defending against patent infringement claims being brought against us our products or technologies; or

- we are unable to obtain reimbursement for our product or such reimbursement may be less than is necessary to produce a reasonable profit.

Our growth strategy includes the commercialization of more than one product. We may not be able to identify and acquire complementary products, businesses or technologies and if acquired or licensed, they might not improve our business, financial condition or results of operations. The failure to successfully acquire, develop and commercialize products will adversely affect our business, financial condition and results of operations.

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 in the future. To maintain the listing of our common stock on the NASDAQ Capital Market, we are required, among other things, to maintain a daily closing bid price per share of $1.00 (the "Minimum Bid Price Requirement"). By letter dated June 18, 2007, we were notified by the NASDAQ Listing Qualification Staff (the "Staff") that the bid price for our common stock had closed below $1.00 per share for the previous 30 consecutive business days and that in accordance with NASDAQ marketplace rules, we had been granted a 180-calendar day period, or through December 17, 2007, to regain compliance with the Minimum Bid Price Requirement. By letter dated December 20, 2007, the Staff notified us that we had failed to regain compliance with the Minimum Bid Price Requirement and that our common stock would be delisted from the NASDAQ Stock Market on December 31, 2007, if we did not transfer the listing to the NASDAQ Capital Market or appeal the Staff decision to a NASDAQ Hearings Panel (a "Panel"). By letter dated, December 26, 2007, we requested a hearing before a Panel and on January 24, 2008, we attended a Panel hearing in connection with our failure to meet the Minimum Bid Price Requirement. By decision dated February 27, 2008, the Panel transferred our common stock to the NASDAQ Capital Market and granted us the balance of the second 180-calendar day period, or until June 12, 2008, in accordance with NASDAQ marketplace rules, to regain compliance with the Minimum Bid Price Requirement. We did not regain compliance with the Minimum Bid Price Requirement and accordingly, on June 17, 2008, were notified by the Staff that our common stock would be delisted from the NASDAQ Capital Market if we did not request a hearing before a Panel. By letter dated June 24, 2008, we requested a hearing before a Panel with respect to the continued listing of our common stock on the NASDAQ Capital Market. On July 31, 2008, we had a hearing in front of the Panel. On August 29, 2008, we received a letter from the Panel stating that the Panel had granted our request to remain listed on the NASDAQ Capital Market, provided that, we evidence compliance with the Minimum Bid Price Rule on or before December 15, 2008. Subsequent to the Panel decision, due to market conditions, on October 16, 2008, NASDAQ announced that it was suspending compliance with the Minimum Bid Price Requirement for all listed companies until January 16, 2009. In connection with the suspension of the Minimum Bid Price Requirement, we were notified that the period by which we must be in compliance with the Minimum Bid Price Requirement had been extended until July 17, 2009. If we fail to regain compliance with the Minimum Bid Price Requirement on or before July 17, 2009, the Staff will provide us with written notification that our Common Stock will be delisted from 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.

In order to regain compliance with the Minimum Bid Price Requirement of the NASDAQ Stock Market we may be required to implement a reverse stock split, which could have a material adverse affect on our stock price.

We may be required to implement a reverse stock split in order for our shares of common stock to remain listed on the NASDAQ Capital Market. While such reverse stock split could bring us back into compliance, there can be no assurance that any increase in the market price for our common stock resulting from a reverse stock split, if approved and implemented, 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.

As a result, the trading liquidity of our common stock may not improve as a result of a reverse stock split. Furthermore, the liquidity of our common stock could be adversely affected by the reduced number of shares of our common stock that would be outstanding after the reverse stock split.

If our products fail in pre-clinical or clinical trials or if we cannot enroll enough patients to complete our clinical trials, such failure may adversely affect our business, financial condition and results of operations.

In order to sell our products, we must receive regulatory approval. Before obtaining regulatory approvals for the commercial sale of any of our products under development, we must demonstrate through pre-clinical studies and clinical trials that the product is safe and effective for use in each target indication. In addition, the results from pre-clinical testing and early clinical trials may not be predictive of results obtained in later clinical trials. There can be no assurance that our clinical trials will demonstrate sufficient safety and effectiveness to obtain regulatory approvals for our products still in development. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in late stage clinical trials even after promising results in early stage development. If our developmental products fail in pre-clinical or clinical trials, it will have an adverse effect on 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; and
- competition from other companies' clinical studies for the same patient population.

We believe our planned procedures for enrolling patients are 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 may be required to conduct broad, long-term clinical trials to address concerns that the long-term use of one of our leading products, IPLEX™, in broader chronic indications might increase the risk of diabetic retinopathy. This may materially adversely affect our business, financial condition and results of operations.

In previously published clinical trials of rhIGF-1, concerns were raised that long-term use of rhIGF-1 might lead to an increased incidence and/or severity of retinopathy, a disease of new blood vessel growth in the eye which results in loss of vision. Because IPLEX™ contains rhIGF-I, the FDA may require us to conduct broad, long-term clinical trials to address these concerns prior to receiving FDA approval for broad chronic indications such as diabetes. These clinical trials would be expensive and could delay our commercialization of IPLEX™ for these broader chronic indications. Adverse results in these trials could prevent our commercialization of IPLEX™ for broad chronic indications or could jeopardize existing development in other indications.

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 corporate 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 EMEA, approval. The regulatory approval process in these other territories includes at least all of the risks associated with obtaining FDA and EMEA approval detailed above. Approval by the FDA or the EMEA 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 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.

The transfer of the Boulder facility to Merck takes away our internal IPLEX™ production capability. We believe, however, that we have sufficient inventory of IPLEX™ to support our ongoing ALS EAP in Europe through 2010 together with the IPLEX™ requirement for the clinical trial currently being planned with the FDA for ALS patients in the US. Any requirements for IPLEX™ beyond 2010 or any significant increase in demand beyond our current commitments either in the MMD or ALS fields will require that we identify a Contract Manufacturing Organization or CMO to produce the necessary IPLEX™ to meet the demand. We estimate that the tech transfer of our IPLEX™ production process could take 12 to 18 months once a CMO has been identified.

We also intend to manufacture rhIGFBP-3 clinical drug substance and INSM-18 with contract manufacturers. In addition, we intend to utilize contract manufacturers for sterile filtering, filling, finishing, labeling and analytical testing.

The number of contract manufacturers with the expertise and facilities to manufacture our products is limited and it would take a significant amount of time and resources to arrange for alternative manufacturers. Even if we were to find alternative manufacturers, the prices they charge may not be commercially reasonable or may only be able to provide our products in a quantity that is less than our needs. Furthermore, if we need to change to other contract manufacturers, we would also need to transfer to these new manufacturers and validate the processes and analytical methods necessary for the production and testing of our products. Any of these factors could lead to (1) the delay or suspension of our clinical studies, regulatory submissions and regulatory approvals, or (2) higher costs of production, or (3) our failure to effectively commercialize our products.

The facilities of contract manufacturers must undergo inspections by the FDA and the EMEA for compliance with cGMP regulations. In the event these facilities do not continue to receive satisfactory cGMP inspections for the manufacture and testing of our products, we may need to fund additional modifications to our manufacturing or testing processes, conduct additional validation studies, or find alternative manufacturing and testing facilities, any of which would result in significant cost to us as well as a significant delay of up to several years in the development of our products. In addition, the facilities of any contract manufacturer we may utilize, will be subject to ongoing periodic inspection by the FDA, the EMEA and other foreign agencies for compliance with cGMP regulations and similar foreign standards. We have limited control over contract manufacturers' compliance with these regulations and standards which could limit our production of final drug product.

If our products fail to achieve market acceptance for any reason, such failure may materially adversely affect our business, financial condition and results of operations.

There can be no assurance that any of our product candidates if approved for marketing, will achieve market acceptance. If our product candidates, once approved, do not receive market acceptance for any reason, it will adversely affect our business, financial condition and results of operations. The degree of market acceptance of any drugs we develop will depend on a number of factors, including:

- the establishment and demonstration in the medical community of the clinical efficacy and safety of our products;
- our products' potential advantages over existing and future treatment methods;

- the price of our products; and

- reimbursement policies of government and third-party payers, including hospitals and insurance companies.

For example, even after we obtain regulatory approval to sell our products, physicians and healthcare payers could conclude that our products are not safe and effective and physicians could choose not to use them to treat patients. Our competitors may also develop new technologies or products which are more effective or less costly, or that seem more cost-effective than our products.

In addition, legislation and regulations affecting the pricing of pharmaceuticals may change in ways adverse to us. While we cannot predict the likelihood of any legislative or regulatory proposals, if the government or an agency adopts such proposals, they could materially adversely affect our business, financial condition and results of operations.

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 our 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 strategy includes acquiring complementary businesses or technologies that may not be available or, if available and purchased or licensed, might not improve our business, financial condition or results of operations.

As part of our business strategy, we expect to pursue acquisitions and in-license new products and technologies. Nonetheless, we cannot assure you that we will identify suitable acquisitions or products or that we can make such acquisitions or enter into such license agreements on acceptable terms. If we acquire businesses, those businesses may require substantial capital, and we cannot provide assurance that such capital will be available in sufficient amounts or that financing will be available in amounts and on terms that we deem acceptable. Furthermore, the integration of acquired businesses may result in unforeseen difficulties that require a disproportionate amount of management's attention and our other resources. Finally, we cannot provide assurance that we will achieve productive synergies and efficiencies from these acquisitions.

We intend to conduct proprietary development programs with collaborators, and any conflicts with them could harm our business, financial condition and results of operations. We intend to enter into collaborative relationships which will 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 reduce our revenues and 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 acquire complementary businesses or technology or continue our research and development activities. As of December 31, 2008, we had $2.4 million of cash and investments on hand. On March 31, 2009, we completed the sale of our FOB assets for an aggregate purchase price of $130 million. After fees, taxes and other costs related to the transaction, we expect net proceeds of approximately $123 million as a result of this transaction. However, our future capital requirements will depend on many factors, including factors associated with:

- research and development, including, among other items, preclinical testing and clinical studies,
- process development;
- 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 IPLEX™ 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 than 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.

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

rhIGF-1 manufactured by other parties may be approved for use in other indications in the United States in the future, including MMD and HARS. In the event there are other rhIGF-1 products approved by the FDA to treat indications other than those covered by IPLEX™, physicians may elect to prescribe a competitor's product containing rhIGF-1 to treat the indications for which 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 containing rhIGF-1 to prescribe to their patients. As a result, we would have limited ability to prevent off-label use of a competitor's product containing 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 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 drug 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 this 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 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 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 any 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 our business, financial condition and results of operations.

If our settlement agreement with Tercica and Genentech was 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. 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.

Conversion of our outstanding notes and exercise of warrants and options issued by us will significantly dilute the ownership interest of existing shareholders.

As of February 28, 2009, the convertible notes issued by us in March 2005 and the warrants issued by us in May 2007, March 2005, November 2004 and July 2003 were convertible into and exercisable for up to approximately 13 million shares of our common stock, representing approximately 11% of our then outstanding common stock.

As of February 28, 2009, our outstanding restricted stock, restricted stock units and stock options to our employees, officers, directors and consultants were exercisable for up to 9 million shares of our common stock, representing approximately an additional eight percent of our then outstanding common stock.

The conversion or exercise of some or all of our convertible notes, warrants, restricted stock, restricted stock units and options will significantly 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.

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." 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;
- our operating results;
- 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 biopharmaceutical 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 brought 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 by existing shareholders may lower the price of our common stock, which could result in losses to our shareholders. Future sales of substantial amounts of common stock in the public market, or the possibility of such sales occurring, could adversely affect prevailing market prices for our common stock or our future ability to raise capital through an offering of equity securities. Substantially all of our common stock is freely tradable in the public market without restriction under the Securities Act, unless these shares are held by "affiliates" of our company, 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. We are currently reviewing options for the use of the proceeds from the sale of our FOB assets to Merck. One of these options may include a special dividend to common shareholders.

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 2. PROPERTIES

Our headquarters are located in Richmond, Virginia, where we occupy approximately 18,000 square feet of space for corporate and development activities under a lease expiring in October 2016. Our lease contains annual rent escalations of 3%. Our annual cash cost for the Virginia space including utilities and services in fiscal 2008 were approximately $0.4 million.

On March 31, 2009 in connection with the sale of our FOB assets, we assigned the lease for our process development and manufacturing facility located in Boulder, Colorado, where we occupied approximately 25,000 square feet

dedicated to cGMP production of commercial and clinical drug and quality control and 26,000 square feet of space in two adjacent facilities for additional laboratory and research and development operations, administrative functions, and cGMP warehouse and dispensing operations. Our annual cash cost for this facility including utilities and services in fiscal 2008 was approximately $1.2 million under two operating leases that contained annual escalation of 3-5%.

We believe that our existing 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.

ITEM 3. LEGAL PROCEEDINGS

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 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, 2008, 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, 2008. 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.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

PART II

ITEMMARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND 5. ISSUER REPURCHASES OF EQUITY SECURITIES

Our common stock began trading on The Nasdaq SmallCap Market on June 1, 2000 and moved to the Nasdaq Global Market (formerly the Nasdaq National Market) on August 8, 2000. On February 29, 2008 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." 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 2008 and fiscal 2007:

Fiscal Year 2008	High	Low
Fourth Quarter	$ 0.78	$ 0.32
Third Quarter	0.97	0.39
Second Quarter	0.77	0.39
First Quarter	0.92	0.57

Fiscal Year 2007	High	Low
Fourth Quarter	$ 1.07	$ 0.66
Third Quarter	0.82	0.56
Second Quarter	1.22	0.68
First Quarter	1.65	0.68

On February 27, 2009, the last reported sale price for our common stock on the Nasdaq Capital Market was $0.92 per share. As of February 27, 2009, there were approximately 569 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. We are currently reviewing options for the use of the proceeds from the sale of our FOB assets to Merck. One of these options may include a special dividend to common shareholders.

Information about our equity incentive plans can be found in Note 3 of our consolidated financial statements contained within this Form 10-K and in the section "Equity Compensation Plan Information" of our definitive Proxy Statement for our 2009 annual meeting of stockholders as filed with the Securities and Exchange Commission and is herein incorporated by reference.

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, 2008. The financial statements for each of the five fiscal years ended December 31, 2008, have been audited by Ernst & Young LLP, our independent registered public accounting firm. Ernst & Young LLP's report on the consolidated financial

statements for the year ended December 31, 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,				
	2004	2005	2006	2007	2008
Historical Statement of Operations Data:					
Revenues	$ 137	$ 131	$ 1,025	$ 7,581	$ 11,699
Operating expenses:					
Cost of goods sold	-	-	1,490	576	-
Asset Impairment	-	-	7,103	-	-
Research and development	23,260	21,835	21,123	19,198	21,047
General and administrative	4,242	5,730	25,682	8,246	5,063
Total operating expenses	27,502	27,565	55,398	28,020	26,110
Operating loss	(27,365)	(27,434)	(54,373)	(20,439)	(14,411)
Loss on investments	-	-	-	-	(500)
Interest income	222	752	1,937	1,159	500
Interest expense	(60)	(14,247)	(3,703)	(682)	(1,256)
Loss before income taxes	(27,203)	(40,929)	(56,139)	(19,962)	(15,667)
Income tax expense	-	-	-	-	-
Net loss	(27,203)	(40,929)	(56,139)	(19,962)	(15,667)
Basic and diluted net loss per share	(0.69)	(0.84)	(0.59)	(0.17)	(0.13)
Weighted average shares	39,160	48,742	95,321	114,682	122,132
Historical Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 9,222	$ 18,835	$ 24,112	$ 16,479	$ 2,397
Total assets	13,011	22,870	28,348	19,500	4,758
Long-term debt, net	-	6,437	3,161	2,113	487
Stockholders' equity (deficit)	7,235	10,529	13,880	11,488	(2,823)

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

We are a development stage company with expertise in protein drug development. Our corporate office is located in Richmond, Virginia.

On February 12, 2009, we announced that we had entered into a definitive agreement with Merck & Co., Inc. ("Merck") whereby Merck, through an affiliate, would purchase all assets related to our follow-on biologics platform. On March 31, 2009, we completed the sale of these assets for an aggregate purchase price of $130 million. After fees, taxes and other costs related to the transaction, we expect net proceeds of approximately $123 million as a result of this transaction.

As part of this transaction, Merck assumed the lease of our Boulder, Colorado-based manufacturing facility and acquired ownership of all the equipment in the building. In addition, upon closing of the transaction, Merck offered positions to employees of the Boulder facility. We retain our Richmond, VA corporate office, which houses our Clinical, Regulatory, Finance, and Administrative functions, in support of the continuing IPLEX™ program.

Until the sale of our follow-on biologics platform, we pursued a dual path strategy involving entry into the follow-on biologics arena (also known as biosimilars, biogenerics and biologics) and advancing our proprietary protein platform into niche markets with unmet needs. As a result of the sale of our follow-on biologics assets, we will primarily focus on our proprietary protein platform and our product, the FDA-approved IPLEX™, which is in various stages of development for a number of serious medical conditions. Based on a comprehensive market analysis, our current resource allocation strategy for IPLEX™ is focused primarily on Myotonic Muscular Dystrophy ("MMD") followed by Amyotrophic Lateral Sclerosis ("ALS"), also known as Lou Gehrig's disease. Other areas where IPLEX™ has also shown potential include Retinopathy of Prematurity ("ROP").

We plan to use the net proceeds from the sale of our follow-on biologics platform to continue to support the development of IPLEX™ and our proprietary protein platform and we are evaluating other options for use of these proceeds including product licensing, acquisitions of complimentary businesses or technologies, mergers, share repurchase and the distribution of a portion of the proceeds to shareholders.

We have not been profitable and have accumulated deficits of approximately $346 million through December 31, 2008. While we expect that, following the sale of our FOB assets to Merck, for the balance of 2009 we will operate on a cash neutral basis as a result of anticipated revenues on our Expanded Access Program and interest on the net proceeds of the sale of our FOB assets offsetting our ongoing base costs, we expect to incur significant additional losses for at least the next several years until such time as sufficient commercial revenues are generated to offset expenses. Moving forward our major source of income is expected to be the cost recovery charges for our Expanded Access Program and our major expenses will be related to research and development. In general, our expenditures may increase as development of our product candidates progresses. However, there will be fluctuations from period to period caused by differences in project costs incurred at each stage of development.

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 for metabolic and endocrine diseases. Until the sale of our FOB assets on March 31, 2009, our research and development efforts were principally focused on pursuing a dual path strategy involving entry into the follow-on biologics arena (also known as biosimilars, biogenerics and biologics) and advancing our proprietary protein platform into niche markets with unmet needs. Our focus is now principally on our proprietary protein platform. Our lead proprietary protein product, the FDA-approved IPLEX™, is being studied as a treatment for several serious medical conditions including MMD and ALS. We conduct very little of our own preclinical laboratory research. We have outsourced several Phase II clinical studies with IPLEX™ and our other anti-cancer product candidates, INSM-18 and rhIGFBP-3, and plan on conducting additional clinical studies in the future.

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 and amounted to approximately $188 million for the period since inception, in November 1999, through December 31, 2008, and $21.1 million, $19.2 million and $21.0

million, for the years ended December 31, 2006, 2007 and 2008, respectively. 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.

All of our research and development expenditures related to our proprietary protein platform are interrelated as they are all associated with drugs that modulate IGF-I 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 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.

External clinical research of IPLEX™ in the MMD indication together with the development cost of the proposed IPLEX™ trial for ALS patients in the US are expected to represent our main research and development focus for 2009.

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 protocol, 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 affect on our financial position and 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 2008 compared to Fiscal 2007

Revenues for the full-year 2008 totaled $11.7 million, up from $7.6 million in the corresponding period of 2007. This increase was primarily due to a $5.1 million improvement in cost recovery from the EAP to treat patients with ALS in Italy.

The net loss for the 12 months ended December 31, 2008 was $15.7 million or $0.13 per share, compared to $20.0 million or $0.17 per share for the 12 months ended December 31, 2007. R&D Expenses increased to $21.0 million from $19.2 million, reflecting the higher activity as our clinical trials in the FOB and IPLEX™ areas advanced. SG&A Expenses fell to $5.1 million from $8.2 million, due to the elimination of litigation expenses following the March 2007 settlement and the removal of commercial expenses associated with our business restructuring plan.

Interest income for the full-year 2008 was $0.5 million, compared to $1.2 million for the full-year 2007. This decrease was mainly due to lower interest rates and a lower average cash balance for the full-year 2008 as compared to the full-year 2007. Interest expense for the 12 months ended December 31, 2008 was $1.3 million, compared to $682,000 for the corresponding period of 2007. This higher interest expense was due to an increase in the debt discount amortization resulting from the quarterly payment of our 2005 convertible notes, which began in March 2008.

As of December 31, 2008, we had total cash, cash equivalents and short-term investments on hand of $2.4 million, compared to $16.5 million on hand as of December 31, 2007. The $14.1 million decrease in cash, cash equivalents and short-term investments mainly reflected the use of $12.0 million for operating activities and $2.2 million for principal and interest repayments of our 2005 convertible notes, which began on March 1, 2008.

Fiscal 2007 compared to Fiscal 2006

Revenues for the full-year 2007 totaled $7.6 million, up from $1.0 million in the corresponding period of 2006. This increase was due to improvements in the cost recovery from our EAP and the receipt of licensing income from our agreement with NAPO Pharmaceuticals Inc., (“NAPO”), combined with increased sales of IPLEX™ during the first quarter of 2007.

The net loss for the 12 months ended December 31, 2007 was $20.0 million or $0.17 per share, compared to $56.1 million or $0.59 per share for the 12 months ended December 31, 2006. R&D Expenses dropped to $19.2 million from $21.1 million, reflecting lower litigation expenses which were included in R&D Expenses during the first quarter of 2006, and reduced commercial manufacturing activity in 2007. SG&A Expenses fell to $8.2 million from $25.7 million, due to a combination of reduced litigation expenses, which were included in SG&A Expenses for the final three quarters of 2006, and the elimination of commercial expenses in 2007.

Interest income for the full-year 2007 was $1.2 million, compared to $1.9 million for the full-year 2006. This decrease was mainly due to lower interest rates and a lower average cash balance for the full-year 2007 as compared to the full-year 2006. Interest expense for the 12 months ended December 31, 2007 was $682,000, compared to $3.7 million for corresponding period of 2006. This decrease in interest expense resulted from lower amortization of the debt discount associated with our March 2005 financing, as a significant acceleration of the discount took place in 2006 due to the conversion of notes into shares of our common stock.

As of December 31, 2007, we had total cash, cash equivalents and short-term investments on hand of $16.5 million, compared to $24.1 million on hand as of December 31, 2006. The $7.6 million decrease in cash, cash equivalents and short-term investments mainly reflected the use of $25.3 million for operating activities and a $500,000 investment in NAPO, which was partially offset by net proceeds of $17.0 million from an offering of our common stock and warrants to purchase our common stock and $1.0 million from the reduction of an outstanding letter of credit.

Accounts payable and accrued project costs and other decreased $6.9 million, from $8.3 million in fiscal 2006 to $1.4 million in fiscal 2007 as a result of decreased litigation activity. Stockholders' equity decreased $2.4 million, from $13.9 million in fiscal 2006 to $11.5 million in fiscal 2007. In our common stock financing in May 2007, we received net proceeds of $17.0 million, but this was offset by our net loss of $20.0 million for fiscal 2007. Our accumulated deficit at December 31, 2007, increased to approximately $330.8 million from $310.8 million at December 31, 2006 due to our fiscal 2007 net loss of $20.0 million.

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 seek to raise the funds necessary for such development primarily through the issuance of equity securities in private placement transactions. However, it is our intention to pursue additional financing options, including entering into agreements with corporate 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 recently announced sale of our FOB manufacturing facility to Merck. We plan to continue incurring losses as we expand our research and development and do not expect material revenues for at least the next several years. At December 31, 2008, our cash and short-term investments were approximately $2.4 million, and were invested in money market instruments and municipal bonds. This is a decrease of $14.1 million from fiscal 2007, as a result of our cash use during the year.

Expenditures in fiscal 2008 were principally related to research and development, clinical trial activity, manufacturing activity and administrative activity at our sites in Boulder, Colorado, and Richmond, Virginia. Planned expenditures in 2009 include the funding of our ongoing research and development activity, such as clinical trial costs, and general and administrative support costs.

On March 31, 2009, we completed the sale of our FOB assets for an aggregate purchase price of $130 million. After fees, taxes and other costs related to the transaction, we expect net proceeds of approximately $123 million as a result of this transaction. We believe these net proceeds will provide sufficient liquidity for us to continue as a going concern.

Even though we currently have sufficient funds to meet our financial needs for the upcoming year, our business strategy also contemplates raising additional capital through debt or equity sales. In the future, we may require additional funds for the continued development of our potential product candidates or to pursue acquisition of complementary businesses or 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 also plan to enter into agreements with corporate partners in order to fund operations through milestone payments, license fees and equity investments.

Off-Balance Sheet Arrangements

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.

Contractual Obligations

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

Contractual Obligations
(in thousands)

	Payments Due by Years				
	Total	Less than 1 year	1 - 2 Years	3 - 5 Years	More than 5 years
Long term debt (1)	$ 2,864	$ 2,307	$ 557	$ -	$ -
Operating lease obligations	8,077	1,025	1,837	4,341	874
	$ 10,941	$ 3,332	$ 2,394	$ 4,341	$ 874

(1) Long-term debt obligations reflect the future interest and principal payments of the Company's convertible notes outstanding as of December 31, 2008. We began repaying these notes in quarterly installments, beginning on March 1, 2008. We will continue to make payments on the notes through 2010 unless they are converted to common shares at an earlier date.

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. 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. We do not have separate accounting policies for internal or external research and development and we do not conduct any research and development for others. 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.

Litigation costs as they relate to our patents are recorded as research and development expenditures. However, from May through December 2006, the Company shifted from research and development operations to commercial operations, and litigation costs were recorded as a selling, general and administrative activity during this time.

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™ 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" described in SFAS No. 148, Accounting for Stock-Based Compensation – Transition and Disclosure. 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 estimated in accordance with the original provisions of SFAS 123, Share Based Payments, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant date fair valued estimated in accordance with the provisions of SFAS 123R, Share-Based Payments.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We invest excess cash in investment grade, interest-bearing securities and, at December 31, 2008, had $2.4 million invested in money market instruments and municipal bonds. Such investments are subject to interest rate and credit risk. Our policy of investing in highly rated securities whose liquidities at December 31, 2008, are all less than six months 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 2008, 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 42 – 60.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Based on their evaluation, as of December 31, 2008, our Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer) have concluded that 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) 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, 2008 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, 2008, our internal control over financial reporting was effective.

Ernst & Young LLP, our independent registered public accounting firm, has issued an audit report on the effectiveness of our internal control over financial reporting. The report of Ernst & Young LLP is contained in Item 8 of this Annual Report on Form 10-K.

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

ITEM 9B. OTHER INFORMATION

None.

PART III

The information required by Items 10, 11, 12, 13 and 14 of Form 10-K is incorporated by reference from the discussion responsive thereto under the captions "Election of Directors" and "Designation of Auditors" in our definitive proxy statement for our 2009 annual meeting of stockholders as 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 and 10.22 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 31st day of March, 2009.

Insmed Incorporated
a Virginia corporation
(Registrant)

By: /s/ GEOFFREY ALLAN
Geoffrey Allan, Ph.D.
Chairman of the Board, President and 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 31st day of March, 2009.

Signature	Title
/s/ GEOFFREY ALLAN Geoffrey Allan, Ph.D.	Chairman of the Board, President and Chief Executive Officer (Principal Executive Officer)
/s/ Kevin P. Tully Kevin P. Tully	Chief Financial Officer (Principal Financial Officer) and Executive Vice President
/s/ KENNETH G. CONDON Kenneth G. Condon	Director
/s/ GRAHAM K. CROOKE Graham K. Crooke, MB.BS	Director
/s/ STEINAR J. ENGELSEN Steinar J. Engelsen, M.D.	Director
/s/ DENNIS LANFEAR Dennis Lanfear	Director
/s/ MELVIN SHAROKY Melvin Sharoky, M.D.	Director

/s/ RANDALL W. WHITCOMB Director

Randall W. Whitcomb, M.D.

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, 2008 and 2007, 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, 2008. 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, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, 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, 2008, 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 31, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Richmond, Virginia
March 31, 2009

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, 2008, 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.

In our opinion, Insmed Incorporated maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, 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, 2008 and 2007, 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, 2008 and our report dated March 31, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Richmond, Virginia
March 31, 2009

INSMED INCORPORATED

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

	December 31, 2008	December 31, 2007
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$ 2,397	$ 16,479
Accounts receivable, net	122	250
Prepaid expenses	74	244
Total current assets	2,593	16,973
Long-term assets:		
Restricted cash - long term	2,095	2,095
Investments	-	258
Deferred financing costs, net	70	170
Property and equipment, net	-	4
Total long-term assets	2,165	2,527
Total assets	$ 4,758	$ 19,500
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,277	$ 904
Accrued project costs & other	936	503
Payroll liabilities	453	631
Restricted stock unit liability	113	-
Interest payable	13	23
Deferred rent	168	115
Deferred income	302	245
Convertible debt	2,211	2,211
Debt discount	(596)	(950)
Net convertible debt	1,615	1,261
Total current liabilities	4,877	3,682
Long-term liabilities:		
Convertible debt	553	2,764
Debt discount	(66)	(651)
Net long-term convertible debt	487	2,113
Asset retirement obligation	2,217	2,217
Total liabilities	7,581	8,012

Stockholders' equity (deficit):		
Common stock; $.01 par value; authorized shares 500,000,000; issued and outstanding shares, 122,494,010 in 2008 and 121,904,312 in 2007	1,225	1,219
Additional paid-in capital	342,378	341,270
Accumulated deficit	(346,426)	(330,759)
Accumulated other comprehensive loss:		
Unrealized loss on investment	-	(242)
Net stockholders' equity (deficit)	(2,823)	11,488
Total liabilities and stockholders' equity (deficit)	$ 4,758	$ 19,500

See accompanying notes.

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

	Twelve Months Ended December 31,		
	2008	2007	2006
Sales, net	$ -	$ 423	$ 263
Royalties	144	121	157
License income	-	1,607	-
Grant revenue	1,044	-	-
Other expanded access program income, net	10,511	5,430	605
Total revenues	11,699	7,581	1,025
Operating expenses:			
Cost of goods sold	-	576	1,490
Asset impairment	-	-	7,103
Research and development	21,047	19,198	21,123
Selling, general and administrative	5,063	8,246	25,682
Total expenses	26,110	28,020	55,398
Operating loss	(14,411)	(20,439)	(54,373)
Interest income	500	1,159	1,937
Interest expense	(1,256)	(682)	(3,703)
Loss on investments	(500)	-	-
Net loss	$ (15,667)	$ (19,962)	$ (56,139)
Basic and diluted net loss per share	$ (0.13)	$ (0.17)	$ (0.59)
Shares used in computing basic and diluted net loss per share	122,132	114,682	95,321

See accompanying notes.

INSMED INCORPORATED
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
YEARS ENDED DECEMBER 31, 2008, 2007, AND 2006
(in thousands, except share amounts)

	Common Stock	Additional Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balance at December 31, 2005	$ 665	$ 264,522	$ (254,658)	$ -	$ 10,529
Net loss	-	-	(56,139)	-	(56,139)
Issuance of 36,500 shares of common stock upon exercise of stock options	-	19	-	-	19
Issuance of 280,234 shares of common stock from Employee Stock Purchase Plan	3	254	-	-	257
Issuance of 4,912,971 shares of common stock upon conversion of notes	49	6,313			6,362
Issuance of 6,572,621 shares of common stock upon exercise of warrants	66	9,003	-	-	9,069
Issuance of 23,000,000 shares of common stock for cash, net of offering costs of $421,000	230	42,589	-	-	42,819
Recognition of stock compensation expense for consultants	-	79	-	-	79
Recognition of stock option expense in accordance with FAS 123R	-	885	-	-	885
Balance at December 31, 2006	1,013	323,664	(310,797)	-	13,880
Comprehensive earnings:					
Net loss	-	-	(19,962)	-	(19,962)
Unrealized loss on investment	-	-		(242)	(242)
Comprehensive loss					(20,204)
Issuance of 18,000 shares of common stock upon exercise of stock options	-	9	-	-	9
Issuance of 186,870 shares of common stock from Employee Stock Purchase Plan	2	127	-	-	129
Issuance of 116,573 shares of common stock upon conversion of notes	1	150	-	-	151
Issuance of 20,255,367 shares of common stock for cash, net of offering costs of $1,266,135	203	16,761	-	-	16,964
Recognition of stock compensation expense for consultants	-	38	-	-	38
Recognition of stock option expense in accordance with FAS 123R	-	521	-	-	521
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 349,698 shares of common stock from Employee Stock Purchase Plan	4	117	-	-	121
Issuance of 240,000 shares of common stock for consulting services	2	141	-	-	143
Recognition of stock option expense in accordance with FAS 123R	-	850	-	-	850
Balance at December 31, 2008	$ 1,225	$ 342,378	$ (346,426)	$ -	$ (2,823)

See accompanying notes.

INSMED INCORPORATED
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Twelve Months Ended December 31,		
	2008	2007	2006
Operating activities			
Net loss	$ (15,667)	$ (19,962)	$ (56,139)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,043	406	3,369
Stock based compensation expense	850	521	885
Stock and stock options issued for services	143	38	79
Realized loss on investments	500	-	-
Impairment of property, plant & equipment	-	-	5,020
Changes in operating assets and liabilities:			
Accounts receivable	128	(9)	(241)
Inventory	-	576	(576)
Other assets	170	(157)	(4)
Accounts payable	373	(6,282)	6,219
Accrued project costs & other	433	(612)	(875)
Payroll liabilities	(178)	(671)	(272)
Deferred rent	53	61	(232)
Deferred income	57	245	-
Restricted stock unit liability	113	-	-
Asset retirement obligation	-	591	592
Interest payable	(10)	-	(29)
Net cash used in operating activities	(11,992)	(25,255)	(42,204)
Investing activities			
Decreases in short-term investments	12,673	9,066	(12,191)
Purchases of investments	-	(500)	-
Purchases of property, plant and equipment	-	-	(5,020)
Net cash provided by (used in) investing activities	12,673	8,566	(17,211)
Financing activities			
Proceeds from issuance of common stock			
Public Offering	-	18,230	43,240
Issuance costs	-	(1,266)	(421)
Warrants converted into shares	-	-	9,069
Other	121	138	325
Total proceeds from issuance of common stock	121	17,102	52,213
Repayment of convertible notes	(2,211)	-	-
Other	-	1,020	288
Net cash (used in) provided by financing activities	(2,090)	18,122	52,501
(Decrease) Increase in cash and cash equivalents	(1,409)	1,433	(6,914)

Cash and cash equivalents at beginning of period	3,554	2,121	9,035
Cash and cash equivalents at end of period	$ 2,145	$ 3,554	$ 2,121
Supplemental information			
Cash paid for interest	$ 234	$ 279	$ 319

See accompanying notes.

INSMED INCORPORATED

NOTES TO

CONSOLIDATED FINANCIAL STATEMENTS

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

On February 12, 2009 we announced that we had entered into a definitive agreement with Merck & Co., Inc. (“Merck”) whereby Merck, through an affiliate, would purchase all assets related to our follow-on biologics platform. On March 31, 2009, we completed the sale of these assets for an aggregate purchase price of $130 million. After fees, taxes and other costs related to the transaction, we expect net proceeds of approximately $123 million as a result of this transaction. We did not incur any severance expenses as a result of the transfer of assets and employees to Merck.

As part of this transaction, Merck assumed the lease of our Boulder, Colorado-based manufacturing facility and acquired ownership of all the equipment in the building. In addition, upon closing of the transaction, Merck offered positions to employees of the Boulder facility. We retain our Richmond, VA corporate office, which houses our Clinical, Regulatory, Finance, and Administrative functions, in support of the continuing IPLEX™ program. The transfer of the Boulder facility to Merck takes away our internal IPLEX™ production capability. We believe however, that we have sufficient inventory of IPLEX™ to support our ongoing ALS EAP in Italy through 2010 together with the IPLEX™ requirement for the clinical trial currently being planned with the FDA for ALS patients in the US. Any requirements for IPLEX™ beyond 2010 or any significant increase in demand beyond our current commitments either in the MMD or ALS fields will require that we identify a Contract Manufacturing Organization (‘CMO”) to produce the necessary IPLEX™ to meet the demand. We estimate that the tech transfer of our IPLEX™ production process could take 12 to 18 months once a CMO has been identified.

Until the sale of our follow-on biologics platform, we pursued a dual path strategy involving entry into the follow-on biologics arena (also known as biosimilars, biogenerics and biologics) and advancing our proprietary protein platform into niche markets with unmet needs. Following the sale of our follow-on biologics assets, we plan to continue to support our proprietary protein platform and our product, the FDA-approved IPLEX™, which is in various stages of development for a number of serious medical conditions including Myotonic Muscular Dystrophy (“MMD”), Amyotrophic Lateral Sclerosis (“ALS”), also known as Lou Gehrig’s disease and Retinopathy of Prematurity (“ROP”).

We have also engaged the services of RBC to act as financial advisor in evaluating other options for use of these proceeds which could include acquisitions of complimentary businesses or technologies, product licensing, mergers, share repurchase and the distribution of a portion of the proceeds to shareholders.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, 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.

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. These securities are carried at market, which approximates cost and are classified as Level 1 as defined in the Statement of Financial Accounting Standards (SFAS) No. 157, Fair Value Measurements fair value hierarchy. The cost of the specific security sold is used to compute the gain or loss on the sale of marketable securities. The table below details the breakdown of our cash and cash equivalents and our short-term investments:

	December 31, 2008	December 31, 2007
Cash and Cash Equivalents	$ 2,145	$ 3,554
Short-Term Investments	252	12,925
Total Cash and Cash Equivalents and Short-Term Investments	$ 2,397	$ 16,479

On April 14, 2004, we announced that we had acquired a lease to operate a recombinant protein manufacturing facility located in Boulder, Colorado. We intended to use the facility for the commercial manufacture of our FDA approved product, IPLEX™. On June 20, 2007, we notified our landlord that we wish to renew our lease. In November 2007 we provided a new Letter of Credit (“LOC”) to the landlord of the manufacturing facility in the amount of $2.1 million to cover facility restoration expenses upon termination of the lease. This LOC is supported by a certificate of deposit which is classified as restricted cash on the balance sheet. The accrued restoration expenses as of December 31, 2008 were $2.2 million and is recorded in asset retirement obligation on the balance sheet. Accretion expense for the years ended December 31, 2008, 2007 and 2006 totaled zero, $0.6 million and $0.6 million, respectively.

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, 2008 and 2007 due to the short-term maturities of these instruments. We have adopted Financial Accounting Statement 157, Fair Value Measurements for our financial assets and liabilities. 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 temporary impaired as NAPO was de-listed from the London Stock Exchange in 2008. This amount is reported as a loss on investments on our consolidated statement of operations. The carrying value of the convertible debt is $2.1 million which approximates fair value. This is calculated using the intrinsic value of the conversion feature.

Stock-Based Compensation

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement 123(R), Share-Based Payment, a revision of SFAS No. 123, Accounting for Stock-Based Compensation, which superseded APB Opinion No. 25, Accounting for Stock Issued to Employees. Statement 123(R) addresses the accounting for share-based payment transactions in which a company receives employee services in exchange for equity instruments of the company or liabilities that are based on the fair value of the company’s equity instruments or that may be settled by the issuance of such equity instruments. This statement requires that share-based transactions be 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™ 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 $0.4 million for 2008 and $0.3 million for 2007.

Research and Development

Research and development costs are expensed as incurred. 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. We do not have separate accounting policies for internal or external research and development and we do not conduct any research and development for others. 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.

Litigation costs as it relates to our patents are recorded as research and development expenditures. However, from May through December 2006, the Company shifted from research and development operations to commercial operations, and litigation costs were recorded as a selling, general and administrative activity during this time.

Income Taxes

Income taxes are accounted for in accordance with FAS 109, Accounting for 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.

In June 2006, FASB issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes (“FIN 48”). This Interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise’s financial statements in accordance with FASB 109. FIN 48 clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. It also

provides guidance on disclosure requirements, measurement and classification provisions, and transition requirements. We implemented FIN 48 on January 1, 2007 and due to the accumulated loss position of the Company, such implementation did not have a material impact on our consolidated financial statements.

Net Loss Per Share

Basic net loss per share is computed based upon the weighted average number of common shares outstanding during the year. The Company's diluted net loss per share is the same as its basic net loss per share because all stock options, warrants, and other potentially dilutive securities are antidilutive and, therefore, excluded from the calculation of diluted net loss per share.

Segment Information

The Company currently operates in one business segment, which is the development and commercialization of pharmaceutical products for the treatment of metabolic and endocrine diseases. 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 as defined by FASB Statement No. 131, Disclosure about Segments of an Enterprise and Related Information.

Recent Accounting Pronouncements

In December 2007, FASB ratified Emerging Issue Task Force ("EITF") Issue No. 07-1, Collaborative Arrangements. The consensus requires participants in a collaborative arrangement to present the results of activities for which they act as the principal on a gross basis and to report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative literature or a reasonable, rational and consistently applied accounting policy election. The consensus also requires significant disclosures related to collaborative arrangements. This Issue shall be effective for us beginning after January 1, 2009. We are evaluating the effect the adoption of EITF No. 07-1 will have on our financial statements.

In June 2008, FASB ratified EITF Issue No. 08-4, Transition Guidance for Conforming Changes to Issue No. 98-5 ("EITF No. 08-4"). Per EITF No. 08-4, conforming changes made to EITF Issue No. 98-5, Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios, that result from EITF Issue No. 00-27, Application of Issue No. 98-5 to Certain Convertible Instruments, and SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, shall be effective for us beginning after January 1, 2009. We are evaluating the effect the adoption of EITF No. 08-4 will have on our financial statements.

In May 2008, FASB issued FSP Accounting Principles Board No. 14−1, Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement) ("FSP APB 14−1"). FSP APB 14−1 requires the issuer of certain convertible debt instruments that may be settled in cash (or other assets) on conversion (including partial cash settlement) to separately account for the liability and equity components of the instrument in a manner that reflects the issuer's non−convertible debt borrowing rate when interest cost is recognized in subsequent periods. FSP APB 14−1 is effective for us beginning after January 1, 2009. We are evaluating the effect the adoption of FSP APB 14−1 will have on our financial statements.

2. Risks and Uncertainties

For the period from inception to December 31, 2008, the Company has incurred recurring operating losses and has accumulated a deficit of $346 million. During 2008, the Company incurred an operating loss of $15.7 million and net cash used in operations of $12 million. The Company's ability to continue as a going concern is dependent upon its

ability to take advantage of raising capital through securities offerings, debt financing, and partnerships and use these sources of capital to fund operations. On March 31, 2009 we sold our follow-on biologics assets and manufacturing facility to Merck for $130 million. Please see footnote 12 for detailed information concerning the net proceeds from this sale.

3. Debt and Stockholders' Equity

Common Stock & Convertible Debt

On May 7, 2007, Insmed entered into definitive subscription agreements with certain investors relating to the sale of an aggregate of 20,255,367 units, each unit consisting of one (1) share of Common Stock and one Warrant to purchase 0.1 shares of Common Stock at an exercise price of $1.10 per share, for a purchase price of $0.90 per unit. Net proceeds from the offering were $17.0 million. The offering was made pursuant to the Company's effective shelf registration statement on Form S-3 (Registration No. 333-131535).

On March 15, 2006, Insmed entered into an underwriting agreement (the "Underwriting Agreement") with Lazard Capital Markets LLC, as representative of the underwriters (together, the "Underwriters"), relating to the public offering, issuance and sale of 23,000,000 shares of the Company's common stock, $0.01 par value per share. The price to the public was $2.00 per share, and the Underwriters purchased the shares from the Company pursuant to the Underwriting Agreement at a price of $1.88 per share. Proceeds from the offering were $42.8 million, net of $0.4 million in offering costs. The offering was made pursuant to the Company's effective shelf registration statement on Form S-3 (Registration No. 333-131535).

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, in the aggregate, approximately 14,864,883 shares of our common stock, at an exercise price of $1.36 per share (the "2005 Warrants").

As of June 1, 2005, the holders of the 2005 Notes began to receive interest payments at a rate of 5.5% per annum, and such interest payments are payable quarterly until March 1, 2010. As of March 1, 2008, the 2005 Notes matured and beginning on March 1, 2008, the holders of the 2005 Notes were entitled to receive nine quarterly installments of $552,778 in the aggregate each quarter. Any outstanding 2005 Notes must be repaid in cash or converted into shares of our common stock (at the option of the holder) by March 1, 2010. Subject to the terms of the 2005 Note purchase agreements, the holders of the 2005 Notes may convert such notes into shares of our common stock at a conversion price of $1.295 per share (as adjusted in accordance with certain adjustments for stock splits, dividends and the like) at any time prior to the close of business on March 1, 2010. Between April 1, 2005 and December 31, 2008, we received notices from certain holders of the 2005 Notes electing to voluntarily convert approximately $30,025,000 principal amount of such notes into approximately 23,185,328 shares of our common stock at the conversion rate of one share of common stock for each $1.295 in principal amount of the 2005 Notes. Following such conversions and principal repayment as of December 31, 2008, $2,763,889 principal amount of the 2005 Notes remained outstanding. The holders of the 2005 Notes could elect to convert such principal into an aggregate of approximately 2.1 million shares of our common stock. The holders of the 2005 Notes have the right to require us to repurchase such notes with cash payments upon the occurrence of specified "events of default" and "repurchase events" described in the 2005 Notes. The 2005 Warrants were initially exercisable in the aggregate for 14,864,883 shares of common stock at an exercise price of $1.36 per share. In connection with our May 2007 public stock offering, the exercise price of the 2005 Warrants was reduced to $1.21 per share and the 2005 Warrants are currently exercisable into the aggregate of 6,021,692 shares of common stock. The 2005 Warrants will expire on March 15, 2010.

	Payments Due by Years

	Total	2009	2010
Long term debt	$ 2,764	$ 2,211	$ 553

In connection with the issuance of the 2005 Notes and 2005 Warrants, we entered into registration rights agreements with the purchasers thereof pursuant to which we agreed to file a registration statement under the Securities Act of 1933, as amended, registering for resale the shares of our common stock issuable upon the conversion of the 2005 Notes or exercise of the 2005 Warrants.

Periodically, the Company has issued shares of common stock in exchange for services provided by shareholders and others. These issuances have been recorded at their estimated fair value at the time of the respective transactions and corresponding amounts have been reflected as expense in the accompanying consolidated statements of operations.

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, 2008	11,910,975	$ 1.66
Expired	(960,713)	$ 4.10
Outstanding at December 31, 2008	10,950,262	$ 1.32

As of December 31, 2008, 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 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 9,250,000 (adjusted for stock splits) shares of common stock. These shares are reserved for awards to all participants in the 2000 Plan, including non-employee directors.

The 2000 ESPP was adopted by the Board on April 5, 2000 and approved by our shareholders on the same date. It was amended by the Board to increase the number of shares available for issuance, and such amendment was approved by our shareholders on May 11, 2005. The 2000 ESPP was subsequently amended and restated by action of the Board on October 4, 2006 and the amendment and restatement was approved by our shareholders on December 14, 2006. Under the terms of the 2000 ESPP, eligible employees have the opportunity to purchase our common stock through stock options granted to them. 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 1,500,000 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 9,250,000. There were 986,561 awards issuable at December 31, 2008. Options may be granted at the discretion of the board of directors, compensation committee or a delegate. There were no exercises of stock options during 2008. The weighted-average fair value of options granted during 2008, 2007, and 2006 was $0.84, $0.77, and $1.25, respectively. A summary of stock option activity is as follows:

Description	2008	Average Exercise Price	Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Options outstanding at January 1, 2008	5,238,249	$ 2.31		
Granted	229,000	0.84		
Exercised	-	-		
Cancelled	(1,185,000)	2.78		
Options outstanding at December 31, 2008	4,282,249	2.10	3.22	-
Exercisable at December 31, 2008	3,392,338	$ 2.31	2.79	-

A summary of the status of nonvested shares during the year ended December 31, 2008 is presented below:

	2008
Nonvested at January 1, 2008	1,439,281
Granted	229,000
Exercised	-
Cancelled	(778,370)
Nonvested at December 31, 2008	889,911

The Company valued stock options granted in 2006, 2007 and 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, 4.65% in 2007 and 4.3% in 2006, no dividends, volatility of 107% in 2008, 91% in 2007 and 113% in 2006, an expected life of 4.07 years in 2008, 3.47 years in 2007 and 2.59 years in 2006 and a forfeiture rate of 33% in 2008, 32% in 2007 and 28% in 2006.

The following table summarizes awards outstanding at December 31, 2008:

Plan Category	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	7,437,783	$ 1.21	986,561
Amended and Restated 2000 Employee Stock Purchase Plan	—	—	365,380
Total:	7,437,783	$ 1.21	1,351,941

Restricted Stock and Restricted Stock Units

In May 2008, under the 2000 Plan, we granted Restricted Stock ("RS") and Restricted Stock Units ("RSUs") to eligible employees, including our executives. Each RS and RSU represents a right to receive one share of our common stock upon the completion of a specific period of continued service or our achievement of certain performance metrics. Shares of RS are valued at the market price of our common stock on the date of grant and RSUs are valued based on the market price on the date of settlement. RSUs are classified as liabilities, as they are settled with a cash payment for each unit vested, equal to the fair market value of our common stock on the vesting date. We recognize noncash compensation expense for the fair values of these RS and RSUs on a straight-line basis over the requisite service period of these awards, which is generally four years. Below is a table of RS and RSU grants for the twelve months ended December 31, 2008, all of which are non-vested.

	Number of Shares
Restricted Stock	3,155,534
Restricted Stock Units	1,846,605

The weighted-average grant date fair value of RS and RSUs granted during the twelve months ended December 31, 2008 was $0.60. As of December 31, 2008, unrecognized stock-based compensation expense related to unvested RS and RSUs of $1.6 million is expected to be recognized over a weighted-average period of four years. Stock-based compensation expense related to RS and RSUs was approximately $360,000 for the twelve months ended December 31, 2008.

A total of 22,734,306 shares of common stock were reserved at December 31, 2008 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 $1.0 million for 2008, $0.5 million for 2007 and $0.9 million for 2006. 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, 2008, there was $2.0 million of total unrecognized compensation cost related to stock awards expected to be recognized over the remaining vesting period of those awards.

4. Income Taxes

The Company adopted FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes and Interpretation of FASB Statement No. 109 ("FIN 48"), as of January 1, 2007. Due to the accumulated loss position of the Company, the adoption had no material impact on the Company's consolidated financial statements. As of the date of adoption and as of December 31, 2007 and 2008, the Company has recorded no reserves for unrecognized income tax benefits. 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, the Company is a development-stage pharmaceutical company which has incurred net operating losses since inception. Such loss carryforwards would be subject to audit in any tax year in which those losses are carried and applied, 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 does not anticipate any material changes in the amount of unrecognized tax positions over the next twelve months.

The deferred tax assets of approximately $119 million and $122 million at December 31, 2008 and 2007, 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, 2008 and 2007, the Company had net operating loss carryforwards for income tax purposes of approximately $288 million and $306 million, respectively, expiring in various years beginning in 2009. Utilization of these carryforwards will 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:

	2008	2007
Deferred tax assets	(in thousands)	
General Business Credits	$ 2,130	$ 3,198
Other	7,780	6,178
NOL Carryforwards	109,461	112,817
Total deferred tax assets	119,371	122,193
Deferred tax liabilities		
Other	-	-
Total deferred tax liabilities	-	-
Tax deferred asset/(liability)	119,371	122,193
Valuation allowance	(119,371)	(122,193)
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:

	2008	2007	2006
Statutory federal tax rate	34%	34%	34%
Permanent items	-2%	-1%	-3%
State income taxes net of federal benefit	4%	4%	4%
Research and development credit	-7%	-3%	-1%
Expired net operating loss carryforwards	-46%	-39%	-15%
Change in valuation allowance	17%	5%	-19%
Total Expense	0%	0%	0%

5. Leases

The Company leases office space in Richmond, Virginia under an operating lease agreement expiring in October 2016. The lease provides for monthly rent of approximately $30,800 with a 3% escalation per year. The Company also leases a manufacturing facility and warehouse in Boulder, Colorado under an operating lease agreement expiring in February 2013. The lease provides for monthly rent of approximately $30,000 with a 3% escalation per year. 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, 2008 is presented in the table below. Rent expense for all operating leases approximated $1,081,000 in 2008, $1,094,000 in 2007, and $1,427,000 in 2006.

	Payments Due by Years					
	Total	2009	2010	2011	2013	2014 & Beyond

Operating lease obligations	$ 8,077	$ 1,025	$ 1,022	$ 814	$ 836	$ 4,380

6. Employee Benefit Plans

In 2000, the Company adopted a stock purchase plan whereby eligible employees may purchase common stock. Purchases may be made through payroll deductions subject to annual limitations. The purchase price per share under the plan is the lesser of 85% of the fair market value of a share of common stock at the beginning of each offering period or 85% of the fair market value on the date the purchase is made. As of December 31, 2008 there were 1,500,000 shares authorized for issuance under the plan and 1,134,620 had been issued.

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.

7. Restructuring Plan

On February 21, 2007, our Board committed to a business restructuring plan following our announcement of the Settlement Agreement with Tercica, Inc. and Genentech, Inc., which laid out the terms for settlement of all of the outstanding litigation between the parties and includes our agreement to withdraw IPLEX™ from the short stature market. The restructuring eliminated our commercial department and downsized our manufacturing facility located in Boulder, Colorado, resulting in an immediate reduction of approximately 34% of our previous workforce of 150. Employees who were affected by the restructuring were provided with severance payments.

As a result of the restructuring plan, we incurred a restructuring charge in March 2007 of approximately $1.7 million for severance payments. The $1.7 million represented the total amount of restructuring charges that were incurred. These charges were recorded as research and development expenses and selling, general and administrative expenses in the income statement and the remaining payouts of $5,000 were classified as payroll liabilities on the consolidated balance sheet as of December 31, 2007.

8. Asset Impairment

In accordance with FAS 144, Accounting for the Impairment or Disposal of Long-Lived, (FAS 144) assets are reviewed for impairment losses whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. Following the Settlement, License and Development agreement with Tercica, Inc. and Genentech Inc. on March 5, 2007, Insmed entered into a Consent Judgment and Permanent Injunction whereby Insmed ceased supplying IPLEX™ to patients with Primary IGF-D and other short stature indications.

In accordance with the provisions of FAS 144, the Company recorded an asset impairment of approximately $5.0 million in December 2006, related to fixed assets previously capitalized to support the production of IPLEX™. In addition to the asset impairment noted above, the Company considered the realizability of IPLEX™ inventory in accordance with applicable guidance. We also recorded an inventory write-down of approximately $2.1 million in December 2006, to adjust inventory to its net realizable value.

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 III enabling clinical trial of IPLEX™ in the Myotonic Muscular Dystrophy indication.

Pharmacia

In August 2002, we entered into an agreement with Pharmacia that grants us an exclusive license to Pharmacia's portfolio of regulatory filings pertaining to rhIGF-I. In consideration for the exclusive license we have agreed to make therapy available to the 17 Growth Hormone Insensitivity Syndrome subjects that were previously being treated with rhIGF-I supplied by Pharmacia.

NAPO

On January 5, 2007, we entered into an agreement with NAPO Pharmaceuticals, whereby NAPO will license from us the technology surrounding INSM-18 also know 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 delivery of certain milestones. During 2007 we received $1.5 million in milestone payments.

10. Quarterly Financial Data (Unaudited)

	Fiscal Quarter							
	First		Second		Third		Fourth	
	2008	2007	2008	2007	2008	2007	2008	2007
Revenues	$ 2,342	$ 1,660	$ 2,676	$ 2,275	$ 4,020	$ 1,511	$ 2,661	$ 2,135
Operating Loss	(4,798)	(10,403)	(4,435)	(2,569)	(1,886)	(4,123)	(3,292)	(3,344)
Net Loss	(4,873)	(10,253)	(4,667)	(2,500)	(2,163)	(3,912)	(3,964)	(3,297)
Net Loss Per Share (Basic and Diluted)	$ (0.04)	$ (0.10)	$ (0.04)	$ (0.02)	$ (0.02)	$ (0.03)	$ (0.03)	$ (0.03)

11. Legal Proceedings

In fiscal 2006, our patent infringement litigation with Tercica and Genentech continued in both the United States District Court for the Northern District of California and in the United Kingdom at the High Court of Justice, Chancery Division, Patents Court. In addition, in June 2006, Tercica filed an unfair competition suit against us in the United States 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 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, 2008, 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, 2008. 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.

12. Subsequent Event

On February 12, 2009 we announced that we had entered into a definitive agreement with Merck & Co., Inc. ("Merck") whereby Merck, through an affiliate, would purchase all assets related to our follow-on biologics platform. On March 31, 2009, we completed the sale of these assets for an aggregate purchase price of $130 million. After fees, taxes and other costs related to the transaction, we expect net proceeds of approximately $123 million as a result of this transaction. We did not incur any severance expenses as a result of the transfer of assets and employees to Merck.

As part of this transaction, Merck assumed the lease of our Boulder, Colorado-based manufacturing facility and acquired ownership of all the equipment in the building. In addition, upon closing of the transaction, Merck offered positions to employees of the Boulder facility. We retain our Richmond, VA corporate office, which houses our Clinical, Regulatory, Finance, and Administrative functions, in support of the continuing IPLEX™ program. The transfer of the Boulder facility to Merck takes away our internal IPLEX™ production capability. We believe however, that we have sufficient inventory of IPLEX™ to support our ongoing ALS EAP in Italy through 2010 together with the IPLEX™ requirement for the clinical trial currently being planned with the FDA for ALS patients in the US. Any requirements for IPLEX™ beyond 2010 or any significant increase in demand beyond our current commitments either in the MMD or ALS fields will require that we identify a Contract Manufacturing Organization ("CMO") to produce the necessary IPLEX™ to meet the demand. We estimate that the tech transfer of our IPLEX™ production process could take 12 to 18 months once a CMO has been identified.

We have also engaged the services of RBC to act as financial advisor in evaluating other options for use of these proceeds which could include acquisitions of complimentary businesses or technologies, product licensing, mergers, share repurchase and the distribution of a portion of the proceeds to shareholders.

EXHIBIT INDEX

Exhibit Number	Exhibit Title
2.1	Asset Purchase Agreement, dated February 12, 2009, between Protin 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 on February 13, 2009 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 with the Securities and Exchange Commission 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).
4.1	Description of Capital Stock (contained in the Articles of Incorporation filed as Exhibit 3.1).
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	Article VI of the Articles of Incorporation of Insmed Incorporated (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, dated as of May 16, 2001, between Insmed Incorporated and First Union National Bank, as Rights Agent (which includes as (i) Exhibit A the form of Articles of Amendment to Insmed Incorporated's Articles of Incorporation, as amended, (ii) Exhibit B the form of Rights Certificate, and (iii) Exhibit C the Summary of the Rights to Purchase Preferred Stock) (previously filed as Exhibit 4.4 to Insmed Incorporated's Registration Statement on Form 8-A filed with the Securities and Exchange Commission on May 17, 2001 and incorporated herein by reference).
4.5	Form of Rights Certificate (previously filed as Exhibit B 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 with the Securities and Exchange Commission on May 17, 2001 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 July 2003 private placement of common stock and warrants to purchase common stock (previously filed as Exhibit 4.6 to Insmed Incorporated's Registration Statement on Form S-3 (Registration No. 333-107308) on July 24, 2003 and incorporated herein by reference).
4.7	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).
4.8	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 on November 10, 2004 and incorporated herein by reference).
4.9	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 on November 10, 2004 and incorporated herein by reference).
4.10	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 on March 16, 2005 and incorporated herein by reference).

4.11	Form of 5.5% Note Due 2008-2010 dated March 15, 2005 between Insmed Incorporated and each of the investors in the March 2005 private placement of notes and warrants to purchase common stock (previously filed as Exhibit 4.2 to Insmed Incorporated's Current Report on Form 8-K on March 16, 2005 and incorporated herein by reference).
4.12	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 4.3 to Insmed Incorporated's Current Report on Form 8-K on March 16, 2005 and incorporated herein by reference).
4.13	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 on March 16, 2005 and incorporated herein by reference).
4.14	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 on March 16, 2005 and incorporated herein by reference).
4.15	Form of Warrant dated May 4, 2008 between Insmed Incorporated and each of the investors in the May 2008 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 on May 4, 2008 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 be reference).

10.9 Form of Warrant of Insmed to be issued pursuant to Purchase Agreement among Insmed Incorporated, Insmed Pharmaceuticals, Inc. and certain investors dated January 13, 2000 (previously filed as Exhibit 10.13 to Insmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).

10.10 Form of Registration Rights Agreement among Insmed Incorporated, Insmed Pharmaceuticals, Inc. and certain investors party to the Purchase Agreement among Insmed Incorporated, Insmed Pharmaceuticals, Inc. and certain investors dated January 13, 2000 (previously filed as Exhibit 10.14 to Insmed Incorporated's Registration Statement on From S-4 (Registration No. 333-30098) and incorporated herein by reference).

10.11 Sublease, dated March 30, 2001, between Rhodia Inc. and Insmed Incorporated (previously filed as Exhibit 10.15 to Insmed Incorporated's Quarterly Report on form 10-Q for the quarter ended March 31, 2001 and incorporated herein by reference.

10.12 Consent to Sublease, dated as of April 12, 2001, among A & W Virginia Corporation, as Landlord, Rhodia Inc., as Tenant, and Insmed Incorporated, as Subtenant (previously filed as Exhibit 10.16 to Insmed Incorporated's Quarterly Report on form 10-Q for the quarter ended March 31, 2001 and incorporated herein by reference).

10.13+ License and Supply Agreement, dated as of August 28, 2003, between Insmed Incorporated and Pharmacia AB (previously filed as Exhibit 10.16 to Insmed Incorporated's Annual Report of 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 From 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 10.18 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 dated February 6, 2009 to original December 14, 2005 Lease for 5797 Central Avenue, Boulder Co. (previously filed as Exhibit 10.2 to Insmed's Current Report on Form 8-K on February 13, 2009 and incorporated herein by reference).

10.20 Change in Control Agreement entered into between Insmed Incorporated and Geoffrey Allan, Ph.D. (previously filed as Exhibit 10.19 to Insmed Incorporated's Annual Report on Form 10-K for the year ended December 31, 2006 and incorporated herein by reference).

10.21 Change in Control Agreement entered into between Insmed Incorporated and Ronald Gunn (previously filed as Exhibit 10.20 to Insmed Incorporated's Annual Report on Form 10-K for the year ended December 31, 2006 and incorporated herein by reference).

10.22 Form of Change in Control Agreement entered into between Insmed Incorporated and Kevin Tully and Doug Farrar (previously filed as Exhibit 10.21 to Insmed Incorporated's Annual Report on Form 10-K for the year ended December 31, 2006 and incorporated herein by reference).

10.23 Amended and Restated 2000 Employee Stock Purchase Plan (previously filed as Exhibit 10.22 to Insmed Incorporated's Annual Report on Form 10-K for the year ended December 31, 2006 and incorporated herein by reference).

10.24 Form of Subscription Agreement entered into between Insmed Incorporated and each of the investors the May 2007 private placement of common stock and warrants to purchase common stock (previously filed as Exhibit 4.1 to Insmed's Current Report on Form 8-K on May 4, 2007 and incorporated herein by reference).

*10.25

Settlement, license and development agreement, dated March 6, 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 on May 10, 2007.

21.1 Subsidiaries of Insmed Incorporated

23.1 Consent of Ernst & Young LLP.

31.1 Certification of Geoffrey Allan, Ph.D., chairman of the Board and Chief Executive Officer of Insmed Incorporated, pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1932, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2003.

31.2 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.

32.1 Certification of Geoffrey Allan, Ph. D., Chairman of the Board and Chief Executive Officer (Principal Financial 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.

32.2 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.