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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, 2002

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.)**
4851 Lake Brook Drive	**(804) 565-3000**
Glen Allen, Virginia 23060	
(Address of principal executive offices)	**(Registrant's telephone number**
(zip code)	**including area code)**

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

Title of each class	**Name of each exchange on which registered**
None	**None**

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

(Title of class)
Common Stock

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 an accelerated filer (as defined in Exchange Act Rule 12b-2).
Yes [] No [ ]

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant on June 28, 2002 was $46,392,779 (based on the closing price for shares of the registrant's Common Stock as reported on the Nasdaq National 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.

As of February 28, 2003, there were 33,186,336 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 after the registrant's fiscal year ended December 31, 2002, and to be delivered to shareholders in connection with the 2003 Annual Meeting of Shareholders, are incorporated in Part III by reference.

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INSMED INCORPORATED

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REPORT: FORM 10-K

In this Form 10-K, the "Company," "Insmed," "Insmed Incorporated," "we," "us" and "our" refer to Insmed 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

ITEM 1.BUSINESS

Introduction

Insmed Incorporated is a biopharmaceutical company focused on the discovery and development of drug candidates for the treatment of metabolic diseases and endocrine disorders. Our approach is to correct metabolic defects in the human body, by replacing key regulatory molecules in a physiologically relevant fashion. We believe this approach will translate into an intrinsic safety advantage for our products in the marketplace. We currently have two lead drug candidates, recombinant human (rh) IGF-I/rhIGFBP-3 (also known as SomatoKine) and rhIGFBP-3 and are actively developing these drugs to treat indications in the metabolic and oncology fields.

On September 10, 2002, we announced that we would immediately discontinue the internal development of one of our investigational drug candidates, INS-1, based on the results of recently completed Phase II clinical trials. Similarly, our Japanese partner to develop INS-1 in Japan and Asia, Taisho Pharmaceuticals, Co., Ltd., also indicated its intention to discontinue its involvement in any future development in INS-1, and terminated the joint development agreement in accordance with the terms of the agreement.

Following our announcement on September 10, 2002, we reorganized our business by realigning our staff and resources around our more promising clinical candidates to support our long term success and preserve our capital.

Medical Background

One of the main factors in maintaining normal healthy growth and metabolism is the equilibrium of the triumvirate of insulin, growth hormone and insulin-like growth factor I (IGF-I). Any imbalance in the various levels of these key components will result in multiple endocrine and metabolic conditions such as Growth Hormone Deficiency and Diabetes. It is believed that the administration of IGF-I, bound together with its most common binding protein IGFBP-3 addresses certain deficiencies and instabilities caused by an imbalance in this key axis.

Growth Disorders

Growth hormone insensitivity syndrome (GHIS) is a syndrome whereby the body does not have, or has lost, its ability to recognize human growth hormone and therefore fails to respond in the normal manner. This results in defective cell and tissue growth. There are two main types of GHIS, primary GHIS where an individual is born with a growth hormone receptor (GHR) defect, and secondary GHIS, where an individual acquires the GHR defect sometime during their life.

A subset of primary GHIS is Laron syndrome (LS), a rare genetic condition. LS patients are differentiated by molecular defects of the GHR. Although LS patients may normally produce growth hormone (GH), the defects in the extra-cellular part of the GHR prevent IGF-I production. There are over 250 LS patients worldwide. These patients are characterized by severe dwarfism and metabolic dysfunction. LS patients have normal to high levels of human GH and low levels of IGF-I and IGFBP-3. Most LS patients are diagnosed around the age of two and if untreated often grow to adult heights of less than four feet. As adults, LS patients experience progressive obesity, insulin resistance, and a predisposition towards high total cholesterol and diabetes.

We plan on initiating a pivotal clinical trial in the pre-pubertal LS population, utilizing our rhIGF-I/rhIGFBP-3 complex. This trial is expected to begin in the first half of 2003. We believe this limited population could obtain a great deal of therapeutic benefit as the patients have yet to enter their normal key growth phase.

We also believe the commercial opportunities for rhIGFI/rhIGFBP-3 reach far beyond the indication for the treatment of LS. We believe that if we receive initial approval of our rhIGF-I/rhIGFBP-3 complex for GHIS it may become a platform to enter other potentially very large markets which could include diabetes, severe burns and hip fracture.

Oncology

Cancer is a term applied to a variety of diseases, all of which are characterized by abnormal and unregulated cell growth. The World Health Organization estimates that by 2020, the number of annual worldwide cancer related deaths is expected to reach 10 million. Although there are several drugs available to treat cancer, their use often produces significant side effects and decreases the quality of life of the patient.

Clearly there are a number of factors that can contribute to the development and progression of malignancies. Scientific research over the past two decades has brought about the identification of key cellular pathways that regulate tumor growth. As a result, novel agents that target these growth-promoting pathways are emerging as promising new treatments for cancer.

Our oncology program focuses on IGFBP-3 as a naturally occurring anti-tumor agent. This proprietary product is normally found in the human bloodstream, and several clinical studies have demonstrated that cancer risk increases with decreasing blood levels of IGFBP-3.

rhIGF-I/rhIGFBP-3

Our lead product candidate, rhIGF-I/rhIGFBP-3, is the recombinant protein complex of IGF-I and its most abundant binding protein, IGFBP-3. In animal studies, rhIGF-I/rhIGFBP-3 displays metabolic and anabolic activities similar to those observed with rhIGF-I. Of most importance, rhIGF-I/rhIGFBP-3 has a longer half life than, and may have an improved safety and efficacy profile compared to, rhIGF-I.

rhIGF-I/rhIGFBP-3 is IGF-I derived from *E. coli* containing a gene encoding human IGF-I, bound to IGFBP-3 derived from *E. coli* containing a gene encoding human IGFBP-3. When injected into animals and humans, rhIGF-I/rhIGFBP-3 mimics the physiological effects of IGF-I and offers certain benefits over the administration of rhIGF-I, including:

- providing a convenient once daily dose regimen; and

- possibly providing an improved safety profile.

Several short and long-term (greater than five years) studies to evaluate the effects of rhIGF-I in children with GHIS, such as LS, have demonstrated the effectiveness of rhIGF-I to significantly increase growth velocity.

In 2002, the FDA granted us Orphan Drug Status for rhIGF-I/rhIGFBP-3 for the treatment of GHIS, thus allowing an extended period of exclusivity. We are also in the process of applying for Orphan Drug Status in Europe through the European Medical Evaluation Agency (EMEA). We plan on initiating a pivotal trial for rhIGF-I/rhIGFBP-3 in GHIS in Europe during the first half of 2003. Commercial approval of rhIGF-I/rhIGFBP-3 for the treatment of GHIS is one of our main priorities. We intend to use the small LS indication to support the efficacy and safety of rhIGF-I/rhIGFBP-3 for the treatment of GHIS and fast-track the product for approval in the US and Europe for the treatment of GHIS, during the second half of 2004.

We have also previously conducted clinical trials with rhIGF-I/rhIGFBP-3 for the treatment of diabetes.

In April 2000, the *Journal of Clinical Endocrinology & Metabolism* published the results of our first completed Phase II clinical trial with rhIGF-I/rhIGFBP-3 for type 1 diabetes. This trial demonstrated that rhIGF-I/rhIGFBP-3 significantly improves insulin sensitivity and lowers glucose in patients with type 1 diabetes with no clinically relevant adverse side effects. This data was based on a double-blind, placebo-controlled study

involving 12 patients with type 1 diabetes. Specifically, data from this study revealed that when compared to placebo, average daily insulin requirements were significantly reduced ($p<0.01$), average daily blood glucose levels declined ($p<0.02$) and cholesterol levels declined ($p<0.05$). Published results of previous studies by other companies of rhIGF-I administered alone without rhIGFBP-3 indicate that patients frequently reported jaw pain, muscular pain, headache and tissue swelling. There were no reports of clinically relevant side effects in this Phase II trial of rhIGF-I/rhIGFBP-3.

At the 2001 American Diabetes Association meeting, we reported results from our clinical study of rhIGF-I/rhIGFBP-3 in type 2 diabetes patients. Data from this randomized, double-blind study demonstrated that the drug reduced insulin consumption by 51% to 83% and fasting blood glucose levels by 29% to 31%.

In January 2002, we announced positive results from a Phase II dose-ranging trial of rhIGF-I/rhIGFBP-3 in patients with type 2 diabetes. This study was placebo-controlled and double-blinded with eight-day treatment duration to determine the efficacy, safety and pharmacokinetics of rhIGF-I/rhIGFBP-3 in subjects with type 2 diabetes. Thirty-seven subjects were randomized to receive either placebo or rhIGF-I/rhIGFBP-3 at dose levels between 0.125 mg/kg and 2 mg/kg once daily in the evening. All subjects were on insulin therapy prior to enrollment and continued to receive appropriate insulin doses during a four-day run-in period as well as during the treatment period. The data demonstrated that statistically significant improvements in insulin sensitivity and fasting blood glucose occurred with the administration of rhIGF-I/rhIGFBP-3, with the most pronounced changes achieved with a dose of 2 mg/kg. At this dose a significant decrease in average daily insulin requirement from 70.8 units at baseline to 56.5 units (-20.2%) at the end of the treatment period was observed. Other outcome measurements included the change in fasting blood glucose, which was decreased from 171.5mg/dL at baseline to 102.2mg/dL on treatment day eight (-40.4%) for the patient group receiving 2mg/kg of rhIGF-I/rhIGFBP-3 versus a decrease from 151.5mg/dL to 134.8mg/dL (-11%) for the patient group receiving placebo. The study further revealed a dose-dependent occurrence of mild hypoglycemia, which suggests that patients on rhIGF-I/rhIGFBP-3 therapy could have further lowered their daily insulin dose to achieve a desirable fasting blood glucose concentration. We believe the results demonstrated that a single daily dose of rhIGF-I/rhIGFBP-3 can be an effective adjunct to insulin in patients with type 2 diabetes whose blood glucose is poorly controlled by standard insulin regimens.

In January 2003, we announced positive results from a dose-ranging trial of rhIGF-I/rhIGFBP-3 in adolescent patients with type 1 diabetes. The double-blind placebo controlled dose-range finding study was designed to investigate the effects of the addition of a single daily dose of rhIGF-I/rhIGFBP-3 on insulin sensitivity, growth hormone and IGF-I levels in adolescent subjects with type 1 diabetes. The study was conducted at the University of Cambridge in Cambridge, England. All subjects were on insulin therapy prior to enrollment and continued to receive appropriate insulin doses during the study. The study revealed that following the administration of rhIGF-I/rhIGFBP-3, IGF-I blood levels were restored and increases in insulin sensitivity occurred in a dose-dependent manner.

rhIGFBP-3

Our second product candidate, rhIGFBP-3 is currently in preclinical development to evaluate its potential as a novel anti-tumor agent to treat human cancers. In January 2003 we announced the results of studies conducted by our collaborators at McGill University in Montreal, Canada and the Bristol Royal Infirmary in Bristol, England. These studies demonstrated that rhIGFBP-3 caused a significant reduction in cancer cell growth and a marked inhibition of tumor growth in animals with no adverse side effects. Ongoing preclinical work is directed toward defining the optimal clinical protocol in which to translate the promising observations.

This program is very focused and is moving forward at a rapid pace. Toxicology studies in support of the Phase I clinical program are set to begin in the first half of 2003 and we plan to file an IND application in the second half of 2003. In addition, we are actively seeking strategic partnerships to expedite the clinical development of this compound.

Business Strategy

We are a company focused on product development and commercialization, whose goal is to become a leading biopharmaceutical company treating metabolic and endocrine diseases. The key elements of our strategy are listed below.

Focus on products to treat metabolic and endocrine diseases. Our approach is to correct metabolic defects in the human body by replacing key regulatory molecules in a physiologically relevant fashion. We will work to complete the development and approval of our products to treat indications with unmet medical needs. We will initially focus on diseases characterized by abnormalities in the growth hormone/insulin-like growth factor axis. We believe these are largely underserved, niche markets. Our management team has significant experience in drug development and we will use this expertise to complete our clinical development programs and, if successful, file for regulatory approval in the U.S. and Europe.

Retain commercial rights to market products in selected markets. Our goal is to retain relevant marketing rights to our products, commercializing them in selected niche markets.

Establish corporate partnerships in certain markets. We plan to establish corporate partnerships and other relationships to develop, market and commercialize our products that are not within our core focus.

Outsource manufacturing to deploy resources efficiently. Our management team has significant experience in negotiating and supervising contractual arrangements with third parties for the manufacture of drug products on a cost effective basis. To deploy our resources efficiently, we currently plan to continue to outsource the manufacture of rhIGF-I/rhIGFBP-3 and rhIGFBP-3.

Acquire and in-license additional products and technologies. We intend to acquire additional products and technologies that complement our activities within the field of metabolic and endocrine diseases. We believe such acquisitions in fields where we have expertise can be rapidly integrated into our development and commercialization programs.

Research and Development

We have devoted substantially all of our resources since we began our operations to the research and development of pharmaceutical product candidates for metabolic and endocrine diseases. Our research and development expenses were approximately $18.1 million in 2002, $35.5 million in 2001 and $21.6 million in 2000.

Strategic Licensing Agreements

Avecia Limited

In May 2002, we entered into an agreement with Avecia Limited, Europe's largest privately held specialty chemical company, for the process development and manufacture of rhIGF-I/rhIGFBP-3 In consideration for this process development and manufacturing agreement, we are obligated to pay success fees for process development milestones and manufacturing costs associated with ongoing production of rhIGF-I/rhIGFBP-3 and rhIGFBP-3.

Pharmacia, Inc.

Pharmacia, Inc. was granted marketing approval in several European and Scandinavian countries for rhIGF-I for the treatment of GHIS. Pharmacia is no longer producing rhIGF-I. In October 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 for the treatment of GHIS. We have made a commitment to make rhIGF-I/rhIGFBP-3 available on a compassionate named patient basis to GHIS subjects that were previously being treated with rhIGF-I supplied by Pharmacia.

University of Virginia Alumni Patents Foundation

We have a license agreement with the University of Virginia Alumni Patents Foundation that grants a worldwide, exclusive license, including the right to grant sublicenses, to use and practice certain patents related to INS-1 for the treatment of diabetes. The license extends for the full term of the patents. The Foundation may terminate the license upon untimely payment of royalties or our bankruptcy or insolvency. We may terminate the license upon 90 days notice to the Foundation. Either party may terminate upon a material breach by the other party.

In consideration for the license agreement, we are obligated to pay minimum annual licensing fees of $100,000, as well as patent costs through the expiration of the patent rights. We may also have to pay a royalty on net sales of any therapeutic drugs covered by the agreement. Royalties earned by the Foundation will reduce licensing fees and, in the case of patent infringement, we may use up to 50% of royalties otherwise payable to the Foundation to pay expenses we incur to defend the patents.

Following the discontinuation of our INS-1 program we are currently evaluating this agreement.

Patents and Proprietary Rights

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 intend to file additional patent applications, when appropriate, relating to improvements in our technology and other specific products that we develop. As with any pending patent application, there can be no assurance that any of these applications issue in the United States or in foreign countries. There also can be no assurance that United States or foreign patents issuing from any of these applications will not later be held invalid or unenforceable.

rhIGF-I/rhIGFBP-3

We hold 25 United States issued or allowed patents related to the composition, production, antibodies and methods of use for rhIGF-I/rhIGFBP-3 and rhIGFBP-3, including:

- Two issued patents for rhIGFBP-3 composition-of-matter.

- 12 therapeutic use patents for rhIGF-I/rhIGFBP-3, IGF-I, rhIGFBP-3 or rhIGFBP-3 fragments for the treatment of various disease conditions.

- 11 patents regarding novel expression, production or analysis methods, some of which may be used for the manufacture of rhIGF-I/rhIGFBP-3 and pharmaceutical compositions of rhIGF-I/rhIGFBP-3.

Many of the above patents have been issued or are pending issue in the major pharmaceutical markets including Canada, Japan and Europe.

As part of the ongoing development of rhIGF-I/rhIGFBP-3 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. The various issued patents related to rhIGF-I/rhIGFBP-3 and rhIGFBP-3 compositions methods of production and methods of treatment expire at various times during the years 2010 through 2019.

As part of our development and manufacturing agreement with Avecia Limited, we have also obtained certain nonexclusive rights to Avecia's proprietary manufacturing technology.

In 1998 Genentech requested a hearing with the European Patent Office to oppose the validity of one of our European patents with claims to rhIGFBP-3, uses of rhIGFBP-3 and uses of rhIGF-I/rhIGFBP-3. As of yet, no hearing date has been set by the European Patent Office. Should the opposition hearing be held and should Genentech prevail, some or all of the claims of this patent may be revoked.

This result could lessen our ability to exclude others, but would not affect our own ability to practice these claims.

Third parties, including Genentech, Chiron, Amgen, Novartis AG, Fujisawa, Beth Israel Hospital and Robert Rieveley hold United States and/or foreign patents possibly directed to the composition, production and/or use of rhIGF-I, rhIGFBP-3, rhIGF-I/rhIGFBP-3 and/or recombinant proteins in general. After examining these patents, we do not believe they present an obstacle to our plans to commercialize rhIGF-I/rhIGFBP-3 and rhIGFBP-3. However, we can provide no assurance that any one of these third parties will not assert in the future a contrary position, for instance in the context of an infringement action. Moreover, while we cannot predict with certainty the outcome of such a proceeding, an adverse ruling could impact our ability to make, use or sell our products.

INS-1

We currently possess the rights through ownership or license to ten issued United States patents related to our INS-1 technology, including seven issued patents that we have exclusively licensed from the University of Virginia Patent Foundation. We also own two pending patent applications claiming new medical uses of INS-1 and improved methods to manufacture INS-1.

The various issued patents cover use of compounds to treat insulin resistance related diseases, methods for production of INS-1, purified insulin mediators and purification processes. The initial terms of these patents expire at various times between May 2009 and January 2018.

Waxman-Hatch Act

The United States Drug Price Competition and Patent Term Restoration Act of 1984, known as the Waxman-Hatch Act, provides for the return of up to five years of patent term for a patent that covers a new product or its use to compensate for time lost during the regulatory review process. This period is generally one-half the time between the effective date of an investigational new drug application and the submission date of a new drug application (NDA), plus the time between the submission date of a NDA and the approval of that application, subject to a maximum extension of five years. The application for patent term extension is subject to approval by the U.S. Patent and Trademark Office (USPTO), in conjunction with the FDA. It takes at least six months to obtain approval of the application for patent term extension, and there can be no guarantee that the application will be granted. Similar patent term extensions are available under European laws. We intend to apply for such patent term extension(s), where appropriate. However, we cannot provide any assurance that we will receive such patent term extension(s).

The Waxman-Hatch Act also establishes a five-year period of marketing exclusivity from the date of NDA approval for new chemical entities approved after September 24, 1984. In order to obtain this exclusivity, the NDA applicant must submit to the FDA, at the appropriate time, the number and expiration date of any patent which claims the drug that is the subject of the NDA, or which claims a method of using the drug that is the subject of the NDA. Failure to submit this patent information at the appropriate time to the FDA may result in loss of the right to this marketing exclusivity.

During this Waxman-Hatch marketing exclusivity period, no third-party may submit an “abbreviated” NDA or “paper” NDA to the FDA for the same product, using data generated by the NDA holder.

Finally, any abbreviated NDA or paper NDA applicant will be subject to the notification provisions of the Waxman-Hatch Act, which should facilitate our notification about potential infringement of our patent rights. The abbreviated or paper NDA applicant must notify the NDA holder and the owner of any patent applicable to the abbreviated NDA or paper NDA product, of the application and intent to market the drug that is the subject of the NDA.

We intend to apply for such exclusivity, where appropriate. However, we cannot provide any assurance that we will receive such exclusivity for any of our products.

Manufacturing

We currently rely, and plan to continue to rely, on contract manufacturers to produce rhIGF-I/rhIGFBP-3 and rhIGFBP-3. Our product candidates will need to be manufactured in a facility by processes that comply with the FDA's good manufacturing practices and other similar regulations. It may take a substantial period of time to begin manufacturing our products in compliance with such regulations. If we are unable to establish and maintain relationships with third parties for manufacturing sufficient quantities of our product candidates and their components that meet our planned time and cost parameters, the development and timing of our clinical trials and/or product commercialization may be adversely affected.

rhIGF-I/rhIGFBP-3 is a complex of two proteins, rhIGF-I and its binding protein rhIGFBP-3, and is manufactured using recombinant DNA technology. The manufacturing process is complicated and involves expression of the two proteins by bacterial fermentation followed by purification and combination of the two proteins. During the manufacturing process, rhIGF-I and rhIGFBP-3 are produced separately and then combined to make rhIGF-I/rhIGFBP-3. The rhIGFBP-3 can either be utilized to make rhIGF-I/rhIGFBP-3 or kept separate as its own distinct product.

To date, we have supplied all of our pre-clinical and clinical Phase II study requirements with rhIGF-I/rhIGFBP-3 previously produced by our subsidiary, Celtrix. Since Celtrix no longer produces rhIGF-I/rhIGFBP-3, we have identified a new source for this compound for clinical trial and commercial use. We have an agreement with Avecia Limited to manufacture rhIGF-I/rhIGFBP-3 and rhIGFBP-3 at Avecia's site at Billingham, England. We cannot guarantee that Avecia will be able to produce the rhIGF-I/rhIGFBP-3 and rhIGFBP-3 necessary for future clinical trials and commercialization.

Marketing and Sales

We currently have no sales, marketing or distribution capability. In order to commercialize any of our product candidates, we must either internally develop sales, marketing and distribution capabilities or make arrangements with a third party to perform these services.

Our goal is to retain marketing, sales and distribution rights to our product candidates for certain niche markets and find commercial partners to develop and market our products in markets outside of our core focus.

Competition

We are engaged in an industry that is intensely competitive and characterized by rapid technological progress. In each of our potential product areas, we face significant competition from large pharmaceutical, biotechnology and other companies, as well as 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 trials and obtaining regulatory approvals. In addition, many of these companies have greater experience and expertise in manufacturing and marketing pharmaceutical products.

Since all of our products are under development, we cannot predict the relative competitive position of our products if they are approved for use. However, we expect that the following factors will determine our ability to compete effectively:

- safety and efficacy;
- product price;
- ease of administration; and

marketing and sales capability.

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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 United States Food and Drug Administration (FDA) and similar regulatory bodies in other countries. The steps ordinarily required before a new drug may be marketed in the United States are similar to steps required in most other countries and include:

- pre-clinical laboratory tests, pre-clinical studies in animals and formulation studies and the submission of an Investigational New Drug Application (IND);
- adequate and well-controlled clinical trials to establish the safety and efficacy of the drug for each indication;
- the submission of a New Drug Application (NDA); and
- regulatory review and approval of the NDA before any commercial sale or shipment of the drug.

Pre-clinical tests include laboratory evaluation of product chemistry and stability, as well as animal studies to evaluate toxicity. The results of pre-clinical testing are submitted to the FDA as part of an IND. The FDA requires a 30-day waiting period after the filing 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 halt proposed or ongoing clinical trials until the FDA authorizes trials under specified terms. The IND process may become extremely costly and substantially delay development of our products. Moreover, positive results of pre-clinical tests will not necessarily indicate positive results in clinical trials.

Clinical trials to support NDAs are typically conducted in three sequential phases, but the phases may overlap. During Phase I, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess pharmacokinetics and safety.

Phase II usually involves studies in a limited patient population to:

- assess the efficacy of the drug in specific targeted indications;
- assess dosage tolerance and optimal dosage; and
- identify possible adverse effects and safety risks.

If a compound is found to be potentially effective and to have an acceptable safety profile in Phase II evaluations, Phase III trials, also called pivotal studies, are undertaken to further demonstrate clinical efficacy and to further test for safety within an expanded patient population at geographically dispersed clinical study sites.

After completion of the required clinical testing, a NDA is submitted. The FDA may request additional information before accepting a NDA for filing, in which case the application must be resubmitted with the additional information. Once the submission has been accepted for filing, the FDA has 180 days to review the application and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the NDA to an appropriate advisory committee for review, evaluation and recommendation as to whether the application should be approved, but the FDA is not bound by the recommendation of an advisory committee.

If FDA evaluations of the NDA and related manufacturing facilities are favorable, the FDA may issue either an approval letter or an approvable letter. An approvable letter will usually contain a number of conditions that must be met in order to secure final approval of the NDA and authorization of commercial marketing of the drug. The FDA may refuse to approve the NDA or issue a not approvable letter, outlining the deficiencies in the submission or the manufacturing site(s) and often requiring additional testing or information.

The manufacturers of approved products and their manufacturing facilities will be 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 its drugs are on the market could cause subsequent withdrawal of approval, reformulation of the drug, additional pre-clinical testing or clinical trials and changes in labeling of the product.

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 trials and marketing authorization vary widely from country to country. The foreign regulatory approval process includes similar risks as those associated with FDA approval as described above.

Employees

As of December 31, 2002, we had 23 full-time employees. Of these employees, 13 were engaged in research and development and 10 were engaged in general management, finance and administration. None of our employees is covered by any collective bargaining agreement. We consider relations with our employees to be good.

Risk Factors Related to Our Business

Except for the historical information contained in this annual report or incorporated in this annual report by reference, this annual report on Form 10-K and the information incorporated by reference contain forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those discussed here. Factors that could cause or contribute to differences in our actual results include those discussed in the following section, as well as those discussed in Part II, Item 7 entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this annual report and in any other documents incorporated by reference into this annual report. 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.

Because our products are in an early stage of development, we have not received regulatory approval for any of our products or released any products for commercial sale; therefore we can give you no assurances that we will succeed in commercializing our products.

Our long-term viability and growth will depend on the successful commercialization of products resulting from our development activities, including rhIGF-I/rhIGFBP-3 and rhIGFBP-3. All of our potential products and production technologies are in the research or development stages, and we have generated no revenues from product sales. We need to conduct significant additional development, laboratory and clinical testing and invest significant additional amounts of capital before we can commercialize our products. We can give you no assurances that we will identify, develop or produce products with commercial potential or that we will secure market acceptance for our products. The failure to commercialize our potential products will adversely affect our business, financial condition and results of operations. In addition, the research, development, testing, clinical trials and acquisition of the necessary regulatory approvals with respect to any given product will take many years and thus delay our receipt of revenues, if any, from any such products. 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 be ineffective;
- may cause harmful side effects; or
- may be too expensive to manufacture.

Our products may also fail to receive regulatory approval. In addition, even after regulatory authorities approve our products, the products may fail to achieve market acceptance or the proprietary rights of third parties may prevent their commercialization.

Since we have a limited operating history, 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 focused on product development and we currently have no sales. We have incurred losses each year of operation and we expect to continue incurring operating losses for the foreseeable future. The process of developing our products requires significant pre-clinical testing and clinical trials as well as regulatory approvals for commercialization and marketing before we can begin to generate any revenue from product sales. In addition, commercialization of our drug candidates will require us to establish a sales and marketing organization and contractual relationships to enable product manufacturing and other related activity. 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, 2002, our accumulated deficit was $176.2 million. For the year ended December 31, 2002, our consolidated net loss was $36.4 million.

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

We will require substantial future capital in order to continue to conduct the time-consuming research and development, clinical studies and regulatory activities necessary to bring our therapeutic products to market and to establish production, marketing and sales capabilities. 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. Our future capital requirements will depend on many factors, including the progress of pre-clinical testing and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing and prosecuting patent applications and enforcing patent claims and the establishment of strategic alliances and activities required for product commercialization. We believe that existing cash reserves will sufficiently fund our activities through 2004.

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/or relinquish rights to our technologies or product candidates.

If our products fail in clinical trials or if we cannot enroll enough patients to complete our clinical trials, there may be an adverse effect on our business, financial condition and results of operations.

In order to sell our products, we must receive regulatory approval for our products. 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. Therefore, if our products fail in clinical trials, there will be an adverse effect on our business, financial condition and results of operations. 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. 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.

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

- 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 trials 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 sales, if any, of our products. Such delays could materially adversely affect our business, financial condition and results of operations.

If we fail to obtain regulatory approvals for our products under development, such failure may adversely affect our business, financial condition and results of operations.

Because our products are in an early stage of development, none has received regulatory approval or been released for commercial sale. The pre-clinical testing and clinical trials of any compounds we develop and the manufacturing and marketing of any drugs produced from such compounds must comply with regulation by numerous federal, state and local governmental authorities in the United States, principally the FDA, and by similar agencies in other countries. No product can receive FDA approval unless human clinical trials show its safety and effectiveness. There can be no assurance that clinical testing will provide evidence of safety and effectiveness in humans or that regulatory agencies will grant approvals for any of our products.

The regulatory process takes many years and requires the expenditure of substantial resources. Data obtained from pre-clinical and clinical activities are 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 drug and/or the period required for review of any application for regulatory agency approval of a particular compound. Delays in obtaining regulatory agency approvals could adversely affect the marketing of any drugs that our collaborative partners or we 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.

If the FDA grants approval for a drug, such approval may limit the indicated uses for which we may market the drug, and this could limit the potential market for such drug. Furthermore, if we obtain approval for any of our products, the marketing and manufacture of such products remain subject to extensive regulatory requirements. Even if the FDA grants approval, such approval would be subject to continual review, and later discovery of unknown problems could restrict the products future use or cause their withdrawal from the market. Failure to comply with regulatory requirements could, among other things, result in fines, suspension of regulatory approvals, operating restrictions and criminal prosecution. In addition, many countries require regulatory agency approval of pricing and may also

require approval for the marketing in such countries of any drug that our collaborative partners or we develop.

We cannot be certain that we will obtain any regulatory approvals in other countries, and the failure to obtain such approvals may materially adversely affect our business, financial condition and results of operations. In order to market our products outside of the United States, 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 other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries includes all of the risks associated with obtaining FDA approval detailed above. Approval by the FDA does not ensure approval by the regulatory authorities of other countries.

If our products fail to achieve market acceptance for any reason, such failure may 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 products 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 products 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;
- their potential advantage over existing treatment methods; and
- reimbursement policies of government and third-party payers, including insurance companies.

For example, even if 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. We can give no assurance that physicians, patients, third-party payers or the medical community in general will accept and use any products that we may develop.

We currently have no internal manufacturing and limited marketing capability, which may make commercializing our products difficult.

We have no internal manufacturing and limited marketing capability. Failure to successfully manufacture and market our products could materially adversely affect our business, financial condition and results of operations. We intend to enter strategic alliances with other parties that have established commercial scale manufacturing capabilities. There can be no assurance that we will enter such strategic alliances on terms favorable to us, or at all. If we are unable to establish and maintain relationships with third parties for manufacturing sufficient quantities of our product candidates and their components that meet our planned time and cost parameters, the development and timing of our clinical trials may be adversely affected. In addition, there can be no assurance that an adverse FDA inspection of a contractor's manufacturing facilities would not impede our commercial supply capability. As an alternative, we may choose to commercialize such products on our own, which would require substantial additional funds.

If the FDA or any other regulatory agency permits us to commence commercial sales of products, we will face competition with respect to commercial sales, marketing and distribution. These are areas in which we have no experience. To market any of our products directly, we must develop a marketing and sales force with technical expertise and with supporting distribution capability. Alternatively, we may engage a pharmaceutical company with a large distribution system and a large direct sales force to assist us. There can be no assurance that we will successfully establish sales and distribution capabilities or gain market acceptance for our proprietary products. To the extent we enter co-promotion or other licensing arrangements, any revenues we receive will depend on the efforts of third parties and there can be no assurance that our efforts will succeed.

Manufacturing capacity necessary to supply rhIGF-I/rhIGFBP-3 and rhIGFBP-3 may not be available, which may adversely affect our business, financial condition and results of operations.

The available capacity for the manufacture of recombinant proteins that comprise rhIGF-I/rhIGFBP-3 is limited. A shutdown or disruption in any of these facilities due to technical, regulatory or other problems, resulting in an interruption in supply of these materials, could delay our development activities and adversely impact our business, financial condition and results of operations.

Process improvements in the manufacture of rhIGF-I/rhIGFBP-3 and rhIGFBP-3 will be necessary to conduct Phase III clinical trials and produce commercial scale quantities.

We have signed an agreement with Avecia Limited to manufacture rhIGF-I/rhIGFBP-3 and rhIGFBP-3 at Avecia's site at Billingham, England. At present, rhIGF-I/rhIGFBP-3 and rhIGFBP-3 have never been

manufactured by Avecia; we cannot guarantee that they will be able to produce rhIGF-I/rhIGFBP-3 and rhIGFBP-3 at scales necessary for Phase III and commercialization. If process improvements are not successful, our costs will increase and the manufacture of rhIGF-I/rhIGFBP-3 and rhIGFBP-3 for Phase II and Phase III studies will be delayed. Such delay could materially adversely affect our business, financial condition and results of operations.

We need collaborative relationships for success.

We currently rely and may in the future rely on a number of significant collaborative relationships for research funding, clinical development and/or sales and marketing. Reliance on collaborative relationships poses a number of risks, including the following:

- we cannot 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 corporate partners;
- disagreements with corporate partners could 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 our product development or impair commercialization of our products.

Uncertainty regarding third-party reimbursement and healthcare cost containment initiatives may negatively affect our business, financial condition and results of operations.

If we succeed in bringing any of our proposed products to the market, we cannot assure you that third parties will consider the products cost-effective or provide reimbursement in whole or in part for their use. Our commercial success will depend in part on third-party payers agreeing to reimburse patients for the costs of products. Government health administration authorities, private health insurers and other organizations generally provide reimbursement. Third-party payers frequently challenge the pricing of new drugs. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Therefore, third-party payers may not approve our products for reimbursement.

If third-party payers do not approve our products for reimbursement, sales will suffer, as some patients will opt for a competing product that is approved for reimbursement. Even if third-party payers make reimbursement available, these payer's reimbursement policies may adversely affect our corporate partners and our ability to sell such products on a profitable basis.

Moreover, the trend toward managed healthcare in the United States, the growth of organizations such as health maintenance organizations and legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of healthcare services and products, resulting in lower prices and reducing demand for our products which could adversely affect our business, financial condition and results of operations.

In addition, legislation and regulations affecting the pricing of pharmaceuticals may change in ways adverse to us before or after the FDA or other regulatory agencies approve any of our proposed products for marketing. While we cannot predict the likelihood of any such 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.

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 assure you 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 assure you 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 collaborator 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 timely regulatory approvals;
- terminating their agreements with us prematurely; or
- failing to devote sufficient resources to the development and commercialization of products.

We face uncertainties related to patents and proprietary technology that may 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 arising 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.

We can give no assurance that a third party will not claim (with or without merit) that we have infringed or misappropriated their proprietary rights. A variety of third parties have obtained, and are attempting to obtain, patent protection relating to the production and use of rhIGF-I and/or rhIGFBP-3. 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 rhIGF-I/rhIGFBP-3 or rhIGFBP-3. We can give no assurances that such patent(s) can be avoided, invalidated or licensed. If any third party were to assert a claim for infringement, we can give no assurances that we would 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. Furthermore, we may not be able to afford the expense of defending against such a claim.

Third parties, including Genentech, Chiron, Amgen, Novartis AG, Fujisawa, Beth Israel Hospital and Robert Rieveley hold United States and/or foreign patents possibly directed to the composition, production and/or use of rhIGF-I, rhIGFBP-3, rhIGF-I/rhIGFBP-3 and/or recombinant proteins in general. After examining these patents, we do not believe they present an obstacle to our plans to commercialize rhIGF-I/rhIGFBP-3 and rhIGFBP-3. However, we can provide no assurance that any one of these third parties will not assert in the future a contrary position, for instance in the context of an infringement action. Moreover, while we cannot predict with certainty the outcome of such a proceeding, an adverse ruling could impact our ability to make, use or sell our products.

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 cannot assure 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 subject us to significant liabilities to other parties, require us to license disputed rights from other parties or require us to cease using such technology, any of which could materially adversely affect our business, financial condition and results of operations.

In 1998 Genentech requested a hearing with the European Patent Office to oppose the validity of one of our European patents with claims to rhIGFBP-3, uses of rhIGFBP-3 and uses of rhIGF-I/rhIGFBP-3. As of yet, no hearing date has been set by the European Patent Office. Should the opposition hearing be held and should Genentech prevail, some or all of the claims of this patent may be revoked. This result could lessen our ability to exclude others, but would not affect our own ability, to practice these claims.

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

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

Third-party claims that our products infringe on their proprietary rights may adversely affect our business, financial condition and results of operations.

We have entered into license agreements, and may enter into future license agreements, with various licensees to develop and market our products, and we cannot assure that third parties will not claim that we and/or our licensees, by practicing our technology, are infringing on their proprietary rights. If other companies

successfully bring legal actions against us or our licensees claiming patent or other intellectual property infringements, in addition to any potential liability for damages, a court could require us and/or our licensees to obtain a license in order to continue to use the affected processes or to manufacture or use the affected products, or alternatively, require us and/or our licensees to cease using such products or processes. Such a result may have an adverse effect on our business, financial condition and results of operations. Any such claim, with or without merit, could result in costly litigation or might require us and/or our licensees to enter into royalty or licensing agreements, all of which could delay or otherwise adversely impact the development of our potential products for commercial use. If a court requires us to obtain licenses, there can be no assurance that we and/or our licensees will be able to obtain them on commercially favorable terms, if at all. Without such licenses, we and/or our licensees may be unable to develop certain products. Our breach of an existing license or our failure to obtain, or our delay in obtaining, a license to any technology that we require to commercialize our products may materially adversely impact our business, financial condition and results of operations.

An inability to compete successfully would harm our business, financial condition and results of operations.

We engage in a business characterized by extensive research efforts, rapid developments and intense competition. We cannot assure that our products will compete successfully or that research and development by others will not render our products obsolete or uneconomical. Our failure to compete effectively would 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, as well as 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 trials 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 we will. 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.

Rapid technological change could make our products obsolete, which could 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 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 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 highly depend 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, contract manufacturing and marketing, 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 prospects for our success.

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

Our research and development activities involve the controlled use of hazardous materials, including hazardous chemicals and radioactive materials. We believe that our procedures for handling hazardous materials comply with federal and state regulations; however, there can be no assurance that accidental injury or contamination from these materials will not occur. In the event of an accident, we could be held liable for any damages, which could exceed our available financial resources, including our insurance coverage. This liability could materially adversely affect our business, financial condition and results of operations.

We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. These laws and regulations may require us to incur significant costs to comply with environmental laws and regulations in the future that could materially adversely affect our business, financial condition and results of operations.

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 clinical trials and no commercial product liability insurance. 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.

The market price of our stock may continue to be highly volatile.

Our common stock is listed on the Nasdaq National 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 National Market;
- results of our clinical trials 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' announcement of new products;

- government regulations, reimbursement changes and governmental investigations 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/or

- 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.

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 of 1933, unless these shares are held by “affiliates” of our company, as that term is defined in Rule 144 under the Securities Act.

We have never paid dividends on our common stock and do not anticipate paying any cash dividends in the foreseeable future.

We have not thus far paid cash dividends on our common stock. 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 in the foreseeable future.

Certain provisions of Virginia law, our articles of incorporation and our amended and restated bylaws, and our Shareholder 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 Shareholder 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.

Available Information

Our Internet website address is: www.Insmed.com. We make available free of charge through our website our Annual Report 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, as amended, as soon as reasonably practicable after such documents are electronically filed with, or furnished to, the SEC. The information on our website is not, and shall not be deemed to be, a part of this report or incorporated into any other filings we make with the SEC.

ITEM 2.PROPERTIES

We occupy 46,000 square feet of office and laboratory space in Glen Allen, Virginia. Our annual cash cost for the space including utilities and services in 2003 is approximately $1.1 million under an operating lease that contains annual escalations of 1.75% and expires in October 2006. 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 lease expires or when we need additional space.

ITEM 3.LEGAL PROCEEDINGS

We are not involved in any legal proceedings that, in our opinion, could have a material adverse effect on our business or financial condition.

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

There were no matters submitted to a vote of our shareholders during the quarter ended December 31, 2002.

PART II

ITEM 5.MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED SHAREHOLDER MATTERS

Our common stock began trading on The Nasdaq SmallCap Market on June 1, 2000. We moved from The Nasdaq SmallCap Market to the Nasdaq National Market on August 8, 2000. On January 22, 2003, Insmed received a NASDAQ Staff Determination indicating that the Company has failed to comply with NASDAQ's minimum bid price requirement of $1.00 per share for continued listing of the Company's common stock on the NASDAQ National Market as set forth in Marketplace Rule 4450(a)(5). As a result, the Company's common stock was subject to delisting from the NASDAQ National Market on January 31, 2003. Following procedures set forth in the NASDAQ Marketplace Rule 4800 series, the Company requested a hearing before a NASDAQ Listing Qualifications Panel (the Panel) to review the Staff Determination. The hearing occurred on March 6, 2003 and the delisting action has been stayed pending the Panel's decision. The Panel has 30 days from the hearing date to render a decision. At the time of filing of this annual report on Form 10-K with the SEC, no decision had been received from the Panel.

In the event the Panel denies the Company's request for continued listing on the NASDAQ National Market, the Company intends to apply for its common stock to be listed on the NASDAQ SmallCap Market. The Company believes that its common stock will likely be listed on the NASDAQ SmallCap Market if it is delisted from the NASDAQ National Market.

If, at some future date, the Company's common stock should cease to be listed on the NASDAQ National Market and the NASDAQ SmallCap Market, the common stock could publicly trade over-the-counter. In such an event, an investor could find it more difficult to dispose of, or to obtain accurate quotations as to the market value of, our common stock. In addition, if the Company's common stock were to be delisted from trading on the NASDAQ National Market and from the NASDAQ SmallCap Market and the trading price of the common stock were to remain below $5.00 per share, trading in our common stock could also be subject to the requirements of certain rules promulgated under the Securities Exchange Act of 1934, as amended, which require additional disclosure by broker-dealers in connection with any trades involving a stock defined as a "penny stock" (generally, any non-NASDAQ and non-national exchange equity security that has a market price of less than $5.00 per share, subject to certain exceptions). The additional burdens imposed upon broker-dealers by such requirements could discourage broker-dealers from effecting transactions in our common stock, which could severely limit the market liquidity of our common stock and the ability of investors to trade our common stock. Many brokerage firms are reluctant to recommend lower price stocks for their clients, and the policies and practices of a number of brokerage houses tend to discourage individual brokers within those firms from dealing in lower price stocks. Also, the brokerage commission on the purchase or sale of a stock with a relatively low per share price generally tends to represent a higher percentage of the sales price than the brokerage commission charged on a stock with a relatively higher per share price, to the detriment of our shareholders and the market for our common stock.

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 National Market.

	Insmed Common Stock	
Fiscal Year 2002	**High**	**Low**
Fourth Quarter	$ 0.73	$ 0.32
Third Quarter	2.00	0.37
Second Quarter	3.10	1.24
First Quarter	3.99	2.51
Fiscal Year 2001	**High**	**Low**
Fourth Quarter	$ 4.76	$ 2.26
Third Quarter	8.15	2.14
Second Quarter	9.75	3.33
First Quarter	7.00	2.88

On February 28, 2003, the last reported sale price for our common stock on the Nasdaq National Market was $0.49 per share. As of February 28, 2003, there were 521 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 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.

ITEM 6.SELECTED FINANCIAL DATA

In the table below, we provide you with selected consolidated financial data. We have prepared this information using the consolidated financial statements of Insmed for the five years ended December 31, 2002. The acquisition of Celtrix closed on May 31, 2000. The purchase method of accounting was used to account for the transaction. Accordingly, the results of operations for Celtrix are included in the historical financial information commencing June 1, 2000. The financial statements for each of the five fiscal years ended December31, 2002 have been audited by Ernst & Young LLP, our independent auditors.

When you read this selected historical financial data, it is important that you also read the historical financial statements and related notes, as well as "Management's Discussion and Analysis of Financial Condition and Results of Operations" on pages 23 to 27.

	Year Ended December 31,				
	1998	1999	2000	2001	2002
	(in thousands, except per share data)				
Historical Statement of Operations Data:					
Revenues	$ —	$ —	$ 60	$ 296	$ 1,955
Operating expenses:					
Research & development	3,669	5,657	21,608	35,506	18,077
General and administrative	1,626	2,189	5,989	4,881	2,984
Operational restructuring charge	—	—	—	—	2,533
Goodwill Impairment charge	—	—	—	—	15,385
Purchased research and development	—	—	50,434	—	—
Stock compensation	—	285	3,564	95	—
Total operating expenses	5,295	8,131	81,595	40,482	38,979
Operating loss	(5,295)	(8,131)	(81,535)	(40,186)	(37,024)
Interest income, net	486	338	1,873	3,017	607
Loss before income taxes	(4,809)	(7,793)	(79,662)	(37,169)	(36,417)
Income tax expense	—	—	200	—	—
Net loss	$ (4,809)	$ (7,793)	$ (79,862)	$ (37,169)	$ (36,417)
Basic and diluted net loss per share	$ (1.68)	$ (2.47)	$ (4.36)	$ (1.13)	$ (1.10)
Weighted average shares	2,868	3,155	18,319	32,871	33,066
Historical Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 11,677	$ 4,635	$ 83,083	$ 51,250	$ 27,337
Total assets	11,938	5,296	102,718	71,606	28,308
Stockholders' equity	11,661	4,462	96,782	59,695	23,448

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 discover and develop pharmaceutical products for the treatment of metabolic and endocrine disorders. We have two lead drug candidates — rhIGF-I/rhIGFBP-3 and rhIGFBP-3.

We have not been profitable and have accumulated deficits of approximately $176.2 million through December 31, 2002. We expect to incur significant additional losses for at least the next several years until such time as sufficient revenues are generated to offset expenses. 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.

The full cost and completion dates, through commercialization, of our current research and development projects, rhIGF-I/rhIGFBP-3 and rhIGFBP-3, are entirely dependent on the results of our current Phase II and potential Phase III clinical trials for rhIGF-I/rhIGFBP-3, together with the subsequent review of these Phase III results with the FDA, and our pre-clinical trials with rhIGFBP-3. Therefore, the estimated full cost of completion and the final completion dates for our current research and development projects are unknown at this time.

On September 10, 2002, we announced that we would immediately discontinue the internal development of one of our investigational drug candidates, INS-1, based on the results of recently completed Phase II clinical trials. Similarly, our Japanese partner to develop INS-1 in Japan and Asia, Taisho Pharmaceuticals, Co., Ltd., also indicated its intention to discontinue its involvement in any future development in INS-1, and terminated the joint development agreement in accordance with the terms of the agreement.

As a result of the decision to discontinue the INS-1 development program and Taisho's notice to terminate our joint development agreement, we approved a restructuring plan to focus on our remaining drug candidates. In the third quarter of 2002, we recorded a restructuring charge of $2.5 million. The components of the restructuring charge included expenses of $1.2 million related to the anticipated payouts under lease agreements for laboratory space no longer utilized at our headquarters, $0.7 million related to the impairment of idle laboratory equipment at our headquarters, and $0.6 million related to the cost of severance benefits after the termination of 32 employees, or 55% of the workforce, at our headquarters and laboratory in Glen Allen, Virginia. Prior to the end of the third quarter of 2002, all of the affected employees had been terminated. At December 31, 2002, approximately $0.3 million and $1.0 million of these costs remain accrued in the current and long-term portions of the restructuring reserve, respectively. These balances are expected to closely approximate the remaining costs to be incurred by us for lease obligations. As of December 31, 2002, substantially all severance had been paid to all 32 terminated employees. Lease termination costs are anticipated to extend through 2006.

As a result of Taisho's decision to terminate the joint development agreement, we also recognized revenue from the Taisho agreement totaling $1.7 million. This item represents revenues previously deferred from a cash payment made by Taisho at inception of the joint development agreement that was being recognized as revenue over the estimated life of the corresponding agreement. Due to the termination of the agreement, the balance of the unrecognized revenue was reported in 2002.

Results of Operations

Year Ended December 31, 2002 compared to Year Ended December 31, 2001

For the year ended December 31, 2002, we recorded a net loss of $36.4 million. Research and development expenses (which consist primarily of costs associated with clinical trials of our product candidates, including the costs of manufacturing, compensation and other expenses related to research and development personnel and facilities expenses) decreased $17.4 million from $35.5 million in 2001 to $18.1 million in 2002 as a result of decreased clinical trial activity. INS-1 expenses decreased $15.1 million during 2002, compared to 2001, as follows:

- Amounts paid to contract research organizations and for site grants, monitoring and other clinical trial-related costs decreased approximately $12.6 million from $17.8 million in 2001 to $5.2 million in 2002. This decrease was primarily due to the winding down of the INS-1 Phase II clinical trials.

- Contract manufacturing costs to supply INS-1 for our trials decreased $2.5 million from $4.2 million in 2001 to $1.7 million in 2002. This decrease was primarily due to the supply buildup of the INS-1 drug in 2001 and the subsequent use of that drug in 2002.

Clinical and contract manufacturing costs related to the development of rhIGF-I/rhIGFBP-3 decreased approximately $6.2 million, to $3.8 million in 2002 as we completed the development phase and began to scale up our production process for rhIGF-I/rhIGFBP-3 and rhIGFBP-3 with our contract manufacturer, Avecia.

General and administrative expenses decreased $1.9 million from $4.9 million for 2001 to $3.0 million for 2002. The decrease although seen across all support services, is primarily due to lower shareholder expenses, legal fees and accounting services.

In the third quarter 2002, we recorded a restructuring charge of $2.5 million related to the previously announced discontinuation of its INS-1 development program. The components of this charge include expenses of $1.2 million related to the anticipated payouts under lease agreements for laboratory space no longer utilized at our headquarters, $0.7 million related to the impairment of idle laboratory equipment at our headquarters, and $0.6 million related to the cost of severance benefits following the termination of approximately 55% of our workforce.

We also recorded a $15.4 million goodwill write off in the fourth quarter 2002 relating to the Celtrix acquisition in 2000. In accordance with Statement of Financial Accounting Standards (SFAS) No. 142, we tested the goodwill being carried on our balance sheet relating to the Celtrix acquisition for impairment by comparing the carrying amount of the goodwill to its fair value. In accordance with Generally Accepted Accounting Principles (GAAP), we adopted the current market value of our stock as the basis for supporting the fair value of our goodwill. Since the announcement of our decision to discontinue the development of INS-1, our stock price has traded at a level which does not reflect the value of goodwill carried on our balance sheet. As a result, under GAAP, there had been impairment to the goodwill and the entire remaining amount of unamortized goodwill of $15.4 million was written off.

The increase in revenues as compared with 2001 is due to the recognition of approximately $1.7 million of revenue from Taisho Pharmaceutical Co., Ltd. This represents revenues, previously deferred, from a cash payment made by Taisho at the inception of the Joint Development Agreement with us in 2000, which were being recognized as revenue over the life of the corresponding patent. As Taisho announced the termination of this agreement, the balance of the unrecognized revenue was recorded in the third quarter of 2002.

As of December 31, 2002, cash and cash equivalents decreased to $27.3 million from $51.3 million at December 31, 2001. As a result of a decreased average cash balance in 2002 compared to 2001, net interest income decreased $2.4 million to $0.6 million. Net receivables from Taisho for its portion of certain INS-1 development activities decreased $3.3 million to $0.2 million.

Accounts payable and accrued project costs decreased $6.2 million from $9.4 million at December 31, 2001 to $3.2 million at December 31, 2002 as a result of decreased clinical and manufacturing activity. Stockholders' equity decreased $36.3 as a result of the net loss in 2002, net of stock option exercises. The accumulated deficit at December 31, 2001 increased to approximately $176.2 million due to the Company's 2002 net loss of $36.4 million.

Year Ended December 31, 2001 compared to Year Ended December 31, 2000

For the year ended December 31, 2001, we recorded a net loss of $37.2 million. Research and development expenses (which consist primarily of costs associated with clinical trials of our product candidates, including the costs of manufacturing, compensation and other expenses related to research and development personnel and facilities expenses) increased $13.9 million from $21.6 million in 2000 to $35.5 million in 2001 as a result of increased clinical trial activity. INS-1 expenses increased $9.4 million during 2001, compared to 2000, as follows:

- Amounts paid to contract research organizations and for site grants, monitoring and other clinical trial-related costs increased approximately $10.2 million from $7.6 million in 2000 to $17.8 million in 2001.

- Contract manufacturing costs to supply INS-1 to our trials decreased $0.8 million from $5.0 million in 2000 to $4.2 million in 2001. This decrease was primarily due to timing as we took advantage of extended manufacturing runs in 2000 in order to build inventory for our Phase II trials.

Clinical and contract manufacturing costs related to the development of rhIGF-I/rhIGFBP-3, the compound we acquired from Celtrix, increased approximately $5.0 million, to $10.0 million in 2001.

Prior to the fiscal year ended December 31, 2000, we generally did not track our historical research and development cost by project; rather, we tracked such costs by the type of costs incurred, such as clinical trial costs and manufacturing costs.

General and administrative expenses decreased $1.1 million from $6.0 million for 2000 to $4.9 million for 2001. The decrease is primarily due to higher legal, investor relations and other costs resulting from the acquisition of Celtrix in 2000. Legal fees were also incurred in 2000 to finalize the license agreement with Taisho, transition the rhIGF-I/rhIGFBP-3 patent estate and other general corporate matters, and we incurred fees in 2000 to develop our new web site and other investor materials.

As of December 31, 2001, cash, cash equivalents and marketable securities decreased to $51.3 million from $83.1 million at December 31, 2000. As a result of an increased average cash balance in 2001 compared to 2000, net interest income increased $1.1 million to $3.0 million. The issuance of equity securities produced net proceeds of approximately $0.3 million in 2001. Net receivables from Taisho for its portion of certain INS-1 development activities increased $2.3 million to $3.5 million.

Accounts payable and accrued project costs increased $6.0 million from $3.4 million at December 31, 2000 to $9.4 million at December 31, 2001 as a result of increased clinical and manufacturing activity. In addition, we deferred the $2.0 million initial licensing fee paid by Taisho in 2000 as part of the joint development agreement and are recognizing it as revenue over the life of the related INS-1 patents. Stockholders' equity decreased $37.1 million as a result of the net loss in 2001, net of the issuance of equity securities and stock option exercises. The accumulated deficit at December 31, 2001 increased to approximately $139.8 million due to the Company's 2001 net loss of $37.2 million.

Liquidity and Capital Resources

At December 31, 2002, our cash and cash investments were approximately $27.3 million and were invested in money market instruments. We believe that our current cash position will be sufficient to fund our operations through 2004.

Our business strategy contemplates selling additional equity and entering into agreements with corporate partners to fund research and development, and provide milestone payments, license fees and equity investments to fund operations. We will need to raise substantial additional funds to continue development and commercialization of our products. 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.

Critical Accounting Policies

In Management's Discussion and Analysis, we discuss the results of operations and financial condition as reflected in the our consolidated financial statements, which have been prepared in accordance with GAAP. Preparation of financial statements 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. Note 1 to the Company's consolidated financial statements include a discussion of our significant accounting policies. 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. Our financial results might have been different if different assumptions had been used or other conditions had prevailed.

Stock-Based Compensation

We recognize expense for stock-based compensation in accordance with the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* , and related interpretations. Accordingly, compensation cost is recognized for the excess, if any, of the estimated fair value of the stock at the grant date over the exercise price. Disclosures regarding alternative fair value measurement and recognition methods prescribed by Financial Accounting Standards Board ("FASB") Statement No. 123, *Accounting for Stock-Based Compensation* , are presented in Note 3. The fair value for these awards was estimated at the date of grant using the Black-Scholes pricing method assuming a weighted average volatility, a risk-free interest rate, no dividends, and a weighted-average expected life of the option.

Stock options granted to non-employees are accounted for in accordance with the Emerging Issues Task Force (EITF) 96-18, *Accounting for Equity Instruments* that are issued to Other than Employees for Acquiring, or in Conjunction with Selling Goods or Services. Accordingly, the estimated fair value of the equity instrument is recorded on the earlier of the performance commitment date or the date the services required are completed.

ITEM 7A.QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We invest excess cash in investment grade, interest-bearing securities and, at December 31, 2002, had $27.3 million invested in money market instruments. Such investments are subject to interest rate and credit risk. Our policy of investing in highly rated securities whose maturities at December 31, 2002, are all less than one year minimizes such risks. In addition, while a hypothetical 1.0% per annum decrease in market interest rates would reduce interest income in 2003, it would not result in a loss of the principal and the decline in interest income would be deemed immaterial.

ITEM 8.FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by Item 8 is set forth on pages F-1 to F-13.

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

None.

PART III

ITEM 10.DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information presented under the caption "Nominees," "Directors Whose Terms Expire at the 2004 Annual Meeting (Class I Directors)," "Directors Whose Terms Expire at the 2005 Annual Meeting (Class II Directors)" and "Section 16(a) Beneficial Ownership Reporting Compliance" of the Company's definitive Proxy Statement for the 2003 Annual Meeting of Shareholders (the "2003 Proxy Statement") is incorporated herein by reference. Such 2003 Proxy Statement will be filed with the Securities and Exchange Commission in April 2003.

ITEM 11.EXECUTIVE COMPENSATION

The information presented under the captions “Executive Officer Compensation” and “Director Compensation” of the 2003 Proxy Statement is incorporated herein by reference.

ITEM 12.SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS

The information presented under the caption “Stock Ownership” of the 2003 Proxy Statement is incorporated herein by reference.

Equity Compensation Plan Information

The following table presents information as of December 31, 2002, with respect to compensation plans under which shares of Insmed Common Stock are authorized for issuance.

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 [1]
Equity Compensation Plans Approved by Shareholders 2000 Stock Incentive Plan	3,250,227	$ 4.49	2,451,192 [2]
Equity Compensation Plans Not Approved by Shareholders [3]	—	—	—
Total	3,250,227	$ 4.49	2,451,192 [2]

[1] Amounts exclude any securities to be issued upon exercise of outstanding options, warrants and rights.

[2] The 2000 Stock Incentive Plan permits grants of stock options, stock appreciation rights, restricted stock and performance units. If and to the extent that stock options or stock appreciation rights granted under the 2000 Stock Incentive Plan terminate, expire, or are canceled, forfeited, exchanged or surrendered without having been exercised, or if any shares of restricted stock or performance units are forfeited, the shares of common stock underlying such grants are again available for purposes of the 2000 Stock Incentive Plan.

[3] The Company does not have any equity compensation plans that have not been approved by its shareholders.

ITEM 13.CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information presented under the caption “Certain Relationships and Related Transactions” of the 2003 Proxy Statement is incorporated herein by reference.

ITEM 14.CONTROLS AND PROCEDURES

Within the 90 days prior to the filing date of this report, we carried out an evaluation, under the supervision and with the participation of our management, including the Chairman of the Board and Chief Executive Officer and Principal Financial Officer, Treasurer and Controller, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-14 under the Securities Exchange Act of 1934, as amended. Based upon that evaluation, our Chairman of the Board and Chief Executive Officer and Principal Financial Officer, Treasurer and Controller concluded that our disclosure controls and procedures are effective in timely

alerting them to material information relating to us (including our consolidated subsidiaries) required to be included in our periodic SEC filings.

There have been no significant changes in internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

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PART IV

ITEM 15.EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8–K

(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 Auditors.

(ii) Consolidated Balance Sheets.

(iii) Consolidated Statements of Operations.

(iv) Consolidated Statements of Stockholders' Equity.

(v) Consolidated Statements of Cash Flows.

(vi) 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 and 10.2

constitute management contracts or compensatory plans or arrangements required to be filed as exhibits hereto.

(b) Reports on Form 8-K.

None.

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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 28th day of March, 2003.

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 28th day of March, 2003.

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 C.G.A.**	Treasurer and Controller (Principal Financial and Accounting Officer)
/s/KENNETH G. CONDON **Kenneth G. Condon, C.P.A., C.F.P., M.B.A.**	Director
/s/GRAHAM K. CROOKE **Graham K. Crooke, MB.BS**	Director
/s/STEINAR J. ENGELSEN **Steinar J. Engelsen, M.D.**	Director
/s/MELVIN SHAROKY **Melvin Sharoky, M.D.**	Director
/s/RANDALL W. WHITCOMB **Randall W. Whitcomb, M.D.**	Director

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Section 302 Certification

I, Geoffrey Allan, Chairman of the Board and Chief Executive Officer of Insmed Incorporated, certify that:

(1) I have reviewed this annual report on Form 10-K of Insmed Incorporated;

(2) Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

(3) Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

(a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

(c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

(5) The registrant's other certifying officer and I have disclosed, based on the most recent evaluation, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

(a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

(Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's
l internal controls; and
)

(6) The registrant's other certifying officer and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date:March 28, 2003

/s/Geoffrey Allan
Geoffrey Allan, Ph.D.

Chairman of the Board and Chief

Executive Officer

Principal Executive Officer

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Section 302 Certification

I, Kevin P. Tully, Principal Financial Officer, Treasurer and Controller of Insmed Incorporated, certify that:

(1) I have reviewed this annual report on Form 10-K of Insmed Incorporated;

(2) Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

(3) Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

(a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

(c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

(5) The registrant's other certifying officer and I have disclosed, based on the most recent evaluation, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

(a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

(Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's
l internal controls; and
)

(6) The registrant's other certifying officer and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date:March 28, 2003

/s/Kevin P. Tully
Kevin P. Tully C.G.A.

Treasurer and Controller

Principal Financial and Accounting Officer

REPORT OF INDEPENDENT AUDITORS

The Board of Directors and Stockholders

Insmed Incorporated

We have audited the accompanying consolidated balance sheets of Insmed Incorporated as of December 31, 2002 and 2001 and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2002. 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 auditing standards generally accepted in the 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, 2002 and 2001, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2002, in conformity with accounting principles generally accepted in the United States.

As discussed in Note 1 to the financial statements, in 2002 the Company changed its method for accounting for goodwill and other intangible assets to comply with the accounting provisions of Statement of Financial Accounting Standards No. 142.

/s/ Ernst & Young LLP

McLean, Virginia

January 17, 2003

INSMED INCORPORATED

CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 31, 2002	December 31, 2001
ASSETS		
Current assets:		
Cash and cash equivalents	**$ 27,337**	$ 51,250
Due from Taisho Pharmaceutical Co., Ltd.	**199**	3,521
Other current assets	**615**	278
Total current assets	**28,151**	55,049
Property and equipment, net	**157**	1,172
Goodwill, net	**—**	15,385
Total assets	**$ 28,308**	$ 71,606
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	**$ 941**	$ 4,427
Accrued project costs	**2,283**	4,967
Payroll liabilities	**358**	719
Restructuring reserve	**310**	—
Deferred revenue — current portion	**—**	143
Total current liabilities	**3,892**	10,256
Restructuring reserve — long-term portion	**968**	—
Deferred revenue	**—**	1,655
Stockholders' equity:		
Common stock, $.01 par value: authorized shares 500,000,000; issued and outstanding shares, 33,186,336 in 2002 and 32,931,765 in 2001	**332**	329
Additional capital	**199,344**	199,177
Accumulated deficit	**(176,228)**	(139,811)
Total stockholders' equity	**23,448**	59,695
Total liabilities and stockholders' equity	**$ 28,308**	$ 71,606

See accompanying notes.

INSMED INCORPORATED

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Year Ended December 31,		
	2002	2001	2000
Revenues	$ 1,955	$ 296	$ 60
Operating expenses:			
Research and development	18,077	35,506	21,608
General and administrative	2,984	4,881	5,989
Operational Restructuring Charge	2,533	—	—
Goodwill impairment charge	15,385	—	—
Purchased research and development	—	—	50,434
Non-cash stock compensation	—	95	3,564
Total operating expenses	38,979	40,482	81,595
Operating loss	(37,024)	(40,186)	(81,535)
Interest income	607	3,017	1,873
Loss before income taxes	(36,417)	(37,169)	(79,662)
Income tax expense	—	—	200
Net loss	$ (36,417)	$ (37,169)	$ (79,862)
Basic and diluted net loss per share	$ (1.10)	$ (1.13)	$ (4.36)
Shares used in computing basic and diluted net loss per share	33,066	32,871	18,319

See accompanying notes.

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INSMED INCORPORATED

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY YEARS ENDED DECEMBER 31, 2002, 2001, AND 2000

(in thousands, except share amounts)

	Series A Convertible Participating Preferred Stock	Series B Convertible Preferred Stock	Common Stock	Additional Capital	Notes Receivable from Stock Sales	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balance at December 31, 1999	61	36	10	27,210	(64)	(22,780)	(11)	4,462
Issuance of 792,298 shares of common stockuponexerciseof stockoptions	—	—	8	906	—	—	—	914
Issuance of 32,500 shares of common stock upon exercise ofstock warrants	—	—	—	96	—	—	—	96
Issuance of 93,413 shares of common stock to Taisho Pharmaceuticals Co. Ltd.	—	—	1	2,999	—	—	—	3,000
Issuance of 4,969 shares of common stock to licensor	—	—	—	541	—	—	—	541
Issuance of 1,408,169 shares of common stock and 1,725,330 warrants for cash, net of offering costs of $1,775	—	—	14	32,711	—	—	—	32,725
Issuance of 14,470,553 shares of common stock in connection with the acquisition of Insmed Pharmaceuticals, Inc.	(61)	(36)	145	(48)	—	—	—	—
Issuance of 9,527,385 shares of common stock in connection with the acquisition of Celtrix Pharmaceuticals, Inc.	—	—	95	69,425	—	—	—	69,520
Issuance of 5,500,000 shares of common stock for cash, net of offering costs of $4,746	—	—	55	60,512	—	—	—	60,567
Accrued interest on notes receivable	—	—	—	—	(2)	—	—	(2)
Principal payment on notes receivable	—	—	—	—	66	—	—	66
Recognition of stock compensation expense for employee	—	—	—	3,564	—	—	—	3,564
Recognition of stock compensation expense for consultants	—	—	—	1,014	—	—	—	1,014
Comprehensive earnings:								
Unrealized gain on marketable securities	—	—	—	—	—	—	177	177
Net loss	—	—	—	—	—	(79,862)	—	(79,862)
Comprehensive loss	—	—	—	—	—	—	—	(79,685)
Balance at December 31, 2000	—	—	328	198,930	—	(102,642)	166	96,782
Issuance of 115,962 shares of common stock upon exercise of stock options	—	—	1	93	—	—	—	94
Issuance of 18,403 shares of common stock from Employee Stock Purchase Plan	—	—	—	59	—	—	—	59
Recognition of stock compensation expense for director	—	—	—	95	—	—	—	95
Comprehensive earnings:								
Sale of marketable securities	—	—	—	—	—	—	(166)	(166)
Net loss	—	—	—	—	—	(37,169)	—	(37,169)
Comprehensive loss	—	—	—	—	—	—	—	(37,335)
Balance at December 31, 2001	$ —	$ —	$ 329	$ 199,177	$ —	$ (139,811)	$ —	$ 59,695
Issuance of 198,282 shares of common stock upon exercise of stock options	—	—	2	125	—	—	—	127

Issuance of 56,289 shares of common stock from Employee Stock Purchase Plan	—	—	1	42	—	—	—	43
Comprehensive earnings:								
Net loss	—	—	—	—	—	(36,417)	—	(36,417)
Comprehensive loss	—	—	—	—	—	—	—	(36,417)
Balance at December 31, 2002	$ —	$ —	$ 332	$ 199,344	$ —	$ (176,228)	$ —	$ 23,448

See accompanying notes.

INSMED INCORPORATED

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,		
	2002	**2001**	**2000**
Operating activities			
Net loss	**$ (36,417)**	$ (37,169)	$ (79,862)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	**346**	707	302
Amortization of goodwill	**—**	835	487
Goodwill impairment charge	**15,385**	—	—
Operational restructuring	**1,947**	—	—
Initial license fee — Taisho	**—**	—	2,000
Recognition of deferred revenues	**(1,798)**	(143)	(59)
(Gain) loss on sale of marketable securities	**—**	(211)	—
Issuance of stock for services	**—**	—	1,555
Non-cash stock compensation	**—**	95	3,562
Purchased research and development	**—**	—	50,434
Changes in operating assets and liabilities:			
Due from Taisho Pharmaceutical Co., Ltd.	**3,322**	(2,293)	(1,228)
Other current assets	**(337)**	281	(483)
Accounts payable	**(3,486)**	1,810	850
Accrued project costs	**(2,684)**	4,193	534
Payroll liabilities	**(361)**	115	492
Net cash used in operating activities	**(24,083)**	(31,780)	(21,416)
Investing activities			
Purchases of marketable securities	**—**	—	(19,224)
Proceeds from marketable securities matured and sold	**—**	11,500	12,264
Purchases of property and equipment	**—**	(251)	(1,294)
Acquisition of Celtrix Pharmaceuticals, Inc., net of cash acquired	**—**	—	3,613
Net cash provided by (used in) investing activities	—	11,249	(4,641)
Financing activities			
Proceeds from issuance of common stock	**170**	153	97,302
Repayment of notes receivable from stock sales	**—**	—	66
Net cash provided by financing activities	**170**	153	97,368
Decrease (increase) in cash and cash equivalents	**(23,913)**	(20,378)	71,311
Cash and cash equivalents at beginning of year	**51,250**	71,628	317
Cash and cash equivalents at end of year	**$ 27,337**	$ 51,250	$ 71,628

See accompanying notes.

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

Insmed Incorporated (the "Company") discovers and develops pharmaceutical products for the treatment of metabolic and endocrine diseases. Abnormalities in the Growth Hormone (GH)/ Insulin-like Growth Factor I (IGF-I) axis often manifest in multiple endocrine and metabolic conditions, such as growth disorders. Additionally, other conditions such as diabetes are exacerbated by imbalances in the GH/ IGF-I axis. Insmed's cancer development program focuses on rhIGFBP-3, the primary binding protein of IGF-I. Insmed's rhIGFBP-3 technology may curtail abnormal cell growth by introducing an excess of rhIGFBP-3 to bind and regulate free IGF-I. Since rhIGFBP-3 interrupts the cell growth signal early in the sequence, rhIGFBP-3 is considered an upstream growth factor inhibitor.

Insmed has two lead drug candidates: rhIGF-I/rhIGFBP-3, which is expected to begin Phase III Clinical testing for GHIS in 2003, and rhIGFBP-3, which is currently undergoing Pre-Clinical trials in the oncology area. The Company is actively developing rhIGF-I/rhIGFBP-3 to treat GHIS and diabetes, and are concurrently continuing pre-clinical studies on rhIGFBP-3 in the cancer indication as an anti-tumor agent.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Insmed Pharmaceuticals, Inc. and Celtrix Pharmaceuticals, Inc. ("Celtrix") All significant intercompany balances and transactions have been eliminated.

Cash and Cash Equivalents

The Company considers investments with maturities of three months or less when purchased to be cash equivalents.

Property and Equipment

Depreciation is provided using the straight-line method over periods ranging from three to seven years. Property and equipment is stated at cost and consists of the following:

	December 31,	
	2002	2001
	(in thousands)	
Research and development equipment	$ —	$ 1,799
Furniture and office equipment	511	525
	511	2,324
Accumulated depreciation	(354)	(1,152)
Property and equipment, net	$ 157	$ 1,172

Fair Value of Financial Instruments

The Company considers the recorded cost of its financial assets and liabilities, which consist primarily of cash and cash equivalents, accounts payable, and accrued expenses to approximate the fair value of the respective assets and liabilities at December 31, 2002 due to the short-term maturities of these instruments.

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Stock-Based Compensation

The Company recognizes expense for stock-based compensation in accordance with the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* , and related interpretations. Accordingly, compensation cost is recognized for the excess, if any, of the estimated fair value of the stock at the grant date over the exercise price. Disclosures regarding alternative fair value measurement and recognition methods prescribed by Financial Accounting Standards Board ("FASB") Statement No. 123, *Accounting for Stock-Based Compensation*, are presented in Note 3. Stock options granted to non-employees are accounted for in accordance with EITF 96-18, Accounting for Equity Instruments that are issued to Other than Employees for Acquiring, or in Conjunction with Selling Goods or Services. Accordingly, the estimated fair value of the equity instrument is recorded on the earlier of the performance commitment date or the date the services required are completed.

In accordance with SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure* ("SFAS 148"), the effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation is as follows:

Stock Compensation Expense

	Year Ended December 31,		
	2002	2001	2000
	(in thousands)		
Net Loss	$ (36,417)	$ (37,169)	$ (79,862)
Net Loss Per Share (Basic and Diluted)	$ (1.10)	$ (1.13)	$ (4.36)
Stock based employee compensation cost (under APB 25)	—	95	3,564
Pro-forma Fair value stock compensation expense	(2,731)	(2,222)	(627)
Pro-Forma Net Income	(39,148)	(39,391)	(80,489)
Pro-Forma Net Loss Per Share (Basic and Diluted)	$ (1.18)	$ (1.20)	$ (4.39)

The fair value for these awards was estimated at the date of grant using the Black-Scholes pricing method assuming a weighted average volatility of 106% in 2002, 89% in 2001, and 83% in 2000, a risk-free interest rate of 3.0% in 2002, 4.5% in 2001, and 6% in 2000, no dividends, and a weighted-average expected life of the option of 5.7 years in 2002, 5 years in 2001 and 4 years in 2000.

Revenue Recognition

Revenue from license agreements is generally recognized over the term of the agreement, or in certain circumstances, when milestones are met. Amounts received for which there is a future performance obligation, are deferred and recognized on a straight-line basis over the life of the agreement.

Income Taxes

Income taxes are accounted for using the liability method. 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.

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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.

Comprehensive Income (Loss)

Under FASB Statement No. 130 , *Reporting Comprehensive Income* , the Company is required to display comprehensive loss and its components as part of the consolidated financial statements. Comprehensive loss is comprised of the net loss and other comprehensive income (loss), which includes certain changes in equity that are excluded from the net loss. The Company includes unrealized holding gains and losses on available-for-sale securities in other comprehensive income (loss).

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* .

Use of Estimates

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States 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.

Recent Accounting Pronouncements

The Company adopted Statements of Financial Accounting Standards (SFAS) No. 142, Goodwill and Other Intangible Assets, effective January 1, 2002. SFAS No. 142 requires that an acquired, intangible asset shall initially be recognized and measured based on its fair value. The Statement also provides that goodwill shall not be amortized, but shall be periodically tested for impairment by comparing its fair value to its carrying amount. In prior years goodwill was being amortized on a straight-line basis over twenty years. Accumulated amortization of goodwill was approximately $1,322,000 at December 31, 2001. The Company performed the first of the required impairment tests for goodwill and indefinite-lived intangible assets as of January 1, 2002 and determined that the only effect of the adoption of this Statement on the Company's earnings and financial position at that time was the ceasing of amortization of goodwill. The next assessment for impairment, following Financial Accounting Standards Board ("FASB") guidelines, took place in the fourth quarter of 2002. In accordance with SFAS No. 142, the Company has adopted the current market value of the Company's stock as the basis for supporting the underlying value of the goodwill. Since the announcement of the Company's decision to discontinue the development of INS-1, the Company's stock price has traded at a level which does not reflect the value of goodwill carried on the books. Management therefore determined that there had been impairment to the goodwill asset that was being carried at a book value of $15,385,000 and it was written-off in accordance

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

with SFAS No.142. As of December 31, 2002, $15,385,000 of expense was taken as a charge to continuing operations and consequently written-off of the balance sheet. The Company recognized amortization of goodwill of $835,000 and $487,000 for the years ended December 31, 2001 and 2000 respectively. If the pronouncement had been in effect at December 31, 2001 and 2000, net loss as adjusted for the years ended December 31, 2001 and 2000 would have been $36.3 million and $79.4 million, respectively, and net loss per share would have been $1.11 and $4.33, compared to reported net loss for the same periods of $37.2 and $79.9 million, respectively, and net loss per share of $1.13 and $4.36.

In October 2001, the FASB issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* . SFAS No. 144 addresses significant issues relating to the implementation of SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of* , which it supersedes. SFAS No. 144 also supersedes the accounting and reporting provisions of APB Opinion No. 30, *Reporting the Results of Operations-Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions* , that address the disposal of a segment of a business. The Company adopted this Statement effective January 1, 2002. There is no effect of the adoption of this Statement on the Company's earnings and financial position.

In July 2002, the FASB issued SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities. SFAS No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies EITF Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)* . The principal difference between SFAS No. 146 and EITF 94-3 relates to the requirements of SFAS No. 146 for the recognition of the liability for a cost associated with an exit or disposal activity to be recognized when the liability is incurred. The provisions of this Statement are effective for exit or disposal activities that are initiated after December 31, 2002. The adoption of this statement is not expected to impact the Company's earnings or financial position.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation-Transition & Disclosure* . SFAS No. 148 amends SFAS No. 123 to provide alternate methods of transition for an entity that voluntarily changes to the fair-value based method of accounting for stock-based compensation. It also amends the disclosure requirements of SFAS No. 123 to require more prominent disclosures about the effects on reported net income of an entity's accounting policy decisions with respect to stock options. Finally, SFAS No. 148 amends APB Opinion No. 28, Interim Financial Reporting, to require disclosure of the effects of the Company's choice of accounting for stock options in interim financial information. SFAS No. 148 is effective for fiscal years ending after December 15, 2002. The Company recognizes expense for stock-based compensation in accordance with the provisions of SFAS No. 148. Accordingly, compensation cost is recognized for the excess, if any, of the estimated fair value of the stock at the grant date over the exercise price. Disclosures regarding the fair value measurement and recognition methods prescribed by Statement No. 123 are presented in Note 3.

2.Operational Restructuring

On September 10, 2002, the Company announced that it would immediately discontinue the internal development of one of its investigational drug candidates, INS-1, based on the results of recently completed Phase II clinical trials. Similarly, the Company's Japanese partner to develop INS-1 in Japan and Asia, Taisho, also indicated its intention to discontinue its involvement in any future development in INS-1, and terminated the joint development agreement in accordance with the terms of the agreement.

As a result of the decision to discontinue the INS-1 development program and Taisho's notice to terminate the joint development agreement, the Company approved a restructuring plan to focus on its remaining drug

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

candidates. In the third quarter of 2002, the Company recorded a restructuring charge of $2.5 million. The components of the restructuring charge included expenses of $1.2 million related to the anticipated payouts under lease agreements for laboratory space no longer utilized at the Company's headquarters, $0.6 million related to the impairment of idle laboratory equipment at the Company's headquarters, and $0.6 million related to the cost of severance benefits after the termination of 32 employees, or 55% of the workforce, at the Company's headquarters and laboratory in Glen Allen, Virginia. At December 31, 2002, approximately $0.3 million and $1.0 million of these costs remain accrued in the current and long-term portions of the restructuring reserve, respectively. These balances are expected to closely approximate the remaining costs to be incurred by the Company for lease obligations. As of December 31, 2002 substantially all severance had been paid to all 32 terminated employees. Lease termination costs are anticipated to extend through 2006.

As a result of Taisho's decision to terminate the joint development agreement, the Company also recognized revenue from the Taisho agreement totaling $1.7 million. This item represents revenues previously deferred from a cash payment made by Taisho at inception of the joint development agreement that was being recognized as revenue over the estimated life of the corresponding agreement. Due to the termination of the agreement, the balance of the deferred revenue is being recognized in 2002.

3.Stockholders' Equity

Common Stock

On July 28, 2000, the Company's stockholders approved a one-for-four reverse stock split. The split was effective at the close of business on July 28, 2000, and shares of common stock began trading on the post-split basis at the opening of the Nasdaq stock market on July 31, 2000. Stockholders' Equity has been restated to give retroactive recognition to the reverse stock split. In addition, all references in the consolidated financial statements to number of shares and per share amounts have been restated.

On November 1, 2000, the Company sold 6,500,000 shares of common stock at $11.875 per share in a public offering, including 1,000,000 shares that were sold by certain selling shareholders. The proceeds from the sale of 5,500,000 shares approximated $60.6 million after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company.

Periodically, the Company has issued shares of common stock in exchange for services provided by stockholders 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

On May 31, 2000 Insmed Pharmaceuticals, Inc. issued warrants to purchase 1,725,330 shares of the Company's common stock. The warrants are exercisable for five years at a price of $9.00.

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 plan is 6,250,000. The current plan provides for issuance of options to purchase up to 6,157,291 shares of common stock with 92,709 options currently available as at December 31, 2002, which can be added to top up the options available to the 6,250,000 maximum. Options may be granted at the discretion of the board of

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

directors, compensation committee or a delegate. The weighted-average fair value of options granted during 2002, 2001, and 2000 was $1.36, $3.37, and $8.23, respectively. A summary of stock option activity is as follows:

Description	2002	Weighted Average Exercise Price	2001	Weighted Average Exercise Price	2000	Weighted Average Exercise Price
Options outstanding at January 1	3,143,561	$ 6.11	1,701,735	$ 7.39	1,490,558	$ 1.06
Granted	1,984,750	1.98	1,812,465	4.66	1,060,444	11.37
Exercised	(198,282)	0.64	(115,962)	0.81	(792,298)	1.21
Cancelled	(1,679,802)	5.01	(254,677)	6.75	(56,969)	4.12
Options outstanding at December 31	3,250,227	$ 4.49	3,143,561	$ 6.11	1,701,735	$ 7.39

The following table summarizes options outstanding at December 31, 2002:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$ 0.172 – $ 0.916	613,390	7.19	$ 0.59	211,207	$ 0.76
$ 1.38 – $ 4.88	1,712,603	6.09	3.13	440,189	3.57
$ 5.000 – $ 8.25	466,970	6.12	6.20	250,625	6.21
$10.000 – $13.063	138,125	6.86	11.40	126,875	11.28
$13.313 – $14.00	316,250	3.61	13.67	158,126	13.67
$32.116	2,889	4.25	32.12	2,889	32.12
	3,250,227	6.09	$ 4.49	1,189,911	$ 5.86

A total of 8,057,929 shares of common stock were reserved at December 31, 2002 in connection with stock options, stock warrants, and the employee stock purchase plan.

4.Income Taxes

The deferred tax assets of approximately $94.4 million and $84.5 million at December 31, 2002 and 2001, 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, 2002 and 2001, the Company had net operating loss carryforwards for income tax purposes of approximately $222.1 million and $208.4 million (of which $115 million was acquired from Celtrix), respectively, expiring in various years beginning in 2003. Utilization of these carryforwards will be significantly limited due to changes in the ownership of the Company's common stock.

The Company recognized $200,000 of income tax expense in the year ended December 31, 2000 related to foreign taxes withheld from the initial license fee received from Taisho Pharmaceutical Co., Ltd.

5.Leases

The Company leases office and laboratory space under an operating lease agreement expiring in October 2006. The lease provides for monthly rent of approximately $30,500 for the office space and $28,000 for the lab

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

space with a 1.75% escalation per year. With the discontinuation of INS-1 and subsequent abandonment of the lab space, the company recognized $1.2 million of rent expense during the third quarter of 2002. The Company also leases a vehicle and office equipment. Future minimum payments on these leases at December 31, 2002 approximate $770,000, $762,000, $772,000, and $571,000 in 2003, 2004, 2005, and 2006, respectively. Rent expense for all operating leases approximated $702,000 in 2002, $663,000 in 2001, and $319,000 in 2000.

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, 2002 there were 250,000 shares authorized for issuance under the plan and 74,692 have 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.License and Collaborative Agreements

Taisho Pharmaceutical Co., Ltd.

In July 2000, the Company entered into an agreement with Taisho Pharmaceutical Co., Ltd. (“Taisho”) for the development and commercialization of INS-1 in Japan and certain other Asian countries. The collaboration included payments upon achievement of certain development and regulatory milestones as well as the receipt of royalties on INS-1 sales in Japan and the other Asian countries covered by the agreement. Taisho also funded 20% of the development costs for INS-1 in North America and Europe. Development costs reimbursable by Taisho approximated $1.6 million, $6.0 million and $2.3 million in 2002, 2001 and 2000, respectively, and have been applied to reduce research and development expense. The agreement also provided for an initial license fee of $2.0 million, which was previously being amortized into revenue, on a straight-line basis, over the estimated life of the corresponding patents. In addition, Taisho purchased 93,413 shares of the Company’s common stock in 2000. In September 2002, Taisho indicated its intention to discontinue its involvement in any future development in INS-1, and terminated the joint development agreement in accordance with the terms of the agreement. As a result of this termination the Company recognized the remaining amount of the deferred license fee of $1.7 million in the 2002.

UVA Patent Foundation

In 1988, the Company entered into a license agreement with The University of Virginia Alumni Patents Foundation (the “Foundation”). The agreement, as amended, provides the Company with an exclusive, worldwide license to develop and sell products related to certain patent rights for insulin resistance and associated disorders. The Company is obligated to pay minimum annual licensing fees of $100,000, as well as patent costs through the expiration of patent rights. The Company may also have to pay a royalty on net sales of any therapeutic drugs covered by the agreement.

Under the license agreement, the Company was required to issue shares of its common stock each time shares of any class of stock were issued so that the Foundation at all times had a 3% undiluted interest in the Company. The right to receive such stock expired May 31, 2000. Prior to the expiration of this right, the Foundation had received 103,780 shares of common stock under the license agreement. These issuances have

INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

been recorded at their estimated fair value at the time of the respective transaction. Related expenses of $641,000 in 2000 have been included in research and development expense in the accompanying consolidated statements of operations.

Pharmacia

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

Avecia Limited

In May 2002, we entered into an agreement with Avecia Limited, Europe's largest privately held specialty chemical company, for the process development and manufacture of rhIGF-I/rhIGFBP-3. In consideration for this process development and manufacturing agreement, we are obligated to pay success fees for process development milestones and manufacturing costs associated with ongoing production of rhIGF-I/rhIGFBP-3 and rhIGFBP-3.

8.Quarterly Financial Data (Unaudited)

	Fiscal Quarter							
	First		Second		Third		Fourth	
	2002	2001	2002	2001	2002	2001	2002	2001
	(in thousands, except per share data)							
Revenues	$ 102	$ 100	$ 70	$ 69	$ 1,757	$ 66	$ 26	$ 61
Operating Loss	(6,309)	(11,345)	(7,279)	(9,629)	(4,812)	(8,975)	(18,624)	(10,237)
Net Loss	(6,107)	(10,093)	(7,107)	(8,793)	(4,706)	(8,371)	(18,497)	(9,912)
Net Loss Per Share (Basic and Diluted)	$ (0.19)	$ (0.31)	$ (0.21)	$ (0.27)	$ (0.14)	$ (0.25)	$ (0.56)	$ (0.30)

EXHIBIT INDEX

Exhibit Number	Exhibit Title
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	Form of Articles of Amendment to Insmed Incorporated's Articles of Incorporation, as amended, dated as of July 28, 2000, to effect a one-for-four reverse stock split of Insmed Incorporated's outstanding Common Stock.
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).
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., Elan Corporation, plc, Elan 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).

Exhibit Number	Exhibit Title
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 Elan Pharmaceutical Technologies, a division of Elan Corporation, plc, dated as of April 21, 1999 (previously filed as Exhibit 10.10 to Insmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).
10.7	License Agreement, dated as of April 1, 1993, between Genentech, Inc. and Celtrix Pharmaceuticals, Inc. (previously filed as Exhibit 10.11 to Insmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).
10.8	Purchase Agreement among Insmed, Inc., Insmed Pharmaceuticals, Inc. and certain investors named therein dated January 13, 2000 (previously filed as Exhibit 10.12 to Insmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).
10.9	Form of Warrant of Insmed to be issued pursuant to Purchase Agreement among Insmed Incorporated, Insmed Pharmaceuticals, Inc. and certain investors dated January 13, 2000 (previously filed as Exhibit 10.13 to Insmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).
10.10	Form of Registration Rights Agreement among Insmed Incorporated, Insmed Pharmaceuticals, Inc. and certain investors party to the Purchase Agreement among Insmed Incorporated, Insmed Pharmaceuticals, Inc. and certain investors dated January 13, 2000 (previously filed as Exhibit 10.14 to Insmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).
10.11+	License Agreement, dated as of July 10, 2000, between Insmed Pharmaceuticals, Inc. and Taisho Pharmaceutical Co., Ltd. (previously filed as Exhibit 10.15 to Insmed Incorporated's Registration Statement on Form S-1 (Registration No. 333-46552) and incorporated herein by reference).
10.12	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).
10.13	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).
10.14	Termination Agreement, dated as of February 3, 2003, between Insmed Pharmaceuticals, Inc. and Taisho Pharmaceutical Co., Ltd.
10.15 *	Agreement, dated as of July 25, 2002, between Insmed Incorporated and Avecia Limited.
10.16 *	License and Supply Agreement, dated as of August 28, 2002, between Insmed Incorporated and Pharmacia AB.
21.1	Subsidiaries of Insmed Incorporated (previously filed as Exhibit 21.1 to Insmed Incorporated's Annual Report on Form 10-K for the year ended December 31, 2001 and incorporated herein by reference).
23.1	Consent of Ernst & Young LLP.
99.1	Certification of Geoffrey Allan, Ph.D., Chairman of the Board and Chief Executive Officer of Insmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Exhibit Number	Exhibit Title
99.2	Certification of Kevin P. Tully, Treasurer and Controller (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 2002.

+ The Securities and Exchange Commission has granted confidential treatment with respect to certain information in these exhibits.

* Subject to a request for confidential treatment, certain portions of this agreement have been intentionally ommitted. A complete version of this agreement has been filed separately with the Securities and Exchange Commission.

Exhibit 3.4

Articles of Amendment
to the
Articles of Incorporation, as amended,
of
INSMED INCORPORATED

I.

The name of the corporation is Insmed Incorporated (the "Company").

II.

Article III of the Company's Articles of Incorporation, as amended, shall be amended by the addition of the following additional paragraph after the last paragraph of that Article III:

8. Reverse Stock Split. Simultaneously with the effective date of this amendment (the "Effective Time"), each four shares of the Company's Common Stock, par value $.01 per share, issued and outstanding immediately prior to the Effective Time (the "Old Common Stock") shall, automatically and without any action on the part of the holder thereof, be reclassified as and changed, pursuant to a reverse stock split (the "Reverse Split"), into one share of the Company's outstanding Common Stock (the "New Common Stock"), subject to the treatment of fractional share interests as described below. Each holder of a certificate or certificates which immediately prior to the Effective Time represented outstanding shares of Old Common Stock (the "Old Certificates," whether one or more) shall be entitled to receive upon surrender of such Old Certificates to the Company's Transfer Agent for cancellation, a certificate or certificates (the "New Certificates," whether one or more) representing the number of whole shares of the New Common Stock into and for which the shares of the Old Common Stock formerly represented by such Old Certificates so surrendered, are reclassified under the terms hereof. From and after the Effective Time, Old Certificates shall thereupon be deemed for all corporate purposes to evidence ownership of New Common Stock in the appropriately reduced whole number of shares. No certificates or scrip representing fractional share interests in New Common Stock will be issued, and no such fractional share interest will entitle the holder thereof to vote, or to any rights of a shareholder of the Company. In lieu of any fraction of a share of New Common Stock to which the holder would otherwise be entitled, the holder will receive a cash payment in U.S. dollars equal to such fraction multiplied by four times the average of the closing bid and ask price per share of Common Stock as quoted on The Nasdaq SmallCap Market for the five trading days immediately preceding the Effective Time. If more than one Old Certificate shall be surrendered at one time for the account of the same shareholder, the number of full shares of New Common Stock for which New Certificates shall be issued shall be computed on the basis of the aggregate number of shares represented by the Old Certificates so surrendered. In the event that the Company's Transfer Agent determines that a holder of Old Certificates has not surrendered all his certificates for exchange, the Transfer Agent shall carry forward any fractional share until all certificates of that holder have been presented for exchange such that payment for fractional shares to any one person shall not exceed the value of one share.

If any New Certificate is to be issued in a name other than that in which it was issued, the Old Certificates so surrendered shall be properly endorsed and otherwise in proper form for transfer, and the stock transfer tax stamps to the Old Certificates so surrendered shall be properly endorsed and otherwise in proper form for transfer, and the person or persons requesting such exchange shall affix any requisite stock transfer tax stamps to the Old Certificates surrendered, or provide funds for their purchase, or establish to the satisfaction of the Transfer Agent that such taxes are not payable. From and after the Effective Time, the amount of capital shall be represented by the shares of the New Common Stock into which and for which the shares of the Old Common Stock are reclassified, until thereafter reduced or increased in accordance with applicable law. All references elsewhere in the Articles of Incorporation, as amended, to the "Common Stock" shall, after the Effective Time, refer to the "New Common Stock".

III.

The amendment was proposed by the board of directors and submitted to the shareholders of the Company in accordance with Chapter 9 of Title 13.1 of the Code of Virginia. The designation, number of outstanding shares, and number of votes entitled to be cast by each voting group entitled to vote separately on the amendment are as follows:

Designation	Number of Outstanding Shares	Number of Votes
Common	108,127,568	108,127,568

The total number of undisputed votes cast for the amendment by each voting group was as follows:

Designation	Number of Undisputed Votes for the Amendment
Common	93,583,881

The number of votes cast for the amendment by each voting group was sufficient for approval by that voting group.

IV.

Pursuant to Section 13.1-606 of the Virginia Stock Corporation Act, the effective time and date of this Amendment to the Company's Articles of Incorporation, as amended, shall be 11:59 p.m. on July 28, 2000.

INSMED INCORPORATED

Dated: July 28, 2000 *By: /s/ Geoffrey Allan*

Geoffrey Allan, Ph.D.

Chairman of the Board, President and Chief Executive Officer

Exhibit 10.14

TERMINATION AGREEMENT

THIS TERMINATION AGREEMENT (the "Termination Agreement") is entered into as of this 3rd day of February 2003, but effective as of the Effective Date as set forth below, by and between INSMED PHARMACEUTICALS, INC., a corporation organized under the laws of the Commonwealth of Virginia and having a business address at 4851 Lake Brook Drive, Glen Allen, Virginia 23060 ("Insmed") and TAISHO PHARMACEUTICAL CO., LTD., a corporation organized under the laws of Japan and having a business address at 24-1, Takata 3-chome, Toshima-ku, Tokyo, 170-8633 ("Taisho").

WHEREAS, effective July 10, 2000 Insmed and Taisho entered into a License and Development Agreement ("License Agreement") for the development of D-chiro-inositol; and

WHEREAS, by Amendment dated September 5, 2002 ("the Amendment") Insmed and Taisho agreed to amend the License Agreement to release Taisho from any obligations relating to the use of D-chiro-inositol for the polycystic ovary syndrome indication and agreed on payments due to Insmed; and

WHEREAS, under the License Agreement as amended by the Amendment Taisho had the right to terminate the License Agreement upon six months written notice to Insmed or earlier with the approval of Insmed; and

WHEREAS, by letter dated September 30, 2002 Taisho notified Insmed of its intent to terminate the License Agreement in accordance with the terms of the Amendment; and

WHEREAS Insmed has agreed to an earlier termination subject to the fulfillment by Taisho of certain obligations which are expressly provided in this Termination Agreement and are regarded as all and exclusive obligation of Taisho;

NOW, THEREFORE, in consideration of the foregoing recitals and the covenants and undertakings set forth below and all other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by the parties, Insmed and Taisho hereby agree as follows:

1. Effective upon the date of Insmed's receipt of the payment of $52,500.00 from Taisho ("the Effective Date"), which represents outstanding expenses incurred by Insmed for the prosecution and maintenance of relevant patents in the Territory and was agreed to be paid pursuant to the terms of the Amendment, the License Agreement will be terminated. The Effective Date shall be notified in writing to Taisho upon receipt by Insmed of such payment for the record.

2. Effective as of the Effective Date, Taisho releases, assigns and transfers to Insmed all rights to the Technical Information, New Intellectual Property, Licensed Patents, and other intellectual property which are owned by Insmed and granted by Insmed to Taisho under the License Agreement. Taisho confirms that there are no Technical Information, New Intellectual Property, Licensed Patents, and other intellectual property which are obtained from research

and/or development under the License Agreement and owned or controlled by Taisho except for data and materials which are listed in the affixed Attachment which was prepared through agreement of the parties and which shall be delivered to Insmed after the execution of this Termination Agreement in order for Insmed to use them without any payment to Taisho in the world.

3. The provisions of Articles 5 and 10 of the License Agreement survive the termination of the License Agreement

4. Effective as of the Effective Date, each party releases the other from any and all obligations, monetary or otherwise, under the License Agreement, except for the obligations and agreements which are expressly provided in this Termination Agreement.

IN WITNESS WHEREOF, the parties have caused this Termination Agreement to be executed by their duly authorized officers as of this 3rd day of February 2003 but effective as of the Effective Date as set forth in this Agreement.

INSMED PHARMACEUTICALS, INC.

By: _____
Geoffrey Allan, President and CEO
Date: _____

TAISHO PHARMACEUTICAL CO., LTD.

By: _____
Akira Uehara, President
Date: _____

Exhibit 10.15

THIS AGREEMENT is made this 25th day of July 2002 between:

(1) AVECIA LIMITED, acting through its Avecia Biotechnology business of Hexagon House, Blackley, Manchester, M9 8ZS, England ("Avecia"); and

(2) INSMED INCORPORATED of 4851, Lake Brook Drive, Glen Allen, VA 23060, USA ("Insmed").

WHEREAS

A Avecia has experience and knowledge with regard to process development and manufacture of recombinant proteins.

B Insmed is carrying out research and development in relation to the Product (as defined below) with a view to conducting clinical trials and commercial launch of a new drug.

C Insmed wishes Avecia to carry out a programme for the further development, scale up and manufacture of the End Product to support clinical trials and future commercial launch of new drugs.

D The Feasibility Study (as defined below) was commenced under the Letter of Intent and it is intended that the Feasibility Study, the Development Programme and the GMP Stage (all as defined below) shall be carried out and completed under the terms of this Agreement.

NOW IT IS HEREBY AGREED AS FOLLOWS:

1. Definitions:

Affiliate	any corporation, association or other business entity which directly or indirectly controls, is controlled by or is under common control with Avecia or Insmed and "control" shall mean the legal power to direct or cause the direction of the general management and policies of such entity whether through the ownership of at least 50% of voting securities or capital stock of such business entity or any other comparable equity or ownership interest with respect to a business entity other than a corporation.
Avecia Default	failure by Avecia to progress the Programme (including without limitation failure to use GMP) and any other failure to discharge its obligations hereunder, or negligence or wilful malfeasance by Avecia in carrying out the Programme, except that discovery of a factor which affects the Process or production of the End Product which was not known and could not reasonably have been known at the commencement of the Programme shall not be considered to be an Avecia Default.

Background the Intellectual Property developed	any Intellectual Property owned by or in possession of a party (and to which that party has the necessary rights) at the Commencement Date of this Agreement or Intellectual Property independently of the Programme by any employee of that party without reference to any of the Confidential Information disclosed by the other party.
Cancellation Fee	a sum calculated in accordance with Schedule 7, payable on termination in respect of cancellation of the GMP Stage.
Cell Banks	the Master Cell Bank and the Working Cell Bank together.
Commencement Date	12th November 2001.
Completion	completion of the Programme as defined in Clause 2.2.
Confidential Information	any technical and commercial information relating Information to the Programme and any other information of a confidential nature disclosed (whether disclosed in writing, verbally, by way of sample or by any other means and whether directly or indirectly) by either party ("the Disclosing Party") to the other ("the Receiving Party"), including and without limitation any information relating to the Disclosing Party's business affairs.
Confidentiality Agreement	the confidentiality agreement entered into between the parties dated 10th May 2001.
Defective Product	a quantity of the End Product which does not comply with the appropriate Specification or which has not been manufactured in accordance with ISO9001 or GMP, as appropriate.
Development Programme	the programme for development and scale up of the Process intended to be used during the GMP Stage as outlined in Schedule 5 and as amended in accordance with the provisions of Clause 2.5.
End Product	SomatoKine(R), being a combination of insulin-like growth factor-I (IGF-1) and insulin-like growth factor binding protein-3

	(BP3) or BP3 individually, when produced to Insmed's Specification under Schedule 1 as a drug substance.
Feasibility Study	the study to ascertain the feasibility of developing the existing process to manufacture the End Product foruse in Phase II and Phase III clinical trials and commercial scale as outlined in Schedule 4 and as amended in accordance with the provisions of Clause 2.5.

Force Majeure	any cause beyond the reasonable control of the party in question which for the avoidance of doubt and without prejudice to the generality of the foregoing shall include governmental actions, war, riots, civil commotion, fire, flood, epidemic, labour disputes (excluding labour disputes involving the work force or any part thereof of the party in question), restraints or delays affecting shipping or carriers, currency restrictions and act of God.
GMP	current good manufacturing practice and standards as provided for (and as amended from time to time) in European Community Directive 91/356/EEC (Principles and guidelines of good manufacturing practice for medicinal products) and in the Current Good Manufacturing Practice Regulations to the US Code of Federal Regulations Title 21 as referenced in Schedule 9 in relation to the production of pharmaceutical intermediates and active pharmaceutical ingredients, as interpreted by ICH Harmonised Tripartite Guideline, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients, Q7A and subject to any arrangements, additions or clarifications agreed from time to time between the parties in the QA Agreement.
GMP Stage [REDACTED]	manufacture of the End Product at litre scale in accordance with GMP in Avecia's Advanced Biologics Centre as outlined in Schedule 6 and as amended in accordance with the provisions of Clause 2.5.
Insmed Materials	Products, End Product, rhIGF-1 and rhIGFBP3 protein samples, cell banks and all other associated project materials.
Intellectual Property	all know-how, inventions, discoveries, devices, data, patents, designs, copyrights, or other industrial or intellectual property in all applications therefore.
JPMC	the joint programme management committee set up by Avecia and Insmed to oversee the conduct of the Programme, having the constitution referred to in Clause 2.6.
Letter of Intent	the letter dated 12th November 2001

	confirming the terms on which the Feasibility Study was started by Avecia.
Master Cell Bank	the master cell bank produced during the Development Programme, in accordance with ICH cell substrate guidelines.

Milestones Appendix	the schedule of milestones intended to be achieved during the Programme and attached at Schedules 4, 5 & 6.
New Intellectual Property	Intellectual Property arising during and as a direct result of the Programme.
Nominated Manufacturer	any manufacturer other than Avecia, nominated by or partnered with Insmed to carry out manufacture of the End Product.
pPoP(TM) System	the system for expression of genes in micro-organisms claimed in patent application WO9905297 owned by AstraZeneca AB and licensed (with rights to sublicense) to Avecia under an agreement between Avecia and Zeneca Limited (assigned to AstraZeneca UK Limited) and dated 30th June 1999, and further developed by Avecia though ongoing project work.
Process	the process for manufacture of the End Product.
Products	Insmed's proprietary proteins, the derivatives thereof and the respective DNA coding sequences and constructs, including Dsb-3C protease, Dsb-3C-IGF-I, Ubiquitin-3C-IGF-I, rhIGF-I (hereafter IGF-I), rhIGFBP-3 (hereafter BP-3), and SomatoKine(R), being a combination of insulin-like growth factor-I and insulin-like growth factor binding protein-3.
Programme	the Feasibility Study, the Development Programme and the GMP Stage.
Programme Amendment Order	means a document in the form set out in Schedule 3 detailing changes to the Programme or to the Specification agreed and signed by both parties.
QA Agreement	the document agreed by the parties setting out: (i) the mutually agreed quality standards applicable for the manufacture of the End Product; and (ii) the roles and responsibilities of each party's personnel in relation to quality assurance matters a copy of which is attached at Schedule 2.
Specification	the specification for the End Product to be

manufactured during the Development Programme and GMP Stage and attached at Schedule 1, or such revised specification as may be agreed by the parties in a Programme Amendment Order and in accordance with the QA Agreement.

Technical Transfer	communication of Insmed's existing process for production of the Products to Avecia.
Third Party	any person other than the parties or their respective Affiliates.
Working the Cell Bank(s)	the working cell bank(s) produced during Development Programme or preparatory to clinical drug substance manufacture, in either case subject to GMP.

2. Performance of the Programme

2.1 QA Agreement. Avecia will carry out the work as detailed in the Programme under GMP and its ISO9001 compliant quality system. In order for Avecia to carry out the Programme, each party shall fulfil its responsibilities as set out in the QA Agreement.

2.2 Programme Details. The Programme has three stages and shall be conducted as follows:

(a) Stage 1 - The Feasibility Study

(i) The Feasibility Study commenced on the Commencement Date.

(ii) The Feasibility Study shall be deemed to be complete when Avecia has notified Insmed that it has completed the Feasibility Study and delivered to Insmed the material and documentation set out in the Milestones Appendix in respect of the Feasibility Study, and such performance is mutually agreed by the JPMC.

(b) Stage 2 - The Development Programme.

(i) Following completion of the Feasibility Study, the parties shall jointly determine whether the Feasibility Study has been successful and indicates that there is scope for further development of the Process.

(ii) If the parties agree that the Feasibility Study has been successful, Avecia shall commence the Development Programme, including the production of the Cell Banks in accordance with the requirements set out therefor in Schedule 8.

(iii) Subject to Clause 2.2(b)(iv), the Development Programme shall be complete when Avecia notifies Insmed that it has completed manufacture of the Product in accordance with the Specification at [REDACTED] litre scale, tested such manufactured Product, and provided Insmed with (i) analytical data in a form to be agreed and (ii) revised cost models for manufacture of the

Product at large scale, and such performance is mutually agreed by the JPMC.

(iv) The parties anticipate that further work will need to be carried out during the Development Programme, the exact nature of which is not certain at the date of this Agreement. Such further work shall be carried out subject to agreement under Clause 2.5.

(c) Stage 3 - GMP Stage

(i) Avecia shall commence the GMP Stage following completion of the Development Programme.

(ii) The GMP Stage shall be complete when Avecia notifies Insmed that it has completed manufacture of the End Product in accordance with the Specification in its Advanced Biologics Centre at [REDACTED] litre scale, tested such manufactured End Product, delivered the End Product so manufactured in accordance with Clause 4 and provided Insmed with (i) a certificate of analysis showing that the End Product manufactured during the GMP Stage accords to the Specification and (ii) a batch production record on such activities, and such performance is mutually agreed by the JPMC.

(iii) The Programme shall be complete when the GMP Stage has been completed, and the parties have agreed whether the Master Cell Bank is to be shipped to Insmed or whether it is to be stored by Avecia under Clause 4.2.

2.3 Conduct of the Programme. For the avoidance of doubt, it shall not be considered a breach of this Agreement by Avecia if an objective of the Programme is not achieved:

(a) so long as Avecia uses its best commercial endeavours to perform its obligations; or

(b) due to delay caused or contributed to by Insmed.

The parties acknowledge that, having regard to the fact that the work to be performed hereunder is by its nature developmental, Avecia does not guarantee to Insmed the achievement of each individual milestone, or a successful outcome for the overall Programme.

2.4 Information Exchange. The parties shall conduct regular information exchanges in a manner to be agreed between the parties to enable ongoing review of the Programme and its continuation. Each party shall nominate a key point of contact for such information exchange. At the date of this Agreement, the points of contact are as follows:

(a) for Avecia - Dr I Hodgson, Project Manager; and

(b) for Insmed - Dr. Andreas Sommer , Project Manager.

2.5 Programme Amendment Orders. The parties may agree to vary any element of the Programme, including the Specification or sums to be paid under Clause 3, provided that such variation is made in writing in a Programme Amendment Order. The parties recognise that, in the event that Insmed requires Avecia to carry out additional or different development work to that specified in Schedules 4 & 5, the work carried out under the Programme may require changes which may cause a change in the payments set out in Schedules 4, 5 or 6 appended hereto, as appropriate. The Specification shall be subject to review and possible revision in accordance with this Clause 2.5, in light of process experience or pursuant to a requirement of a regulatory authority.

2.6 Joint Programme Management Committee. Insmed and Avecia shall each appoint at least two (2) managers to the JPMC. The number of members appointed by each of Insmed and Avecia may be more than two, but shall always be an equal number appointed by each party. The committee shall regularly review progress towards agreed milestones and resolve any issues arising due to variance from agreed deliverables that cannot be resolved in the normal course of project team meetings. The JPMC shall make earnest, timely efforts to resolve issues to mutual satisfaction and agree upon such Programme Amendment Orders as are needed to advance the Programme.

If the JPMC cannot reach mutually agreeable resolution on an issue(s) affecting critical deliverables or associated payments, the matter shall be referred by the JPMC to the CEO and VP of the respective parties under Clause 19.2 for final resolution. At the date of this Agreement, the JPMC members are as follows:

(a) for Avecia - Dr I Hodgson, Project Manager; Mr. Ryan Scanlon, Key Account Manager; and Mr. David Byrom, Project Manager.

(b) for Insmed - Robert Falconer, VP Technical Operations; Dr. Steven Ye, Director Biologics Programme; and Dr. Andreas Sommer, Principal Scientist.

2.7. Technical Assistance. During the Programme and following Completion, Avecia will offer reasonable assistance to Insmed in respect of Insmed's regulatory filing activities for the End Product and the Process both during and after Completion, subject to payment by Insmed of Avecia's reasonable expenses agreed to in advance and in writing between the parties.

2.8 Future Manufacture. At the date of this Agreement, it is the parties' intention that Avecia shall carry out manufacture of the End Product in Avecia's Multiplex facility on behalf of Insmed at a commercial scale following Completion for use in Phase III clinical trials and commercial launch of the End Product. The parties agree to continue negotiations in good faith with a view to agreeing the terms of an agreement to

govern manufacture by Avecia and supply to Insmed of Insmed's and any of Insmed's licensees' requirements for the End Product as soon as possible following signature of this Agreement.

3. Payments

3.1 Total Payment Due. In consideration of Avecia carrying out the research, development, manufacturing and other activities pursuant [REDACTED] to the Programme, Insmed shall pay to Avecia the sum of [REDACTED] US Dollars (US$[REDACTED]).

Such sum has been paid and shall be paid in the instalments set out in Schedules 4, 5 and 6 when Avecia notifies Insmed that the Programme milestones, with associated benchmarks set out in those Schedules have been achieved, and such achievement is mutually agreed by the JPMC.

3.2 Stage 1 - Feasibility Study, Major Milestones
(Details and Payments in Schedule 4)
(a) Commencement Fee on Commencement Date. (Paid)

(b) Mutually agreed completion of the Technical Transfer to enable development work under the Feasibility Study to commence. (Paid)

(c) Completion of construct re-engineering for IGF-I, BP3 and associated process improvements - see Schedule 4 for details

3.3 Stage 2 - Development Programme, Major Milestones
(Details and Payments in Schedule 5)
(a) Completion of four (4) replicate runs at [REDACTED] litre scale.

(b) Completion of downstream purification process development.

(c) Completion of duplicate runs on downstream purification.

(d) Completion of new construct description on fermentation batch records.

(e) Completion of development and scale up of the Process by carrying out duplicate runs at [REDACTED] litre scale, with analytical data in a form to be agreed.

(f) Completion of refined cost sensitivity models and the final feasibility report.

3.4 Stage 3 - the GMP Stage, Major Milestones (Details and Payments in Schedule 6)
(a) Preparation of Avecia's Advanced Biologics Centre and GMP documentation and transfer of the Process in order to carry out development work for production of the End Product in Avecia's Advanced Biologics Centre.

(b) GMP manufacture of the End Product.

3.5 Excluded Items. The sums set out in Schedules 4, 5, and 6, pursuant to Clauses 3.1 - 3.4 above do not include:

(a) any capital costs for new process specific equipment which may be required to operate the Process; or

(b) costs actually incurred by Avecia for major consumable items (including, without limitation, costs associated with chromatography resins, filtration membranes, and chemical raw material costs) involved in the manufacturing process.

Avecia shall obtain Insmed's approval in writing prior to incurring such costs in Clauses 3.5 (a) and (b). If such approval is given, the provisions of Clause 3.6 will apply.

3.6 Fees for Excluded Items. Avecia shall invoice Insmed for further sums for development work and consultancy to cover management, administration and quality control activities. These further sums shall equal the cost which Avecia incurs in respect of capital items and consumables under Clauses 3.5(a) and (b), plus, in the case of consumables intended to be used during the GMP Stage, a sum equivalent to [REDACTED]% of the cost of such consumables and in the case of capital items requiring validation and installation, a sum equivalent to [REDACTED]% of the cost of such capital items, subject to Insmed approval in advance of the associated installation and validation expenses for capital items.

3.7 Issue of Invoices. Avecia shall issue invoices for the sums set out in Schedules 4, 5, and 6, pursuant to Clauses 3.1 to 3.4 and 3.6 above as such sums fall due and Insmed shall pay such sums within 30 days of the date of the relevant invoice.

3.8 Bank Account Details. All amounts payable to Avecia under this Agreement shall be paid in US dollars and credited by bank transfer to Chase Manhattan Bank, New York, for Account Chase Manhattan Bank, London CHASGB2L), in favour of Avecia Limited trading as Avecia Biocides, Effects and Fine Chemicals. Account Number 23075411.

3.9 Value Added Tax. All sums payable under this Agreement are stated exclusive of any VAT which may be payable and which shall be for the account of Insmed.

4. Delivery of End Product and Cell Banks

4.1 Delivery of Material. Subject to the provisions of Clauses 4.3 and 4.4 in relation to storage, delivery of all material, including the End Product manufactured during the Programme and reserve samples of the Cell Banks, will be made EXW Avecia's Billingham facility (Incoterms 2000).

4.2 Packing. If requested, Avecia shall arrange for packing of the material delivered under Clause 4.1 at Insmed's expense and shall comply with all reasonable requirements of Insmed, including GMP in packing the material. Risk and title in respect of all material supplied to Insmed under this Agreement shall pass on delivery at Avecia's Billingham facility.

4.3 Storage of the End Product. Insmed shall have an option to request that Avecia store the End Product, subject to written agreement on the terms of such storage, including fees and liability for such storage provided that, in the event that Insmed exercises such option:

(a) storage shall be at Insmed's expense under conditions to be agreed in writing; and

(b) storage shall be at Avecia's risk, unless, despite storage in accordance with the conditions agreed under Clause 4.3(a), the End Product alters or deteriorates from its condition at the start of such storage; and

(c) risk of loss in the End Product shall pass in the event of delivery to Insmed under Clause 4.1 but title will pass on the later of (i) Avecia's notification that the End Product has passed the quality assurance release protocols set out in the QA Agreement or (ii) agreement between the parties that Avecia will store the End Product.

In the absence of agreement on the terms of such storage, Avecia shall not be obliged to store the End Product and shall deliver it to Insmed subject to the provisions of Clauses 4.1 and 4.2.

4.4 Storage of Cell Banks. On completion of the Programme, Insmed shall have an option to request that Avecia store the Cell Banks, subject to written agreement on the terms of such storage, including fees and liability for such storage provided that, in the event that Insmed exercises such option:

(a) storage shall be at Insmed's expense under conditions to be agreed in writing; and

(b) storage shall be at Avecia's risk, unless, despite storage in accordance with the conditions agreed under Clause 4.3(a), the Cell Banks alter or deteriorate from their condition at the start of such storage; and

(c) risk of loss in the Cell Banks shall pass in the event of delivery to Insmed under Clause 4.1 but title shall immediately vest in Insmed upon creation of the Cell Banks; and

(d) Avecia shall submit a reserve sample of both the Master Cell Bank and Working Cell Bank(s) to Insmed, in accordance with agreed written instructions as to quantities, shipment and storage conditions, within thirty (30) days of their creation, at Insmed's risk.

In the absence of agreement on the terms of such storage, Avecia shall not be obliged to store the Master Cell Bank or the Working Cell Bank and shall deliver them to Insmed subject to the provisions of Clauses 4.1 and 4.2.

5. Intellectual Property

5.1 Ownership of Background Intellectual Property. Nothing in this Agreement shall affect the ownership by either party of its Background Intellectual Property.

5.2 Licence to Intellectual Property for the Programme. Insmed grants to Avecia a non-exclusive, royalty-free licence to use Insmed's Background Intellectual Property and its New Intellectual Property whilst this Agreement remains in force for the sole purpose of carrying out the Programme.

5.3 New Intellectual Property - pPOP(TM) Technology. All New Intellectual Property which relates to the pPOP(TM) Technology, except where such New Intellectual Property relates solely to the Products or processes solely for the manufacture of the Products, shall be owned by Avecia.

5.4 New Intellectual Property - Other. All New Intellectual Property not owned by Avecia under Clause 5.3 shall be owned by Insmed.

5.5 New Intellectual Property - Not Clearly Within Scope of Clauses 5.3 or
5.4. In respect of New Intellectual Property not clearly falling within the scope of either of Clauses 5.3 or 5.4, the parties shall negotiate in good faith to determine the ownership of such New Intellectual Property

5.6 Further Assistance. Each party shall, and shall ensure that its employees shall, at the expense of the party owning the New Intellectual Property, perform all acts and execute all instruments necessary to vest in the owning party all rights, title and interest in the registrations together with all patents and patent applications or otherwise for such New Intellectual Property. All legal fees, costs and expenses connected with the filing, prosecution and maintenance of a patent or other protection shall be borne and paid by the party owning such Intellectual Property.

5.7 Utilisation of Third Party Intellectual Property. In the event that Avecia considers it expedient for the Programme or the Process to utilise Intellectual Property belonging to a Third Party, Avecia shall first notify Insmed in writing and obtain Insmed's written consent for utilisation of such Third Party Intellectual Property in order that terms for access to such Third Party Intellectual Property may be agreed either between such Third Party and Avecia or between such Third Party and Insmed.

5.8 Utilisation of pPOP(TM) Technology by Insmed or a Nominated Manufacturer. If it is agreed to use the pPoP(TM) Technology at the completion of the Development Programme, the specific details of the licence from Avecia to Insmed to enable Insmed to operate the Process using the pPoP(TM) Technology are to be finalised and the

following guidelines shall apply in respect of payment for access thereto: a royalty shall be payable at a rate to be negotiated by the parties relative to sales potential estimated at the completion of Insmed's Phase III clinical programme on the net sales value of sales of the Products manufactured using the Process by Insmed or a Nominated Manufacturer. Such licence shall include a licence under New Intellectual Property owned by Avecia under Clause 5.3.

5.9 Utilisation of Avecia's Background Intellectual Property. In the event that Avecia decides that it considers it expedient for the Process to utilise part of Avecia's Background Intellectual Property to which Avecia would normally only grant access to a Third Party under a licence, Avecia shall within 30 days of such decision notify Insmed in writing and obtain Insmed's written consent for utilisation of such Background Intellectual Property in the Process. In the event that Insmed consents to use of such Background Intellectual Property, the provisions of Clause 5.10 shall apply. No royalty is payable for Insmed Product manufactured directly by Avecia.

5.10 Provision of Technical Assistance and Access to Avecia's Intellectual Property. If:

(a) following Completion, or at any time while this Agreement is in effect Avecia is unable to carry out the Programme due to Force Majeure, or following termination of this Agreement for any reason, Insmed or a Nominated Manufacturer requires Avecia's technical assistance; and/or

(b) at any time while this Agreement is in effect Avecia is unable to carry out the Programme due to Force Majeure, and Insmed or Nominated Manufacturer requires a licence under Avecia's Background Intellectual Property following consent to the use of such Background Intellectual Property in the Process and under New Intellectual Property owned by Avecia under Clause 5.3, in order to complete or continue the Programme during the existence of such Force Majeure; and/or

(c) following Completion or following termination of this Agreement for any reason Insmed or a Nominated Manufacturer requires a licence under Avecia's Background Intellectual Property following consent to the use of such Background Intellectual Property in the Process and under New Intellectual Property owned by Avecia under Clause 5.3

to operate the Process and/or manufacture the End Product, then such assistance and/or access shall be provided to Insmed or such Nominated Manufacturer by Avecia subject to agreement of reasonable commercial terms between Insmed and Avecia. Any such negotiations shall be carried out between the parties in good faith. The parties when agreeing the terms of the licence to Avecia's Background Intellectual Property shall take any benefit derived by Avecia from its use of the New Intellectual Property under the licence granted under Clause 5.11 below into consideration.

5.11 Licence under Insmed New Intellectual Property. Insmed hereby grants to Avecia a royalty-free, irrevocable, non-exclusive, world-wide licence, with power to sub-license, under process related New Intellectual Property owned by Insmed under Clause 5.4 for use other than for production of the Products.

6. Warranties, Liability and Indemnity

6.1 General Warranty. Each party warrants to the other that:

(a) it has the necessary right and authority to enter into this Agreement and that to the best of its knowledge at the date of this Agreement it is the rightful owner or licensee of all of its Background Intellectual Property; and

(b) to the best of its knowledge at the date of this Agreement, the use of its Background Intellectual Property made available by it to the other party pursuant to this Agreement for the purposes set out in this Agreement will not infringe the Intellectual Property of a Third Party.

6.2 Warranty and Indemnity in respect of pPOPTM Technology. Avecia warrants that it is a licensee under patent application WO9905297 and national applications derived therefrom. Avecia shall be liable for and indemnify Insmed against any liability, loss, claim, damage, proceedings and costs whatsoever arising out of any breach of the warranty under this Clause 6.2.

6.3 Indemnity. Each party ("the First Party") shall be liable for and indemnify the other ("the Second Party") against any liability, loss, claim, damage, proceedings and costs whatsoever arising out of an IP Infringement (as defined below). In the event of an IP Infringement, the Second Party shall:

(a) give the First Party prompt written notice of any such claim or action;

(b) (i) give the First Party the sole conduct of the defence and settlement to any claim or action in respect of the IP Infringement, provided, however, that the First Party shall not accept any settlement which imposes liability not covered by this indemnification or restrictions on the Second Party or which would otherwise result in expense to the Second Party without the Second Party's prior written consent, which consent shall not be unreasonably withheld or delayed; and

(ii) and shall not at any time admit liability or otherwise settle or compromise or attempt to settle or compromise the said claim or action except upon the express instructions of the First Party; and

(c) act in accordance with the reasonable instructions of the First Party and give the First Party such assistance as it shall reasonably require in respect of the conduct of such defence.

For the purposes of this clause, the expression "IP Infringement" shall mean:

(i) where the First Party is Insmed, an allegation or claim by a Third Party that Avecia's use of Background Intellectual Property provided by Insmed in the performance of the Programme infringes such Third Party's Intellectual Property rights; and

(ii) where the First Party is Avecia, an allegation or claim by a Third Party that Avecia's use on behalf of Insmed of Background Intellectual Property provided or otherwise used by Avecia in connection with the Programme infringes such Third Party's Intellectual Property rights.

6.4 Liability for the End Product

(a) Avecia's liability to Insmed in respect of the End Product manufactured for Insmed shall be limited to ensuring that such End Product complies with the Specification and is manufactured in accordance with ISO 9001 and GMP (as appropriate).

(b) In the event that the End Product to be delivered to Insmed is a Defective Product, such Defective Product shall not be delivered to Insmed. The following provisions shall apply in the respect of Defective Product:

(i) In the event that the End Product to be delivered to Insmed is a Defective Product as a result of an Avecia Default, Avecia shall either rework the Defective Product if Insmed consents to such rework, or manufacture a quantity of the End Product to replace the Defective Product as soon as reasonably practicable (and in no event more than 90 days after Avecia realises that such End Product is Defective Product) and at no further cost to Insmed.

(ii) In the event that the End Product to be delivered to Insmed is a Defective Product other than due to an Avecia Default, the parties shall meet to discuss availability of Avecia's Advanced Biologics Centre for rework of the Defective Product if Insmed consents to such rework, or manufacture of a quantity of the End Product to replace the Defective Product and, subject to Clause 2.5, agree on a revised period during which such rework or manufacture of replacement End Product will take place and the amount payable by Insmed to Avecia in respect of such rework or manufacture.

(c) Subject to Clauses 6.4(d) and (e), Avecia shall not have any liability whatsoever resulting from, and Insmed shall fully indemnify Avecia against all claims, suits, actions, demands, liabilities, expenses and/or losses (including reasonable legal fees) suffered by any Third Party and brought or made against Avecia, its directors, officers or employees, and against all costs incurred in connection therewith, arising out of or resulting from the use of the End Product following delivery.

(d) If:

(i) a Defective Product is delivered to Insmed by Avecia and such Defective Product is a Defective Product as a result of an Avecia Default; or

(ii) a Third Party claim arises with respect to an End Product as a result of Avecia's gross negligence or wilful malfeasance

then Insmed shall not have any liability whatsoever resulting from use of such Defective or End Product, and Avecia shall fully indemnify Insmed against all claims, suits, actions, demands, liabilities, expenses and/or losses (including reasonable legal fees) suffered by any Third Party and brought or made against Insmed, its directors, officers or employees, and against all costs incurred in connection therewith, arising out of or resulting from the use of such Defective Product or End Product.

(e) Avecia's liability to indemnify Insmed under Clause 6.4(d) in respect of use of Defective Product or End Product shall cease in respect of continuing use by Insmed of the Defective Product or End Product in question following either:

(i) notification by Avecia to Insmed that the End Product delivered to Insmed is a Defective Product; or

(ii) Insmed becoming aware that the End Product delivered to Insmed is a Defective Product; or

(iii) Insmed receiving notification that the End Product is the subject of a Third Party claim.

(f) Insmed shall not have any liability whatsoever, and Avecia shall be responsible for replacement at cost, of any raw materials, intermediates or End Product lost or stolen within Avecia's own premises prior to delivery of End Product ordered by Insmed, excluding normal in-process losses consistent with GMP manufacture and prior process history.

(g) Insmed shall not be liable whatsoever for raw materials or consumable items purchased by Avecia in excess of the needs of End Product ordered by Insmed, consistent with GMP, with the exception of specific cases requiring long lead times or

minimum quantity orders, which shall be approved in writing in advance by Insmed.

6.5 Liability for the Process. Liability in respect of use or operation of the Process (or any part of the Process), by or on behalf of Insmed shall rest solely on Insmed, except to the extent that Avecia is required to indemnify Insmed in accordance with Section 6.2 or 6.3(e) above or except to the extent that such liability arises from a Third Party claim for property damage or personal injury arising from Avecia's failure to operate the Process in accordance with mutually agreed batch records and standard procedures or methods. Insmed shall indemnify Avecia against any liability, loss, damages, costs, legal costs, professional and other expenses whatsoever incurred or suffered by Avecia arising out of or in respect of use or operation of the Process (or any part of the Process) by or on behalf of Insmed (except to the extent that such loss, damages, costs, legal costs, professional and other expenses arise from a Third Party claim for property damage or personal injury arising from Avecia's failure to operate the Process in accordance with mutually agreed batch records), unless otherwise specifically provided for in any subsequent manufacturing agreement between the parties or Avecia is required to indemnify Insmed in accordance with Section 6.2 or 6.3(e) above.

6.6 Limitation on Liability. Subject to the unlimited indemnity provisions under Clauses 6.1, 6.2, 6.3, 6.4, liability for consequential losses under Clause 6.7, and breaches of confidentiality under Section 7, Avecia's total liability (whether for breach of contract, negligence, breach of statutory duty and/or other tort, or otherwise) in connection with or as a result of the work carried out under this Agreement shall be limited to the aggregate amount received by Avecia from Insmed under this Agreement during the period of twelve months prior to such liability arising.

6.7 No Liability for Indirect Losses. Neither party shall be liable to the other for any indirect, consequential or special loss, loss of profits or damage howsoever arising, excluding:

(a) all IP Infringement indemnifications;

(b) product liability claims arising from Avecia delivering Defective Product; or

(c) breaches of confidentiality.

7. Confidentiality

7.1 Maintenance of Confidentiality. In consideration of the Disclosing Party disclosing the Confidential Information to the Receiving Party, the Receiving Party hereby undertakes to maintain confidential all such Confidential Information and it will accordingly not directly or indirectly use any of the Confidential Information in whole or in part save for the purposes envisaged in this Agreement or disclose any of the Confidential Information to any Third Party other than under and in

accordance with the terms of Clauses 7.6, 7.7 or 7.8.

7.2 Use of Insmed Materials. Insmed Materials and project documentation conveyed from Insmed to Avecia shall be used solely for the Programme and held in Avecia's custody, in accordance with the provisions of this Clause 7. Conveyance of any Insmed Materials or project documentation from Avecia to any party other than Insmed requires the express written approval of Insmed.

7.3 Return or Destruction of Insmed Materials. Avecia agrees to either return or send all Insmed Materials and project documentation containing Insmed's Confidential Information to Insmed or, if Insmed agrees, certify that such Insmed Materials and project documentation have been destroyed within forty-five (45) days of Completion or after termination under Clause 8, subject to payment of any sums owed to Avecia under Clauses 3 or 8. Nothing in this Agreement is to be construed as permitting the granting of any contractual ownership rights, either of Insmed Materials, project documentation or Intellectual Property, to anyone without written authorisation from Insmed, except as expressly provided herein to Avecia.

7.4 Exceptions. The foregoing restrictions on the Receiving Party shall not apply to any Confidential Information which:

(a) the Receiving Party can prove was already in its possession and at its free disposal before the disclosure hereunder to it;

(b) is hereafter disclosed to, purchased or otherwise legally acquired by the Receiving Party by or from a Third Party who has not derived it directly or indirectly from the Disclosing Party under an obligation of confidentiality;

(c) is or becomes available to the public whether in printed publications or otherwise through no act or default of the Receiving Party in violation of this Clause 7; or

(d) the Receiving Party can prove to the reasonable satisfaction of the Disclosing Party has been developed independently of the Programme by the Receiving Party without reference to any of the Confidential Information disclosed by the Disclosing Party.

7.5 Exercise of Reasonable Precautions. In order to secure the obligations set out in this Clause 7 the Receiving Party agrees to exercise every reasonable precaution to prevent and restrain the unauthorised disclosure and use of information subject to confidentiality, including without limitation restricting access to such information to such of its employees as are bound to keep such information confidential and need to have such access for the purpose of this Agreement.

7.6 Disclosure to Nominated Manufacturer. Insmed shall be entitled to reveal Confidential Information of Avecia to a Nominated Manufacturer, provided that Insmed either:

(a) does so under confidentiality obligations no less onerous than those contained in this Clause 7; or

(b) Insmed procures the entry of such the Nominated Manufacturer into a confidentiality agreement with Avecia directly.

7.7 Disclosure to Affiliates. Either party may disclose Confidential Information to its Affiliates or receive Confidential Information through its Affiliates, and each party confirms that its Affiliates have been made aware of the obligations contained in this Agreement and agree to be subject to confidentiality obligations no less onerous than those contained in this Agreement. Any breaches of the obligations of confidentiality contained in this agreement by such Affiliate shall be treated as a breach of such obligations by the party making the disclosure to or receiving through the Affiliate.

7.8 Disclosure to Courts or by Law or Other Rules. Nothing in this Clause 7 shall preclude disclosure of any Confidential Information required by any court entitled by law to disclosure of the same, or which is required by law to be disclosed, provided that the Receiving Party promptly notifies the Disclosing Party when such requirement to disclose has arisen, to enable the Disclosing Party to seek an appropriate protective order and to make known to the said court the proprietary nature of the Confidential Information and to make any applicable claim of confidentiality in respect thereof. The Receiving Party agrees to co-operate in any appropriate action which the Disclosing Party may decide to take. If the Receiving Party is advised to make a disclosure in accordance with this Clause 7.8 it shall only make a disclosure to the extent to which it is obliged.

7.9 Survival of Obligations. The provisions of this Clause 7 shall survive termination or expiry of this Agreement and shall continue for a period of ten years from the date of that termination or expiry.

7.10 Continuation of the Confidentiality Agreement. The parties shall remain bound by the obligations in the Confidentiality Agreement, but in the event of any conflict between the terms of the Confidentiality Agreement and the terms of this Agreement, the latter shall prevail.

8. Duration and Termination

8.1 Duration. This Agreement shall be deemed to have commenced on the Commencement Date and shall continue until Completion unless terminated in accordance with the provisions of Clause 8.2.

8.2 Termination. Subject to Clause 9, this Agreement may be terminated in the following ways:

(a) by mutual agreement at any time prior to Completion in the event that both parties agree that the Programme is not technically feasible;

(b) by Insmed at any time by giving written notice to Avecia;

(c) by either party forthwith if the other is in breach of this Agreement and does not rectify such breach within 30 days of receipt of written notice from the first party requiring rectification of the breach; or

(d) by either party forthwith upon written notice if the other has a liquidator, receiver, manager receiver or administrator appointed, or ceases to continue trading or is unable to pay debts as defined in Section 227 of the Insolvency Act 1986 (England and Wales) or the equivalent occurs in any jurisdiction in which the other is resident or carried on business.

9. Consequences of Termination

9.1 Consequences. In the event of termination under Clause 8 above:

(a) Insmed shall pay to Avecia all sums payable up to the date of termination but not yet paid;

(b) if Avecia terminates for Insmed's unremedied breach or insolvency under Clauses 8.2(c) and (d), or if the Agreement is terminated by mutual agreement under Clause 8.2(a), or if Insmed terminates on notice under Clause 8.2(b), any moneys paid by Insmed to Avecia up to the date of termination shall be non-refundable;

(c) if Avecia terminates for Insmed's unremedied breach or insolvency under Clauses 8.2(c) and (d), or if the Agreement is terminated on mutual agreement under Clause 8.2(a), or if Insmed terminates on notice under Clause 8.2(b), Insmed shall pay to Avecia:

(i) all reasonable costs already incurred by Avecia in accordance with the Agreement at the date of termination or costs incurred by Avecia after termination which could not reasonably be avoided; provided, however, that in no event shall the sum of the amounts payable to Avecia under 9.1(a) and (c) and the amounts previously paid to Avecia hereunder exceed the total amount that would have been paid to Avecia if the Agreement had not been terminated and Avecia had performed this Agreement in full; and

(ii) the Cancellation Fee (except if the Agreement is terminated on mutual agreement under 8.2(a)).

(d) if Insmed terminates for Avecia's unremedied breach or insolvency under Clauses 8.2(c) or (d) above, Avecia shall refund to Insmed any monies paid to Avecia, less an agreed

sum in respect of work done by Avecia and not affected by the breach, taking into consideration the payments set out in Clause 3 and in the absence of agreement upon such sum the provisions of Clause 19 shall apply.

9.2 Acquired Rights. Termination or expiry of this Agreement, for whatever reason, shall not prejudice the acquired rights of either party, including the right to payment for the Programme pursuant to Clause 3 (subject to Clause 9.1).

9.3 Survival. The provisions of Clauses 3, 5, 6, 7 - 9, 11 - 17 and 19 shall survive the termination or expiry of this Agreement.

10. Independent Contractor

Nothing in this Agreement shall create, or be deemed to create, a partnership or the relationship of principal and agent or employer and employee between the parties. Each party agrees to perform under this Agreement solely as an independent contractor.

11. Entire Agreement

This Agreement together with the Confidentiality Agreement contains the entire agreement between the parties and supersedes any previous agreements (including the Letter of Intent) relating to the Programme and any understandings between the parties with respect thereto.

12. Announcements And Publicity

Either of the parties may make an official press release, announcement or other formal publicity relating to the transactions which are the subject of this Agreement, or any ancillary matter, unless the other party reasonably objects to the making of such publication. The party wishing to make such release, announcement or publicity shall provide a copy of the text thereof to the other party prior to release and the other party shall raise any objections as soon as possible but not later than fourteen days following receipt.

13. Assignment

This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective legal successors but shall not otherwise be assignable by either party, without the prior written consent of the other party, which consent shall not be unreasonably withheld, provided that either party may assign this Agreement without consent by notice in writing to the other party, to its affiliates, or to a purchaser of the whole or part of the business to which this Agreement relates.

14. Variation

No variation or amendment of this Agreement shall bind either party unless made in writing in the English language and agreed to in writing by duly authorised officers of both parties.

15. Illegality

If any provision of this Agreement is agreed by the parties to be illegal, void or unenforceable under any law that is applicable hereto or if any court of competent jurisdiction in a final decision so determines, this Agreement shall continue in force save that such provision shall be deemed to be excised herefrom with effect from the date of such agreement or decision or such earlier date as the parties may agree.

16. Waiver

A failure by either party hereto to exercise or enforce any rights conferred upon it by this Agreement shall not be deemed to be a waiver of any such rights or operate so as to bar the exercise or enforcement thereof at any subsequent time or times.

17. Notices and Communications

17.1 Formal Notices. Any formal notice required or permitted under this Agreement shall be in writing which may take the form of a letter or facsimile and shall be sent by prepaid post, facsimile, or hand delivery (including messenger service). The addresses for any such notice or other communication shall be those stated on the first page of this Agreement.

17.2 Other Communications. In addition to the methods set out in Clause 17.1, any other communications between the parties may be made by telephone or by email.

17.3 Change of Address. Any party may, at any time by written notice to the other parties, change the address or the facsimile numbers to which notices or other communications shall be sent. All notices and other communications shall have been duly given or made (i) when delivered by hand (including by messenger service) upon delivery or (ii) when delivered by post upon delivery or (iii) when faxed upon receipt of a legible copy by recipient and production of a satisfactory transmission report by sender confirming transmission of the fax in full to the appropriate number by the fax machine which sent the fax.

18. Force Majeure

Neither party shall be liable to the other party in any manner whatsoever for any failure or delay in performing its obligations under this Agreement if and to the extent, and for the duration, that such is due to Force Majeure.

Without prejudice to Clause 8, any said failure or delay shall not give either party the right to terminate this Agreement except, and to the extent that such Force Majeure continues for a period exceeding three (3) months. Termination as a result of Force Majeure shall take effect as if the Agreement had been terminated by mutual agreement under Clause 8.2(a). Insmed shall not be entitled to relief under this Clause 18 for any delay or failure in performing any of its payment obligations under this Agreement, or in the event of failure of the End Product in clinical trials.

19. Law and Jurisdiction

19.1 Governing Law. This Agreement is governed by and shall be construed and interpreted in accordance with, and any arbitration or court action hereunder shall apply, the laws of the State of New York. Any proceedings between the parties shall be conducted in the English language.

19.2 Reference to Parties' Senior Representatives. Prior to any dispute, difference or disagreement concerning this Agreement proceeding to litigation through the Court pursuant to Clause 19.1 the parties shall seek first to resolve the matter via the Joint Programme Management Committee (Clause 2.6) without delay. If resolution is not reached within fifteen days, the matter shall be referred to the Vice-President, Avecia Fine Chemicals and the CEO of Insmed.

19.3 Arbitration. Any matter or dispute arising out of or in connection with this Agreement which is not able to be resolved pursuant to Clause 19.2 shall be finally settled by commercial arbitration to be held in the State of New York. In appointing arbitrators, the parties shall consider the appointment of arbitrators capable of making decisions on the technical aspects of the Programme.

19.4 Interim Steps. Neither of the parties shall be deemed to be precluded from taking such interim formal steps as may be considered necessary to protect such party's position while the procedures referred to in Clauses 19.2 and 19.3 are pursued.

19.5 Other Proceedings. Notwithstanding anything contained in this Clause 19 to the contrary, each party shall have the right to institute judicial proceedings against the other party or anyone acting by, through or under such other party, in order to enforce the instituting party's rights hereunder through reformation of contract, specific performance, injunction or similar equitable relief.

IN WITNESS WHEREOF, the authorised representatives of the parties have executed this Agreement on the date written at the top of this Agreement.

For and on behalf of AVECIA LIMITED

Signature
Name
Position

For and on behalf of INSMED INCORPORATED.

Signature
Name
Position

Exhibit 10.16

LICENSE AND SUPPLY AGREEMENT

LICENSE AND SUPPLY AGREEMENT (this "Agreement") by and between PHARMACIA AB, a Delaware corporation ("Pharmacia"), and INSMED INCORPORATED, a Virginia corporation ("Insmed"), dated as of August 28, 2002 (the "Effective Date").

Recitals

WHEREAS, since 1995, Pharmacia and its Affiliates (defined below) have been engaged in the business of providing the compound known as IGF-1 for the treatment of the short stature of Growth Hormone Insensitivity Syndrome (also known as Laron Dwarfism) to doctors treating the Patients (defined below);

WHEREAS, in connection with the provision of IGF-1 to the Patients, Pharmacia obtained certain rights from [REDACTED] ("[REDACTED]") and Pharmacia and its Affiliates have obtained certain regulatory approvals for IGF-1 and related information as part of Pharmacia's regulatory dossier;

WHEREAS, Insmed has the expertise, through its relationship with a third party contract manufacturer, to manufacture IGF-1 and SomatoKine; and

WHEREAS, Pharmacia desires that Insmed assume the responsibility for providing IGF-1 to the Patients, and Insmed is willing to assume such responsibility in exchange for an exclusive license to Pharmacia's IGF-1 regulatory dossier and an exclusive sublicense under the [REDACTED] Rights (defined below), subject to the terms and conditions of this Agreement.

NOW THEREFORE, in consideration of the premises and the mutual promises of the parties set forth herein, and intending to be legally bound, the parties agree as follows:

1. Certain Definitions.

(a) "Affiliate" means, with respect to any party, its respective direct or indirect parent company, if any, and any company, firm or other entity which is owned or controlled, directly or indirectly, by said party or by its parent company, but only for so long as said ownership or control shall continue. The term "control" means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a company, firm, or other entity, whether through the ownership of at least fifty percent (50%) of voting securities or at least fifty percent (50%) of the equity interest of non-corporate entities, by contract or otherwise.

(b) "[REDACTED] Agreement" means the License and Development Agreement, dated [REDACTED], between Pharmacia (formerly Kabivitrum AB) and
[REDACTED] (formerly [REDACTED]). A copy of the [REDACTED] Agreement is attached hereto as Appendix III.

(c) "[REDACTED] Rights" means the rights under the Patents, the Organism and the Technical Information (as such terms are defined in the
[REDACTED] Agreement) granted by [REDACTED] to Pharmacia pursuant to the
[REDACTED] Agreement.

(d) "[REDACTED] Agreement" means the Assignment Agreement, dated as of [REDACTED], between Pharmacia and [REDACTED] pursuant to which Pharmacia assigned certain rights relating to IGF-1 to [REDACTED]. A copy of the
[REDACTED] Agreement is attached hereto as Appendix IV.

(e) "Confidentiality Agreement" shall mean the confidentiality agreement between the parties dated February 4, 2002.

(f) "License" shall mean the license granted by Pharmacia to Insmed under Section 2(a) below.

(g) "Losses" shall mean losses, damages, costs and expense, including without limitation reasonable attorneys' fees.

(h) "Other Indications" means applications for IGF-1, SomatoKine and/or other compounds developed by or on behalf of Insmed from the use of the Proprietary Information other than the treatment of Growth Hormone Insensitivity Syndrome.

(i) "Patients" mean those patients that have been receiving IGF-1 from Pharmacia listed on Appendix I to this Agreement.

(j) "Product" means IGF-1 and/or SomatoKine (defined as the complex of IGF-1 with IGFBP-3).

(k) "Proprietary Information" means all regulatory submissions made and regulatory approvals obtained by Pharmacia and its Affiliates with respect to IGF-1 and all data and other information relevant to such regulatory approvals, including but not limited to records of communications with and submissions to regulatory agencies, all as more fully described in Appendix II to this Agreement. For clarity, the parties acknowledge and agree that all of the Proprietary Information is derived from IGF-1 manufactured using the yeast process and not the E-coli process.

(l) "Request For Approval" means a written request submitted by Insmed to Pharmacia for the approval to use the Proprietary Information to seek regulatory approval for Other Indications.

(m) "Sufficient Quantities" means therapeutic dosages and dose regimens of the Product required by each Patient as determined in conjunction with each Patient's doctor.

2. License.

(a) Terms of License. Pharmacia hereby grants to Insmed or Insmed's designee(s) an exclusive (except as to Pharmacia's retained rights set forth below), worldwide, royalty-free, fully paid up license, with the right to grant sublicenses, under the Proprietary Information to (i) seek and maintain regulatory approvals in jurisdictions designated by Insmed from time to time for the use of the Product in the treatment of Growth Hormone Insensitivity Syndrome (including Laron Dwarfism), and (ii) develop, make, have made, use, sell, offer for sale and import commercial products incorporating the Product for the treatment of Growth Hormone Insensitivity Syndrome (including Laron Dwarfism). Pharmacia hereby grants to Insmed an exclusive royalty bearing sublicense under the [REDACTED] Rights and to the extent the Proprietary Information contains the
[REDACTED] Rights, the License shall be subject to the terms and conditions of the [REDACTED] Agreement. The License is subject to Pharmacia's and its Affiliates' nonexclusive license under the Proprietary Information to develop, make, have made, use, sell, offer for sale or import any pharmaceutical product or device; provided, however, Pharmacia and its Affiliates' may not grant licenses or sublicenses to the Proprietary Information or the [REDACTED] Rights to any third party, and will terminate any such rights granted by it to any of its Affiliates that ceases to be an Affiliate.

(b) Other Indications. If Insmed desires to use the Proprietary Information to pursue regulatory approval for Other Indications, it will submit to Pharmacia a Request For Approval containing in reasonable detail information regarding the Other Indications, and will provide such additional information regarding the Other Indications as Pharmacia may reasonably request. Pharmacia must respond to a Request For Approval in writing within forty-five (45) days after its receipt thereof; provided, Pharmacia may reject such Request for Approval in its sole discretion. Pharmacia's response to a Request For Approval may contain terms, including without limitation royalties, under which Pharmacia may be willing to grant the licenses specified in such Request For Approval. If Pharmacia does not deliver a written response to Insmed within such forty-five
(45) day period, Insmed shall deliver another copy of such Request For Approval containing the information required in this Section 2(b) (the "Second Request") and Pharmacia shall have fifteen (15) days to respond in writing to the Second Request. If Pharmacia does not deliver a written response to the Second Request within such fifteen (15) day period, it will be deemed to have given its approval for the Other Indications described in the Request For Approval on the same terms as the License. Pharmacia shall treat the information contained in a Request For Approval and all supplementary information provided by Insmed in response to a request from Pharmacia as strictly confidential, and will not make any use of such information other than for the purpose of evaluating the Request For Approval. Pharmacia shall limit access to the Request For Approval to those of its employees and consultants who reasonably require access in order for Pharmacia to evaluate the Request For Approval, and will be responsible for the compliance by all such employees and consultants with Pharmacia's obligations hereunder.

(c) Costs. Insmed will be responsible for all costs and expenses incurred by it in connection with its use of the Proprietary Information, including without limitation its submission of the Proprietary Information as part of its regulatory filings for the Product.

Insmed will have no responsibility for costs incurred by Pharmacia with respect to the Proprietary Information prior to the date hereof.

(d) [REDACTED] Agreement. To the extent the Proprietary Information contains the [REDACTED] Rights, Insmed shall comply with the
[REDACTED] Agreement. However, Pharmacia understands that Insmed desires to renegotiate the terms of the [REDACTED] Agreement, including without limitation the royalties. Promptly after the Effective Date, Insmed shall contact
[REDACTED] and use its commercially reasonable efforts to obtain a license under the [REDACTED] Rights on terms acceptable to Insmed (the "Amended [REDACTED] Agreement"). The Amended [REDACTED] Agreement shall provide that the [REDACTED] Agreement has been terminated and Pharmacia shall have no further obligations to
[REDACTED]. Pharmacia shall reasonably cooperate with Insmed in connection with the termination of the [REDACTED] Agreement. Insmed shall promptly provide a copy of the Amended [REDACTED] Agreement to Pharmacia. In the event Insmed and
[REDACTED] do not execute the Amended [REDACTED] Agreement, Insmed shall have the right, in its sole discretion, to return the Proprietary Information to Pharmacia and the terms of this Agreement relating to Insmed's rights under the Proprietary Information shall terminate upon Insmed's written notice to Pharmacia; provided, however, Insmed shall continue to be responsible for supply of IGF-1 or SomatoKine in accordance with this Agreement.

(e) [REDACTED] Agreement. [REDACTED] pursuant to the [REDACTED] Agreement. The parties further acknowledge that after each party's review of the
[REDACTED] Agreement no rights to the Proprietary Information have been granted to [REDACTED]. In order to induce Pharmacia to enter into this Agreement, Insmed shall be fully responsible for any and all claims by or on behalf of [REDACTED] arising out of the License.

3. Supply to Patients.

(a) Supply Commitment. Insmed agrees that with respect to each Patient, Insmed will supply each Patient's physician with Sufficient Quantities of IGF-1 or SomatoKine as soon as practicable but not later than ninety (90) days after receiving regulatory approval from the specific regulatory authority to treat patients with the Product and continuing for a period of five years from such date, or such earlier time as the Patient's physician determines to discontinue the Patient's use of IGF-1 or SomatoKine. Product will be supplied by Insmed in a timely manner as determined by Insmed in coordination with the Patient's physician. Notwithstanding the foregoing, Insmed may provide SomatoKine to the Patients' physicians in lieu of IGF-1 only in the event that it is determined that SomatoKine is substantially equivalent to IGF-1 with respect to safety and efficacy in the treatment of Growth Hormone Insensitivity Syndrome (including Laron Dwarfism). [REDACTED]. Insmed shall bear the cost of manufacturing and distributing the Product to the Patients' physicians for administration to the Patients.

(b) Compliance. Insmed will carry out its obligations under
Section 3(a) in accordance with all applicable laws and regulations, including without limitation cGMPs.

(c) Reporting. Insmed will provide Pharmacia with quarterly written updates specifying the quantities of Product supplied to each Patient and the timing of such deliveries, provided that Pharmacia is required to keep all confidential medical information regarding Patients strictly confidential.

(d) Supply Default. In the event Insmed fails to (or reasonably anticipates that it will fail to) materially comply with its obligations under Section 3(a), Insmed will deliver prompt written notice to Pharmacia, and if Insmed is unable to cure such failure within ninety (90) days after delivery of such notice, Pharmacia will have the right, in its sole discretion, to either
(i) terminate the License, (ii) require Insmed to enter into a supply arrangement with Pharmacia under which Insmed would be required to supply Sufficient Quantities of the Product for the Patients at Insmed's cost of manufacture, or (iii) require Insmed to arrange for a third party to supply Sufficient Quantities of the Product to the Patients' physicians in accordance with the terms of this Agreement. If Pharmacia elects to terminate the License, Insmed must return all Proprietary Information (and all notes, documents and other materials containing Proprietary Information) in its possession, to Pharmacia, provided that Insmed's counsel may retain one copy of the Proprietary Information to be used solely for the purpose of enabling Insmed to defend itself in or pursue any litigation or other legal proceeding that may arise from or relate to this Agreement or its use of the Proprietary Information. Insmed acknowledges and agrees that money damages may not be a sufficient remedy for any breach of its obligations under Section 3(a) and that, in addition to any and all other remedies available at law or in equity, Pharmacia will be entitled to seek equitable relief, including injunctions and specific performance, as a remedy for any refusal by Insmed to supply Product to the Patients' physicians as contemplated herein.

4. Delivery of Proprietary Information. Upon the execution of this Agreement, Pharmacia will endeavor to reasonably cooperate with Insmed in its pursuit of regulatory approval for the Products and will deliver to Insmed copies of the Proprietary Information in written and (where available) machine-readable format. In addition, Pharmacia will promptly notify Insmed in writing of any and all material developments affecting the Proprietary Information and information which may be otherwise useful in obtaining regulatory approvals for the Product that it or its Affilates develop, if any. Such additional information will be treated as Proprietary Information for all purposes of this Agreement. Notwithstanding anything to the contrary set forth herein, Insmed agrees that Pharmacia's obligations to deliver the Proprietary Information shall be limited to those documents and materials containing Proprietary Information that are available to Pharmacia as of the date of this Agreement, and Pharmacia or its Affiliates shall have no obligation to develop any new data pertaining to the Proprietary Information. Pharmacia represents and warrants that, to its knowledge, the Proprietary Information will, upon delivery to Insmed, be true, accurate and complete with respect to the Proprietary Information available to Pharmacia as of the date of this Agreement.

5. Intellectual Property Rights.

(a) Ownership of Intellectual Property. As between Pharmacia and Insmed, all clinical results and other data resulting from the application of Product provided by Insmed to the Patients shall be the exclusive property of Insmed. In addition, Insmed will be

the sole owner of all patent applications, patents, continuations, divisionals and other intellectual property rights pertaining to SomatoKine and IGF-1 and all know-how and technology derived from Insmed's use of the Proprietary Information. For clarity, nothing in this Agreement shall be deemed to confer any rights in existing patents and patent applications and all patent applications hereafter filed, including any continuations, continuations-in-part, divisions, provisionals or any substitute applications, any patent issued with respect to any such patent applications, any reissue, reexamination, renewal or extension (including any supplementary protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all foreign counterparts of any of the foregoing owned or controlled by Pharmacia or its Affiliates. However, Pharmacia represents and warrants that there are no existing patents or patent applications owned or under the control of Pharmacia or its Affiliates that would preclude Insmed from exercising its rights hereunder.

(b) Infringement Claims. Each party shall promptly notify the other party in writing if it receives or becomes aware of any claim from any third party that the use of the Proprietary Information by Insmed in the manner contemplated herein infringes such third party's intellectual property rights.

6. Representations and Warranties.

(a) Corporate Power and Authority. Each party represents and warrants that is has all requisite corporate power and authority to enter into this Agreement and to perform its obligations hereunder, including but not limited to, in the case of Pharmacia, the power to grant the License to Insmed, except as provided in Section 6(c) below.

(b) Due Authorization. Each party represents and warrants that this Agreement and the performance by it of its obligations hereunder, including, without limitation, the grant of the License, has been duly authorized and that this Agreement is fully binding and enforceable on it in accordance with its terms, subject to applicable laws relating to creditors' rights generally.

(c) No Infringement. Pharmacia represents and warrants that, to its knowledge, neither it nor any of its Affiliates is party to any other agreement or understanding, written or verbal, which is in conflict with the terms of this Agreement. For clarity, Pharmacia has disclosed to Insmed the terms of the [REDACTED] Agreement and Pharmacia makes no representation or warranties with respect to the [REDACTED] Agreement.

7. Indemnification.

(a) Indemnification of Pharmacia. Insmed will indemnify, defend and hold harmless Pharmacia, its Affiliates, and their respective officers, directors, employees and agents from and against all Losses arising out of (i) Insmed's failure to comply with its obligations or Insmed's negligence or willful misconduct in the performance of its obligations, (ii) any acts or omissions of Insmed's sublicensees, (iii) any breach by Insmed of its

representations and warranties set forth in this Agreement, (iv) the [REDACTED] Agreement and the Amended [REDACTED] Agreement, if any, and (v) claims by or on behalf of [REDACTED] relating to the License.

(b) Indemnification of Insmed. Pharmacia will indemnify, defend and hold harmless Insmed, its Affiliates, and their respective officers, directors, employees and agents from and against all Losses arising out of (i) Pharmacia's failure to comply with its obligations set forth herein, and (ii) any breach by Pharmacia of its representations and warranties set forth in this Agreement.

(c) Indemnification Procedures. Any party seeking indemnification pursuant to Section 7(a) or 7(b) (the "Indemnified Party") shall notify the party providing such indemnification (the "Indemnitor") in writing promptly upon becoming aware of any claim, threatened claim, damage, loss, suit, proceeding or liability to which such indemnification may apply (a "Claim"). Failure to provide such notice shall constitute a waiver of the Indemnitor's indemnity obligations hereunder if, and only if, the Indemnitor is materially prejudiced thereby. The Indemnitor shall assume and control the defense of the Claim at its expense through counsel of its own choosing, such counsel to be reasonably acceptable to the Indemnified Party. If the Indemnitor so assumes the defense of the Claim, the Indemnified Party shall cooperate in such defense at the expense of the Indemnitor. If the Indemnitor fails to assume the defense of a Claim, then the Indemnified Party may defend the Claim at the expense of the Indemnitor. The Indemnitor may not settle any Claim (other than a settlement solely involving the payment of money which is paid by the Indemnitor and the payment of which fully releasing the Indemnified Party) without the prior written consent of the Indemnified Party, which consent may not be unreasonably withheld.

(d) Survival. If the License is terminated for any reason, the provisions of this Section 7 shall survive such termination.

8. Miscellaneous.

(a) Force Majeure. Neither party shall be liable to the other for any delay or failure to perform hereunder, which delay or failure is due to causes beyond the reasonable control of said party, including but not limited to acts of God, acts of the public enemy, acts of the United States of America, any other country, or any state, territory or political subdivision thereof or of the District of Columbia, fires, floods, epidemics, quarantine restrictions, strikes or freight embargoes.

(b) Entire Agreement. This Agreement (together with the Appendices hereto) constitutes the entire agreement of the parties with respect to the subject matter hereof and supersedes all prior agreements, written and oral, with respect to such subject matter.

(c) Amendment. This Agreement may not be amended, modified or altered unless in a written agreement signed by Insmed and Pharmacia. Neither the

course of conduct between the parties nor trade practices shall act to modify any provision of this Agreement.

(d) Waiver. No waiver of any breach of this Agreement shall be effective unless in writing and signed by the party to be charged therewith. No waiver of any breach hereof shall constitute a waiver of any other or subsequent breach not expressly set forth in the written waiver.

(e) Assignment. This Agreement may be assigned by either party without the other party's prior written consent upon delivery of written notice to the non-assigning party; provided, that, assignee shall assume all of the obligations under this Agreement and assignor shall continue to be responsible for the performance of assignee under this Agreement.

(f) Independent Contractors. The relationship of Pharmacia and Insmed is that of independent contractors and nothing herein is intended to imply that either party may act as the agent of the other or take any action binding upon the other party.

(g) Severance. In the event any provision of this Agreement is determined by a court of competent jurisdiction to be unenforceable, the remaining provisions of this Agreement shall remain in full force and effect, and such unenforceable provision shall be deemed modified so as to comply with law while maintaining, to the maximum extent possible, the original intent of the provision.

(h) Notices. Any notice permitted or required to be given hereunder, including without limitation notifications of Request For Approval and all information related thereto, shall be in writing and delivered by certified mail, return receipt requested, or by recognized overnight express courier, addressed to the parties as follows:

If to Insmed, to:

Insmed Incorporated
4851 Lake Brook Drive
Glen Allen, VA 23060
Attn: President and CEO
President-

If to Pharmacia, to:

Pharmacia AB
100 Route 206 North
Peapack, New Jersey 07977
Attn: Senior Vice

Global Licensing

With a copy to:

Pharmacia AB
100 Route 206 North
Peapack, New Jersey 07977

Attn: Vice President and

Associate

General Counsel

Either party may change the address to which notices shall be sent by delivery of written notice to the other party in the manner set forth herein.

(i) Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, and together shall constitute one and the same document.

(j) Headings. All section headings in this Agreement have been included herein for reference purposes only and are not to be used in the interpretation of this Agreement.

(k) Governing Law. This Agreement shall be governed in accordance with the laws of the State of New York without giving effect to the principles of conflicts of law. In the event of any dispute between the parties arising under this Agreement, the parties shall seek to resolve the dispute through good faith negotiations by their representatives authorized to settle the matter. Such negotiations will be carried out over a period of thirty (30) days commencing from the date one party notifies the other in writing that it desires to initiate dispute resolution procedures, or such longer period as the parties may agree upon. If such negotiations are unsuccessful, the matter shall be referred to the Chief Executive Officer of Insmed and Vice President - Endocrine Care of Pharmacia for resolution, who will meet within thirty (30) days after the completion of the aforesaid negotiations for the purpose of seeking a resolution of the dispute through good faith discussions. Neither party may commence litigation to resolve a dispute under this Agreement unless they first follow the foregoing procedures and the discussions fail to produce a resolution of the dispute despite the reasonable efforts of the parties; provided, however, that a party seeking injunctive relief for any breach of provisions dealing with confidentiality of information need not comply with the foregoing provisions before commencing legal proceedings.

(l) Mutual Drafting. This Agreement constitutes the joint product of the parties hereto. Each provision has been subject to the mutual consultation and agreement of such parties and shall not be construed for or against either of them.

(m) Costs. Each party will bear its own costs in connection with the preparation and negotiation of this Agreement.

(n) Confidentiality. All of the information disclosed by a party under this Agreement, including without limitation the terms and conditions of this Agreement, shall be subject to the Confidentiality Agreement, which shall remain in full force and effect during the term of this Agreement and for a period of five (5) years thereafter.

IN WITNESS WHEREOF, the undersigned have executed this Agreement as of the date first set forth above.

PHARMACIA AB

By:_____

Name:_____

Title:_____

INSMED INCORPORATED

By:_____

Name:_____

Title:_____

EXHIBIT 23.1

Consent of Independent Auditors

We consent to the incorporation by reference of our report dated January 17, 2003, with respect to the consolidated financial statements of Insmed Incorporated included in the Annual Report on Form 10-K for the year ended December 31, 2002, in the following registration statements:

(1) Insmed Incorporated Employee Stock Purchase Plan Registration Statement Number 333-39198 on Form S-8;

(2) Insmed Incorporated Stock Incentive Plan Registration Statement Number 333-39200 on Form S-8; and

(3) Insmed Incorporated Stock Incentive Plan Registration Statement Number 333-87878 on Form S-8.

/s/ Ernst & Young LLP

McLean, Virginia
March 25, 2003

EXHIBIT 99.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Insmed Incorporated (the "Company") for the period ending December 31, 2002 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Geoffrey Allan, Ph.D., Chairman of the Board and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Geoffrey Allan
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Geoffrey Allan, Ph.D.
Chairman of the Board and
Chief Executive Officer
March 28, 2003

A signed original of this written statement required by ss. 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certificate is being submitted in accordance with the procedure provided in Section III of SEC Release No. 33-8212, 34-47551, IC-25967 (March 21, 2003) for treatment as a document "accompanying" the Annual Report on Form 10-KSB to which it is attached and not as a document "filed" as a part of such Annual Report. This certificate shall not be deemed incorporated by reference into any of the Company's Securities Act registration statements.

EXHIBIT 99.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Insmed Incorporated (the "Company") for the period ending December 31, 2002 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kevin P. Tully, Treasurer and Controller (Principal Financial and Accounting Officer) of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Kevin P. Tully

Kevin P. Tully C.G.A.
Treasurer and Controller
(Principal Financial and Accounting Officer)
March 28, 2003

A signed original of this written statement required by ss. 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certificate is being submitted in accordance with the procedure provided in Section III of SEC Release No. 33-8212, 34-47551, IC-25967 (March 21, 2003) for treatment as a document "accompanying" the Annual Report on Form 10-KSB to which it is attached and not as a document "filed" as a part of such Annual Report. This certificate shall not be deemed incorporated by reference into any of the Company's Securities Act registration statements.

End of Filing