INSMED INC
Form S-1/A
June 13, 2005
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INSMED INCORPORATED

As filed with the Securities and Exchange Commission on June 13, 2005

Registration No. 333-123695

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

AMENDMENT No. 1

to

FORM S-3

on

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

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

Glen Allen, Virginia 23060

(804) 565-3000

(Address, including zip code, and telephone number, including area code,

of Registrant s principal executive offices)

Kevin P. Tully, C.G.A.

Principal Financial Officer,

Treasurer and Controller

Insmed Incorporated

4851 Lake Brook Drive

Glen Allen, Virginia 23060

(804) 565-3000

(Name, address, including zip code, and telephone number, including area code,

of agent for service)

Copies to:

Mitchell S. Bloom

Goodwin Procter LLP

Exchange Place

Boston, Massachusetts 02109

Tel: (617) 570-1000

Fax: (617) 523-1231

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨ _____

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If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective statement for the same offering. ¨ _____

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective statement for the same offering. ¨ _____

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. ¨

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered(1)(2)	Proposed Maximum Offering Price Per Share(3)	Proposed Maximum Aggregate Offering Price(3)	Amount of Registration Fee(3)
Common Stock $0.01 par value(2)	56,675,300(4)	$0.875	$49,590,888	$4,659(5)

(1) In addition to any securities that may be registered hereunder, we are also registering an indeterminable number of additional shares of our common stock, pursuant to Rule 416 under the Securities Act of 1933, as amended, that may be issued to prevent dilution resulting from stock splits, stock dividends or similar transactions affecting the shares to be offered by the selling stockholders.

(2) This Registration Statement also relates to the rights to purchase shares of Series A Junior Participating Preferred Stock of the Registrant which are attached to all shares of common stock issued pursuant to terms of the Registrant s Rights Agreement, dated as of May 16, 2001. Until the occurrence of certain prescribed events, the rights are not exercisable, are evidenced only by the certificates for the common stock and will be transferred with and only with the common stock. Because no separate consideration is paid for the rights, the registration fee therefor is included in the fee for the common stock.

(3) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(c) on the basis of $0.875 per share, which was the average of the high and low prices of the common stock as quoted on the Nasdaq National Market on March 29, 2005.

(4) This amount includes:

(A) shares issuable upon the exercise convertible notes and warrants issued in March 2005, including (i) 28,513,480 shares, representing the 27,027,013 shares of common stock issuable to the selling stockholders upon conversion of the registrant s convertible notes held by such holders, plus up to 1,486,467 shares issuable to such holders in respect of interest accruing on the notes from time to time; and (ii) 16,722,979 shares, representing 14,864,883 shares of common stock issuable upon exercise of the common stock purchase warrants held by the selling stockholders, plus up to 1,858,096 shares that may become issuable pursuant anti-dilution provisions contained in the warrants;

(B) shares issued, and shares issuable upon the exercise of warrants issued, in November 2004, including, (i) 3,306,247 shares of common stock, and (ii) 3,227,775 shares of common stock issuable upon exercise of the common stock purchase warrants held by the selling stockholders, and

(C) shares issued, and shares issuable upon the exercise of warrants issued, in July 2003, including, (i) 3,360,773 shares of common stock, and (ii) 1,544,046 shares of common stock issuable upon exercise of the common stock purchase warrants held by the selling stockholders.

Pursuant to Rule 429 under the Securities Act of 1933, as amended (the Securities Act), the shares being registered from the Registrant s issuances of shares and warrants in November 2004 and July 2003 (referenced in clauses (B) and (C) above) include 11,438,841 shares that were previously registered pursuant earlier Registration Statements on Form S-3 (Nos. 333-107308 and 333-120639).

(5) Pursuant to Rule 429 under the Securities Act, 11,438,841 shares previously registered pursuant to earlier Registration Statements on Form S-3 (Nos. 333-107308 and 333-120639) are being carried forward to this Registration Statement on Form S-1 and the corresponding registration fee for the shares registered under those earlier Registration Statements was previously paid at the time of those Registration Statements were filed.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and the selling stockholders named in this prospectus are not soliciting any offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED JUNE 13, 2005

PROSPECTUS

INSMED INCORPORATED

56,675,300 Shares

Common Stock

This prospectus relates to the offer and sale from time to time of up to 56,675,300 shares of our common stock by the selling stockholders named in this prospectus.

The selling stockholders identified in this prospectus, or their pledgees, donees, transferees or other successors-in-interest, may sell the shares of our common stock at various times and in various types of transactions, including sales in the open market, sales in negotiated transactions and sales by a combination of these methods. Shares may be sold at the market price of the common stock at the time of a sale, at prices relating to the market price over a period of time or at prices negotiated with the buyers of shares. We do not know, however, when the proposed sales of the shares by the selling stockholders will occur. More detailed information concerning the distribution of the shares is contained in the section of this prospectus entitled Plan of Distribution.

We are registering the offer and sale of the shares of common stock to satisfy our contractual obligations to provide the selling stockholders with freely tradable shares. We will not receive any of the proceeds from the sale of the shares.

Our common stock is listed on the Nasdaq National Market under the trading symbol INSM. The reported closing price of our common stock on the Nasdaq National Market on June 10, 2005 was $0.90 per share.

This investment involves a high degree of risk. You should consider carefully the Risk Factors beginning on page 6 of this prospectus before purchasing any of the common stock offered hereby.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if this prospectus is truthful or complete any representation to the contrary is a criminal offense.

The date of this prospectus is _____, 2005

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You should rely on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. The selling stockholders, as defined below, are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the shares of common stock. In this prospectus, selling stockholders refers to the persons identified in the section titled Selling Stockholders. In this prospectus, Insmed, we, us and our re Insmed Incorporated and its subsidiaries.

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PROSPECTUS SUMMARY

This summary highlights important features of this offering and the information included in this prospectus. This summary may not contain all of the information that is important to you. You should read the entire prospectus carefully, including Risk Factors beginning on page 6, before deciding to invest in our common stock.

Insmed Incorporated

Overview

Insmed Incorporated is a biopharmaceutical company focused on the development and commercialization of drug products for the treatment of metabolic diseases and endocrine disorders. Currently, our development activities focus on drugs that modulate IGF-I activity in the human body. We currently have three lead drug candidates, recombinant human insulin-like growth factor-I bound to recombinant human insulin-like growth factor binding protein-3 (rhIGF-I/rhIGFBP-3; also known as SomatoKine®) rhIGFBP-3 and INSM-18. We are actively developing these drugs to treat indications in the metabolic and oncology fields.

We have been granted Orphan Drug Designation by the United States Food and Drug Administration (FDA) and European Medicines Agency for the Evaluation of Medicinal Products for rhIGF-I/rhIGFBP-3 in the treatment of severe growth disturbance due to growth hormone insensitivity syndrome (GHIS) (i.e., Laron s Syndrome). We submitted a New Drug Application (NDA) on January 3, 2005 for use of rhIGF-I/rhIGFBP-3 in the treatment of GHIS, which was accepted for priority review by the FDA with an initial User Fee Goal Date of July 3, 2005. The initial User Fee Goal Date was subsequently postponed to October 3, 2005. A worldwide Phase III clinical trial for this indication is in progress.

We believe the commercial opportunities for rhIGFI/rhIGFBP-3 reach beyond the indication of GHIS and that initial approval of our rhIGF-I/rhIGFBP-3 may offer us an opportunity to enter other potentially very large markets. These markets include other growth disturbances related to IGF-I deficiency, severe insulin resistance, diabetes, myotonic dystrophy, HIV associated adipose redistribution syndrome, severe burns and hip fracture. It is our intention to initiate clinical studies in a variety of these indications with rhIGF-I/rhIGFBP-3. Based on the results from these studies we will select the next indication to pursue for marketing authorization.

Our oncology program focuses on IGFBP-3 as a naturally occurring anti-tumor agent. This protein is normally found in the human bloodstream and several epidemiological studies have demonstrated that cancer risk increases with decreasing blood levels of IGFBP-3. rhIGFBP-3 is a recombinant protein that mimics the effects of IGFBP-3 in the bloodstream. This product is currently in pre-clinical development for a variety of cancers including those of the breast, lung, colon and prostate. A phase I clinical study to study safety and tolerance in human volunteers is in progress.

Insmed is also initiating clinical studies of a compound known as INSM-18, which has novel effects on the activity of the IGF-I and other receptors that can lead to the inhibition of growth of various tumors. Insmed is currently planning the clinical development of this compound in collaboration with the University of California, San Francisco School of Medicine and is preparing to initiate an exploratory clinical study in patients with relapsed prostate cancer.

Corporate Information

Insmed was incorporated in the Commonwealth of Virginia on November 29, 1999. Our principal executive offices are located at 4851 Lake Brook Drive, Glen Allen, Virginia 23060 and our phone number is (804)565-3000.

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Convertible Note and Warrant Issuances

On March 15, 2005, we entered into purchase agreements with several investors, pursuant to which we issued and sold to the investors 5.5% convertible notes due 2008-2010 in an aggregate principal amount of $35 million and related warrants (the 2005 warrants) to purchase, in the aggregate, 14,864,883 shares of common stock. Insmed received net proceeds of approximately $32.8 million from the sale of the convertible notes and related warrants. The notes are convertible into, in the aggregate, 27,027,013 shares of common stock. As of March 15, 2005, there were approximately 44,986,996 shares of common stock outstanding, excluding any shares issuable upon conversion or exercise of the convertible notes and warrants.

On November 19, 2004, we entered into purchase agreements with several investors, pursuant to which we issued 6,455,551 shares of common stock and related warrants (the 2004 warrants) to purchase, in the aggregate, 3,227,775 shares of common stock. Insmed received net proceeds of approximately $8.2 million from the sale of the shares and 2004 warrants.

On July 15, 2003, we entered into purchase agreements with several investors, pursuant to which we issued 5,146,846 shares of common stock and related warrants (the 2003 warrants) to purchase, in the aggregate, 1,540,046 shares of common stock. Insmed received net proceeds of approximately $13.1 million from the sale of the shares and 2003 warrants.

Insmed and each of the investors from the July 2003, November 2004 and March 2005 issuance also entered into registration agreements, pursuant to which we have agreed to register the shares issuable upon conversion of the notes upon the exercise of the warrants for resale by the investors. This prospectus forms a part of a registration statement that was filed pursuant to the registration rights agreements with the investors.

Convertible Notes

Principal Payment under the Notes

The principal amount of the convertible notes will mature and become payable in nine quarterly installments of approximately $3.9 million commencing on March 1, 2008. All outstanding convertible notes shall be repaid in cash or converted by March 1, 2010. The convertible notes may not be prepaid, in whole or in part, or redeemed by us except under certain limited circumstances as provided for in the terms of the convertible notes.

Interest Payments

Commencing on June 1, 2005, the holders of convertible notes will be paid interest at a rate of 5.5% per annum. Interest on the Notes is payable quarterly until March 1, 2010.

Conversion of the Notes

The holders of the convertible notes may convert the notes into common stock at any time prior to the close of business on March 1, 2010, at a conversion price of $1.295 per share. The conversion rate is subject to adjustments based on splits, dividends and similar extraordinary event affecting the common stock. The principal amount of convertible notes are convertible into, in the aggregate, 27,027,013 shares of Common stock. Interest payable pursuant to the convertible notes from time to time may be converted into an additional 1,486,467 shares of common stock.

Events of Default and Repurchase Rights

The holders of the convertible notes have the right to require us to repurchase the convertible notes with cash payments upon the occurrence of specified events of default and other repurchase events.

Restrictive Covenants

The convertible notes contain restrictive covenants, including, but not limited to, covenants that prohibit us from incurring certain indebtedness and establishing certain liens on our property.

Right to Participate in Future Financings

The purchasers of the convertible notes and related warrants in March 2005 have the right to participate in future financings undertaken by us prior to March 16, 2006, and one purchaser of shares and warrants in November 2004 has the right to participate in future equity or equity-linked financings undertaken by us prior to November 9, 2005. The participation right entitles the investors to purchase up to such portion of any subsequent sale of equity securities or securities exercisable for or convertible into equity securities (other than a firm commitment underwritten public offering) on the same terms and conditions as the other parties in the financing so as to enable the investors to maintain their ownership of the common stock on a fully-diluted basis at such time.

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Warrants

The 2005 warrants covering 14,864,883 shares of common stock issued in March 2005 are immediately exercisable and have an exercise price of $1.36 per share. The warrants will expire if not exercised on or prior to March 15, 2010. The 2005 warrants include a full-ratchet anti-dilution provision and other anti-dilution provisions that would cause a decrease in the exercise price and an increase in the number of shares issuable under the 2005 warrants, upon the occurrence of specified events. Up to 1,858,096 additional shares of common stock will be issuable pursuant to the 2005 warrants in the event of any full-ratchet anti-dilution adjustments to the 2005 warrants.

The 2004 warrants covering 3,277,775 shares of common stock are immediately exercisable and have an exercise price of $0.71. per share. The 2004 warrants will expire if not exercised on or prior to November 5, 2009. The 2004 warrants include weighted-average anti-dilution provisions that would cause a decrease in the exercise price upon the issuance or deemed issuance of common stock for less than the exercise price of the warrants, and other anti-dilution provisions that would cause a decrease in the exercise price and an increase in the number of shares issuable under the 2004 warrants.

The 2003 warrants to purchase 1,540,046 million shares of common stock issued are immediately exercisable and have an exercise price of $4.10 per share. The 2003 warrants will expire if not exercised on or prior to July 10, 2008. The 2003 warrants include anti-dilution provisions that would cause a decrease in the exercise price and an increase in the number of shares issuable under the 2003 warrants upon the occurrence of specified events.

Share Limitations

Based on limitations included in the purchase agreements for the March 2005 issuances, the convertible notes, and the 2005 warrants, no holder of the convertible notes or warrants may beneficially own more than 9.9% of the common stock at any time.

Registration Rights Agreements

In connection with the issuance of securities in 2003, 2004 and 2005, Insmed and the investors entered into registration rights agreements, pursuant to which, we agreed to file a registration statement with the Securities and Exchange Commission registering the shares of common stock issuable upon the conversion of the convertible notes or exercise of the warrants issued in 2003, 2004 and 2005. This prospectus forms a part of a registration statement that was filed pursuant to the registration rights agreements with the investors.

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The Offering

Common stock offered by selling stockholders	56,675,300 shares, including 6,670,020 shares issued to investors in July 2003 and November 2004, up to 21,494,800 share issuable upon the exercise of warrants issued to investors in July 2003, November 2004 and March 2005, and up to 28,513,480 shares issuable upon the conversion of convertible notes issued to investors in March 2005.
Use of proceeds	We will not receive any proceeds from the sale of shares in this offering. If the selling stockholders exercise the warrants to purchase our common stock for cash instead of on a net exercise basis, then we will receive the exercise price from the exercise of the warrants. The proceeds, if any, will be added to our working capital and be available to fund the ongoing activities relating to SomatoKine®, rhIGFBP-3 and INSM-18 and for general corporate purposes.
Nasdaq National Market symbol	INSM
Risk Factors	See Risk Factors for a discussion of the factors you should carefully consider before deciding to invest in shares of our common stock.

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RISK FACTORS

You should consider carefully the following risk factors, together with all of the other information included in this prospectus. 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.

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 currently have no commercial 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 activities. We expect that these activities, together with our general and administrative expenses, will result in substantial operating losses for the foreseeable future. As of December 31, 2004, our accumulated deficit was $213.7 million. For the year ended December 31, 2004, and the three months ended March 31, 2005, our consolidated net loss was $27.2 million and $5.8 million, respectively.

We currently have two lead product candidates, rhIGF-I/rhIGFBP-3 (also known as SomatoKine®) and rhIGFBP-3. rhIGF-I/rhIGFBP-3 is currently in development for a number of metabolic and endocrine indications. The most advanced indication in development is the treatment of severe growth disturbance due to growth hormone insensitivity syndrome (GHIS). Our second compound, rhIGFBP-3, is currently in pre-clinical development for a variety of cancers including breast, lung, colon and prostate.

All of our products are currently in the research and development stage and if we are unable to commercialize them it will materially adversely affect our business, financial condition and results of operations.

All of our potential products are in the research and development stage. Our long-term viability and growth depend on the successful commercialization of products which lead to revenue and profits. In order to commercialize any of our products they must first be successfully developed. Pharmaceutical product development is an expensive, high risk, lengthy, complicated, resource intensive process. In order to succeed, among other things, we must be able to:

- identify potential drug product candidates;
- design and conduct appropriate laboratory, pre-clinical and other research;
- submit for and receive regulatory approval to perform clinical studies;
- design and conduct appropriate clinical studies;

select and recruit clinical investigators;

select and recruit subjects for our studies;

collect, analyze and correctly interpret the data from our studies;

submit for and receive regulatory approvals for marketing; and

manufacture the drug product candidates according to current good manufacturing practices (cGMP).

The development program with respect to any given product will take many years and thus delay our ability to generate profit. In addition, potential products that appear promising at early stages of development may fail for a number of reasons, including the possibility that the products may require significant additional testing or turn out to be:

unsafe;

not effective;

too difficult or expensive to manufacture;

too difficult to administer; or

unstable.

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

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

Even if we are successful in developing our products, there are numerous developments that could prevent the successful commercialization of the products such as:

- the regulatory approval of our products are delayed or we are required to conduct further research and development with our products prior to receiving regulatory approval;
- we are unable to build a sales and marketing group to successfully launch and sell our products;
- we are unable to raise the additional funds needed to successfully develop and commercialize our products or acquire additional products for growth,
- an event such as a law suit or other litigation drains our cash;
- we are unable to manufacture the quantity of product needed in accordance with current good manufacturing practices to meet market demand or at all,
- our product is determined to be ineffective or unsafe following approval and is removed from the market or we are required to perform additional research and development to further prove the safety and effectiveness of the product before re-entry into the market,
- competition from other products or technologies prevents or reduces market acceptance of our products;
- we do not have and cannot obtain the intellectual property rights needed to manufacture or market our products without infringing on another company s patents, or
- we are unable to obtain reimbursement for our product. or such reimbursement may be less than is necessary to produce a reasonable profit.

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

The failure to successfully acquire, develop and commercialize products will adversely affect our business, financial condition and results of operations.

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

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

We are currently conducting a Phase III clinical trial of rhIGF-I/rhIGFBP-3 in patients with GHIS and have included some data from this trial as pivotal information in a New Drug Application (NDA) submission to the United States Food and Drug Administration (FDA) which was filed on January 3, 2005. We also plan to include the data from the trial in a Marketing Authorization Application to the European Medicines Agency (EMEA). We must receive approval of these applications before we can market rhIGF-I/rhIGFBP-3 in the respective territories. We are also planning clinical trials with rhIGFBP-3.

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

- Investigator identification and recruitment;
- regulatory approvals to initiate study sites;
- patient population size;
- the nature of the protocol to be used in the trial;
- patient proximity to clinical sites;
- eligibility criteria for the study; and
- competition from other companies clinical 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 commercialization and sales, if any, of our products. Such delays could materially adversely affect our business, financial condition and results of operations.

We may be required to conduct broad, long-term clinical trials to address concerns that the long-term use of rhIGF-I/rhIGFBP-3 in broader chronic indications might increase the risk of diabetic retinopathy. This may materially adversely affect our business, financial condition and results of operations.

In previously published clinical trials of rhIGF-I, concerns were raised that long-term use of rhIGF-I might lead to an increased incidence and/or severity of retinopathy, a disease of new blood vessel growth in the eye which results in loss of vision. Because our product contains rhIGF-I, the FDA may require us to conduct broad, long-term clinical trials to address these concerns prior to receiving FDA approval for broad chronic indications such as diabetes. These clinical trials would be expensive and could delay our commercialization of rhIGF-I/rhIGFBP-3 for these broader chronic indications. Adverse results in these trials could prevent our commercialization of rhIGF-I/rhIGFBP-3 for broad chronic indications or could jeopardize existing development and approvals in other indications.

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

We are required to obtain various regulatory approvals prior to studying our drug products in humans and then again before we market and distribute our products. The regulatory review and approval process required to perform a clinical study in both the United States and Europe

includes evaluation of pre-clinical studies and clinical trials, as well as the evaluation of our manufacturing process and is complex, lengthy, expensive, resource intensive and uncertain. Securing regulatory approval to market our products also requires the submission of extensive pre-clinical and clinical data, manufacturing information regarding the process and facility, scientific data characterizing our product and other supporting data to the regulatory authorities in order to establish its safety and effectiveness. This process is also complex, lengthy, expensive, resource intensive and uncertain. We have limited experience in filing and pursuing applications necessary to gain these regulatory approvals.

Data submitted to the regulators is subject to varying interpretations that could delay, limit or prevent regulatory agency approval. We may also encounter delays or rejections based on changes in regulatory agency policies during the period in which we develop a drug and/or the period required for review of any application for regulatory agency approval of a particular product. Delays in obtaining regulatory agency approvals could adversely affect the 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.

We are currently conducting a Phase III clinical trial of rhIGF-I/rhIGFBP-3 in patients with GHIS and have included data from this trial as a pivotal piece of information in a January 3, 2005 NDA submission to the FDA. We also plan to include the data in a Marketing Authorization Application (MAA) submission to the EMEA. We must receive approval of these applications before we can market rhIGF-I/rhIGFBP-3.

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As part of our normal development we continue to increase our scale of production and refine our manufacturing process. Because of these changes we are required to perform various comparability analyses to demonstrate that the drug product used in our previous development studies is essentially the same as the new drug product produced. We have had several discussions with the FDA and other foreign regulatory agencies regarding our Phase III clinical study and this comparability analysis and believe we understand what is required to satisfy the FDA and EMEA. We plan to submit this data to the appropriate regulatory authorities as part of the regulatory process. If we are unable to produce comparable drug product or meet the regulatory requirements of comparability it will materially adversely affect our business, financial condition and results of operations.

The regulatory authorities have substantial discretion in the approval process and may either refuse to accept our applications, or may decide after review of our applications that our data is insufficient to allow approval of rhIGF-I/rhIGFBP-3. If the FDA or EMEA do not accept or approve our application, it may require that we conduct additional clinical, pre-clinical or manufacturing studies and submit that data before it will reconsider our application. This could materially adversely affect our business, financial condition and results of operations.

Even if the FDA or EMEA 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 or EMEA 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.

If our Phase III clinical trial is unsuccessful or if we cannot produce comparable drug product, have not correctly understood the regulatory requirements associated with comparability of drug products or for various other reasons cannot satisfy ongoing regulatory requirements, we may not receive NDA and/or MAA approvals or such approvals may be substantially delayed or withdrawn. Any of these events could materially adversely affect our business, financial condition and results of operations.

We cannot be certain that we will obtain any regulatory approvals in foreign countries. 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 and European union territories, our corporate partners and we must comply with numerous and varying regulatory requirements of other countries. The approval procedures vary among countries and can involve additional product testing and administrative review periods. The time required to obtain approval in these other territories might differ from that required to obtain FDA or EMEA approval. The regulatory approval process in these other territories includes at least all of the risks associated with obtaining FDA and EMEA approval detailed above. Approval by the FDA or EMEA does not ensure approval by the regulatory authorities of other countries.

We are currently conducting or planning to conduct several clinical studies in the United States, and countries in the European Union and other territories with our products. If we are unable to receive regulatory approval to conduct such studies, it may prevent or substantially delay our development programs which could materially adversely affect our business, financial condition and results of operations.

If another party obtains orphan drug or pediatric exclusivity for a product that is essentially the same as rhIGF-I/rhIGFBP-3 for the treatment of growth disturbance due to GHIS, we may be precluded or delayed from commercializing rhIGF-I/rhIGFBP-3 in that

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

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. The company that obtains the first marketing approval from the FDA for a designated orphan drug for a rare disease receives marketing exclusivity for use of that drug for the designated condition for a period of

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seven years. Similar laws exist in Europe. Pediatric exclusivity can provide an additional six months of market exclusivity in the United States If a competitor obtains approval of the same drug for the same indication or disease before us, we would be blocked from obtaining approval for our product for seven or more years, unless our product can be shown to be clinically superior. In addition, more than one product may be approved by the FDA for the same orphan indication or disease as long as the products are different drugs. As a result, if our product is approved and receives orphan drug status, the FDA can still approve other drugs for use in treating the same indication or disease covered by our product, which could create a more competitive market for us.

We are aware of a drug being developed by Tercica, Inc., which we believe is a product containing essentially only rhIGF-I, that is in development for treatment of severe primary IGF-I deficiency. We believe this population includes patients with GHIS. We believe this company has or will file for orphan designation of their product and pursue pediatric exclusivity. The regulatory agencies could determine that this other product is the same drug as our product and is used for the same indication. if the regulatory agencies make this determination and the other product is approved first, the approval of our rhIGF-I/rhIGFBP-3 for GHIS could be blocked for up to seven or more years, which could force us to curtail or cease our operations. We may not be able to benefit from the orphan drug marketing exclusivity because products that are clinically superior may be approved for marketing regardless of whether we receive orphan drug designation and the first marketing approval.

The failure to successfully obtain orphan drug market exclusivity or pediatric drug market exclusivity will adversely affect our business, financial condition and results of operations.

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. If we are unable to find sufficient manufacturing capacity, it could materially adversely affect our business, financial condition and results of operations.

Failure to successfully manufacture our products could materially adversely affect our business, financial condition and results of operations. We intend to manufacture products at our Insmed Therapeutic Proteins (ITP) facility in Boulder, Colorado and enter into strategic alliances with other parties that have established commercial scale manufacturing capabilities. There can be no assurance that our ITP facility will have the capacity to produce the required products nor that we will enter into such strategic alliances on terms favorable to us or at all. If we are unable to increase production capacity at our ITP facility or 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 pre-clinical and clinical trials may be adversely affected.

In addition, there can be no assurance that an adverse regulatory inspection at our ITP facility or at our contract manufacturers facilities would not impede our commercial supply capability. If we choose to commercialize such products solely on our own, it would be time consuming, resource intensive and capital intensive. If our contract manufacturers facilities or our facilities can not produce our products according to current good manufacturing practices (cGMP) and pass a cGMP inspection or if our contract manufacturers or our facilities become unavailable, we may be unable to develop and commercialize our products. This will materially 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 at our ITP facility or in any of these third party 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.

We have manufactured rhIGF-I/rhIGFBP-3 at our ITP facility and at Avecia s site at Billingham, England. At present, rhIGF-I/rhIGFBP-3 has never been manufactured by our ITP facility or Avecia in quantities necessary for commercialization; we cannot guarantee that they will be able to produce the quantities of rhIGF-I/rhIGFBP-3 necessary for commercialization or that there will not be delays in such production. If we are unable to manufacture rhIGF-I/rhIGFBP-3 or such manufacture is delayed it could materially adversely affect our business, financial condition and results of operations.

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Our ITP facility and the facilities used by our contract manufacturers, including Avecia Limited, to manufacture rhIGF-I/rhIGFBP-3 may undergo an inspection by the FDA and/or EMEA for compliance with cGMP regulations, before rhIGF-I/rhIGFBP-3 can be approved. In the event these facilities do not receive a satisfactory cGMP inspection for the manufacture of our product, we may need to fund additional modifications to our manufacturing process, conduct additional validation studies, or find alternative manufacturing facilities, any of which would result in significant cost to us as well as a significant delay of up to several years in obtaining approval for rhIGF-I/rhIGFBP-3. In addition, our contract manufacturers, and any alternative contract manufacturer we may utilize, will be subject to ongoing periodic inspection by the FDA and EMEA and other foreign agencies for compliance with cGMP regulations and similar foreign standards. We do not have control over our contract manufacturers compliance with these regulations and standards.

Product for our clinical trials is currently made at either our ITP facility or Avecia s manufacturing facility and then sent to an additional third party contract manufacture for sterile filtration and filling into vials. Should our ITP facility, Avecia s facility or our contract sterile filtration and filling manufacturer become unavailable to us for any reason, including damage from any event, including fire, flood, earthquake or terrorism, we may be unable to complete manufacture of rhIGF-I/rhIGFBP-3 or validation of the manufacturing process for rhIGF-I/rhIGFBP-3. This could delay our clinical trials and the approval of our NDA or MAA, which would delay or otherwise adversely affect revenues. If the damage to any of these facilities is extensive, or if they are unwilling or unable to operate in compliance with cGMP or perform under our agreements, we will need to find alternative facilities. The number of contract manufacturers with the expertise and facilities to manufacture rhIGF-I/rhIGFBP-3 bulk drug substance on a commercial scale in accordance with cGMP regulations is extremely limited, and it would take a significant amount of time and resources to arrange for alternative manufacturers. If we need to change to other commercial manufacturers, we would need to transfer and validate the processes and analytical methods necessary for the production and testing of rhIGF-I/rhIGFBP-3 to these new manufacturers. Any of these factors could lead to the delay or suspension of our clinical trials, regulatory submissions, regulatory approvals or commercialization of rhIGF-I/rhIGFBP-3, or higher costs of production and result in our failure to effectively commercialize rhIGF-I/rhIGFBP-3.

Furthermore, if our ITP facility or our contract manufacturers fail to deliver sufficient quantities of bulk drug substance or finished product on a timely basis and at commercially reasonable prices, and we are unable to promptly find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volume and on a timely basis, we will likely be unable to meet demand for rhIGF-I/rhIGFBP-3 and we would lose potential revenues.

We currently have limited sales, marketing and distribution capabilities, which may make commercializing our products difficult. If we are unable to build sales, marketing and distribution capabilities, it will materially adversely affect our business, financial condition and results of operations.

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. Failure to successfully sell, market or distribute our products once approved will materially adversely affect our business, financial condition and results of operations

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

There can be no assurance that any of our product candidates, if approved for marketing, will achieve market acceptance. If our 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;

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their potential advantage over existing and future treatment methods;

their price; and

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

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 payers 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.

If physicians, patients, third-party payers or the medical community in general do not accept and use the products we develop and commercialize, it will materially adversely affect our business, financial condition and results of operations.

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 materially adversely impact our business, financial condition and results of operations.

We will require substantial future capital in order to execute our business plan. Our future capital requirements will depend on many factors, including factors associated with:

manufacturing;

process development;

research and development including among other items, pre-clinical testing and clinical trials,

obtaining regulatory approvals;

obtaining marketing sales and distribution capabilities;

launching products;

retaining employees and consultants;

filing and prosecuting patent applications and enforcing patent claims;

establishing strategic alliances; and

other activities required for product commercialization.

We may also need to spend more money than currently expected because we may change our product development plans, acquire additional products or product candidates or we may misjudge our costs. We have no committed sources of capital and do not know whether additional financing will be available when needed, or, if

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available, that the terms will be favorable. There can be no assurance that our cash reserves together with any subsequent funding will satisfy our capital requirements. The failure to satisfy our capital requirements will adversely affect our business, financial condition and results of operations. We believe that existing cash reserves including the March 15, 2005 financing, will sufficiently fund our activities through the next twelve months.

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

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

We depend highly on the principal members of our scientific and management staff, the loss of whose services might significantly delay or prevent the achievement of research, development or business objectives and would materially adversely affect our business, financial condition and results of operations. Our success depends, in large part, on our ability to attract and retain qualified management, scientific and medical personnel, and on our ability to develop and maintain important relationships with commercial partners, leading research institutions and key distributors. We face intense competition for such personnel and relationships. We cannot assure that we will attract and retain such persons or maintain such relationships.

We expect that our potential expansion into areas and activities requiring additional expertise, such as further clinical trials, governmental approvals, manufacturing, sales, marketing and distribution will place additional requirements on our management, operational and financial resources. We expect these demands will require an increase in management and scientific personnel and the development of additional expertise by existing management personnel. The failure to attract and retain such personnel or to develop such expertise could materially adversely affect our business, financial condition and results of operations.

We need collaborative relationships to be successful. If we are unable to form these relationships it could materially adversely impact our business, financial condition and results of operations.

We currently rely and may in the future rely on a number of significant collaborative relationships for intellectual property rights, research funding, manufacturing, analytical services, pre-clinical development, 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 product.,
- disputes may arise in the future with respect to the ownership of rights to technology developed with, licensed to or licensed from corporate partners;

disagreements with corporate partners could result in loss of intellectual property rights, delay or terminate the research, development or commercialization of product candidates or result in litigation or arbitration;

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

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

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

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

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

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

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

We intend to conduct proprietary development programs with collaborators, and any conflicts with them could harm our business, financial condition and results of operations. We intend to enter into collaborative relationships which will involve our 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 materially adversely affect our business, financial condition and results of operations.

Our success will depend in part on our ability to:

- obtain patent protection for our products;

prevent third parties from infringing on our patents; and

refrain from infringing on the patents of others, both domestically and internationally.

Our patent positions are highly uncertain, and any future patents we receive for our potential products will be subject to this uncertainty, which may adversely affect our business, financial condition and results of operations. We intend to actively pursue patent protection for products 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

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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 Inc. and Chiron Corporation 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.

In addition, Novartis AG and Chiron Corporation have rights to United States and foreign patents relating to the use of IGF-1 for the treatment of type 1 diabetes, and Novartis owns United States and foreign patents relating to the treatment of osteoporosis with IGF-I. Genentech, Inc. owns U.S. and foreign patents directed to using IGF-I to increase the growth rate of certain patients with non-growth hormone-deficient short stature and patients having partial growth hormone insensitivity syndrome. We do not expect that we will infringe these patents. We can give no assurances, however, that such patents can be avoided, invalidated or licensed. Thus, the patents could potentially have an adverse effect on our ability to make, use or sell rhIGF-I/rhIGFBP-3 for certain indications.

We may have to undertake costly litigation to enforce any patents issued or licensed to us or to determine the scope and validity of another party s proprietary rights. We can give no assurances that a court of competent jurisdiction would validate our issued or licensed patents. An adverse outcome in litigation or an interference or other proceeding in a court or patent office could 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.

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

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

Third-party claims that our products infringe on their proprietary rights may materially 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 can give no assurances 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.

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In this regard, we note that on December 20, 2004, Tercica, Inc. and Genentech Inc. filed a complaint against Avecia Limited and Insmed, Inc. in the United Kingdom at the High Court of Justice, Chancery Division, Patents Court alleging infringement of EP patent No. 571,417 (the 417 patent). The litigation regarding the 417 patent is ongoing and Insmed cannot predict with certainty the outcome of this proceeding. We note, however, that an adverse ruling could impact our ability to make, use or sell our products and would have a material adverse effect on our business, financial condition and results of operations.

In addition, Tercica, Inc. filed, on December 23, 2004, a complaint against Insmed in the United States District Court for the Northern District of California alleging infringement of U.S. patent Nos. 5,187,151 and 6,331,414. These patents are directed to certain methods of using IGF-I/IGFBP-3 and methods of producing human IGF-I, respectively. On February 16, 2005, Tercica, Inc. and Genentech, Inc. filed an Amended Complaint, adding allegations of infringement EP patent No. 571,417 (the 417 patent) of U.S. patent No. 5,258,287 (the 287 patent). The claims of the 287 patent are directed to DNA encoding BP53 (i.e. IGFBP-3) and recombinant constructs, transformed host cells and methods for using same. The litigation regarding the 287 patent is ongoing and Insmed cannot predict with certainty the outcome of this proceeding. We note, however, that an adverse ruling could impact our ability to make, use or sell our products and would have a material adverse effect on our business, financial condition and results of operations.

On February 18, 2005, Insmed filed a motion to dismiss the Amended Complaint. In the motion, Insmed asserted that all alleged activities fall within the statutory safe-harbor provided by 35 U.S.C. §271(e)(1), commonly called the clinical trial exemption. This exemption prevents patent infringement actions from being filed against activities reasonably related to obtaining FDA approval of a product, such as when the product is still being tested in clinical trials. Insmed further asserted, among other things, that Plaintiffs have failed to state a claim for the requested relief, have not sued the proper party, have failed to name all the proper plaintiffs and have failed to establish the existence of a sufficiently real and substantial controversy between the parties. Insmed requested immediate dismissal or Summary Judgment against the plaintiff s allegation on these grounds.

Insmed cannot predict with certainty the outcome of this proceeding. We note, however, that an adverse ruling could impact our ability to make, use or sell our products.

An inability to compete successfully will materially adversely affect 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

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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.

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, among others, will determine our ability to compete effectively:

- safety and efficacy;
- product price;
- ease of administration; and
- marketing and sales capability.

Currently, no drug in the United States or Europe is approved and marketed as replacement therapy for the treatment of GHIS. We are aware of only one other company, Tercica, Inc., that is pursuing development of a product for this indication or a similar indication. On February 28, 2005 Tercica announced that it had submitted an NDA for the use of rhIGF-I in the long term treatment of growth failure in children with a severe form of primary IGF-I deficiency. We believe this indication would include patients with GHIS. We believe Tercica may also be planning to develop rhIGF-I for some of the same indications that we plan to pursue with rhIGF-I/rhIGFBP-3.

Growth hormone may also be a competitive product for the treatment of some indications that we may pursue with rhIGF-I/rhIGFBP-3. The major suppliers of commercially available growth hormone are Genentech, Eli Lilly, Novo Nordisk, Pfizer and Serono. We believe that Novo Nordisk may be conducting clinical trials for the use of its growth hormone in pediatric IGF-I deficiency. We are also aware that Serono is conducting a Phase III trial with growth hormone for the treatment of HIV associated adipose redistribution syndrome.

In addition, we believe that Genentech, Merck, Novo Nordisk and Pfizer have previously conducted research and development of orally-available small molecules that cause the release of growth hormone, known as growth hormone secretagogues. We are not aware of any continued clinical development of these molecules by these companies. We believe that Rejuvenon Corporation may have licensed certain rights to Novo Nordisk s growth hormone secretagogues, which are in pre-clinical development. We are also aware that Theratechnologies is developing various peptides that stimulate the release of hormones that could be used in the treatment of some of the same indications we plan to pursue with rhIGF-I/rhIGFBP-3.

Many companies are seeking to develop products and therapies for the treatment of diabetes. Our competitors include multinational pharmaceutical companies, specialized biotechnology firms, and universities and other research institutions. Our largest competitors include Amylin Pharmaceuticals, Bristol-Myers Squibb Company, Eli Lilly, GlaxoSmithKline, Merck, Novartis, Novo Nordisk and Takeda Chemical Industries. Various products are currently available to treat type 2 diabetes, such as insulin and oral hypoglycemic drugs.

In addition, several companies are developing various new approaches to improve the treatments of type 1 and type 2 diabetes. Specifically, Amylin Pharmaceuticals has conducted and is continuing to conduct clinical trials for two products, Symlin and Exenatide, for the treatment of type 2 diabetes. Tercica has indicated that it plans to pursue the development of rhIGF-I in the treatment of severe forms of diabetes.

Many companies are pursuing the development of products for the treatment of cancer. Our competitors include multinational pharmaceutical companies, specialized biotechnology firms, and universities and other research institutions. Although we are unaware of any companies developing rhIGFBP-3 for cancer we are aware of companies who are developing products that are intended to target the same pathway as rhIGFBP-3.

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

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could make our products obsolete, which could materially adversely affect our business, financial condition and results of operations.

Our inability to compete in our industry could materially adversely affect our business, financial condition and results of operations.

Our research, development and manufacturing 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, development and manufacturing 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.

Conversion of the notes and exercise of the warrants issued by Insmed will significantly dilute the ownership interest of existing stockholders.

The convertible notes issued by us on March 15, 2005 and the warrants issued by us in March 2005, November 2004 and July 2003 are convertible into and exercisable for up to 50,008,280 shares of our common stock, representing approximately 111% of the our outstanding common stock as of May 31, 2005. The conversion or exercise of some or all of the notes and warrants will significantly dilute the ownership interests of existing stockholders. Any sales in the public market of the common stock issuable upon such conversion or exercise could adversely affect prevailing market prices of our common stock.

The market price of our stock has been and may continue to be highly volatile, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future.

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 pre-clinical studies, or those of our corporate partners or our competitors;

our operating results;

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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 regulation., reimbursement changes and governmental investigation or audits related to us or to our products,

developments related to our patents or other proprietary rights or those of our competitors;

changes in the position of securities analysts with respect to our stock; and/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.

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

Future sales by existing shareholders may lower the price of our common stock, which could result in losses to our shareholders. Future sales of substantial amounts of common stock in the public market, or the possibility of such sales occurring, could adversely affect prevailing market prices for our common stock or our future ability to raise capital through an offering of equity securities. Substantially all of our common stock is freely tradable in the public market without restriction under the Securities Act 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. 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 holder 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 asking 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 106 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.

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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.

FORWARD-LOOKING INFORMATION

The matters discussed throughout this prospectus that are not historical facts are forward-looking and, accordingly, involve estimates, projections, goals, forecasts, assumptions and uncertainties that could cause actual results or outcomes to differ materially from those expressed in the forward-looking statements. This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934 (the Exchange Act). Our actual results may differ materially from those projected in the forward-looking statements as a result of the risk factors set forth above. In particular, please review the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations.

These forward-looking statements may include, but are not limited to, future capital expenditures, acquisitions (including the amount and nature of acquisitions), future revenues, earnings, margins, costs, demand for new pharmaceutical products, market trends in the pharmaceutical business, inflation and various economic and business trends. In some cases, you can identify forward-looking statements by terms such as may, will, should, could, would, expects, plans, anticipates, believes, estimates, forecasts, projects, predicts, potential, and intended to identify forward-looking statements. Forward-looking statements include all statements regarding commencement of clinical trials, expected financial position, results of operations, cash flows, dividends, financing plans, business strategies, operating efficiencies or synergies, budgets, capital and other expenditures, competitive positions, growth opportunities for our proposed products, plans and objectives of management, proposed relationships with third-party research organizations, manufacturers and suppliers and markets for our stock.

We caution you not to place undue reliance on these forward-looking statements, which speak only as of the date they were made. We do not undertake any obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in this prospectus in greater detail under the heading Risk Factors. In connection with forward-looking statements which appear in these disclosures, prospective purchasers of the shares offered hereby should carefully consider the factors set forth in this prospectus under Risk Factors as well as those concerns discussed in the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere throughout this prospectus. Also these forward-looking statements represent our estimates and assumptions only as of the date of this prospectus.

USE OF PROCEEDS

We will not receive any proceeds from the sale of the shares of our common stock by the selling stockholders. All proceeds from the sale of the shares of common stock by the selling stockholders will be received directly by the selling stockholders. See Selling Stockholders. If the selling stockholders exercise the warrants to purchase our common stock for cash instead of on a net exercise basis, then we will receive the exercise price from the exercise of the warrants. The proceeds, if any, will be added to our working capital and be available to fund the ongoing activities relating to SomatoKine®, rhIGFBP-3 and INSM-18 and for general corporate purposes.

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MARKET PRICES AND DIVIDEND POLICY

Our trading symbol on the Nasdaq National Market 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	
	High ($)	Low ($)
Fiscal Year 2005		
Second Quarter (through June 10, 2005)	1.45	0.79
First Quarter	2.30	0.80
Fiscal Year 2004		
Fourth Quarter	2.48	1.24
Third Quarter	2.33	1.00
Second Quarter	3.40	1.98
First Quarter	4.28	2.87
Fiscal Year 2003		
Fourth Quarter	3.40	2.50
Third Quarter	3.74	1.96
Second Quarter	3.56	0.60
First Quarter	0.65	0.39

On June 10, 2005, the last reported sale price for our common stock on the Nasdaq National Market was $0.90 per share. As of June 1, 2005, there were approximately 567 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.

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SELECTED CONSOLIDATED 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, 2004 and the three-month periods ended March 31, 2004 and 2005. 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 December 31, 2004 have been audited by Ernst & Young LLP, our independent registered public accounting firm. The selected consolidated financial data for the three months ended March 31, 2004 and 2005 and as of March 31, 2004 and 2005 are derived from unaudited financial statements. 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 29.

	Year Ended December 31,					Three Months Ended March 31,	
	2000	2001	2002	2003	2004	2004	2005
						unaudited	unaudited
Historical Statement of Operations Data:							
Revenues	$ 60	$ 296	$ 1,955	$ 150	$ 137	$ 61	$ 57
Operating expenses:							
Research and development	21,608	35,506	18,077	7,140	23,320	3,855	4,287
General and administrative	5,989	4,881	2,984	3,477	4,242	1,041	1,293
Operational restructuring charge			2,533				
Goodwill write-off			15,385				
Purchased research and development	50,434						
Stock compensation	3,564	95		119			
Total operating expenses	81,595	40,482	38,979	10,736	27,562	4,896	5,580
Operating loss	(81,535)	(40,186)	(37,024)	(10,586)	(27,425)	(4,835)	(5,523)
Interest income, net	1,873	3,017	607	288	222	76	64
Interest expense							(305)
Loss before income taxes	(79,662)	(37,169)	(36,417)	(10,298)	(27,203)	(4,759)	(5,764)
Income tax expense	200						
Net loss	(79,862)	(37,169)	(36,417)	(10,298)	(27,203)	(4,759)	(5,764)
Basic and diluted net loss per share	(4.36)	(1.13)	(1.10)	(0.29)	(0.69)	(0.12)	(0.13)
Weighted average shares	18,319	32,871	33,066	35,600	39,160	38,395	44,986
Historical Balance Sheet Data:							
Cash, cash equivalents and marketable securities	$ 83,083	$ 51,250	$ 27,337	$ 29,526	$ 9,222	$ 9,222	$ 35,771
Total assets	102,718	71,606	28,308	29,812	13,011	13,011	41,125
Stockholders equity	96,782	59,695	23,446	26,220	7,235	7,235	17,549

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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 three lead drug candidates rhIGF-I/rhIGFBP-3, rhIGFBP-3 and INSM-18. During 2004 we initiated a pivotal Phase III study with rhIGF-I/rhIGFBP-3 in GHIS and a Phase I study with rhIGFBP-3 in cancer. Also during 2004 we were successful in manufacturing clinical grade rhIGF-I/rhIGFBP-3 at Avecia and commissioned our ITP facility in Boulder, Colorado. On January 3, 2005 we submitted an NDA to the FDA for the use of rhIGF-1/rhIGFBP-3 in the treatment of GHIS, and on March 4, 2005 we received acceptance of the filing for FDA review. We are continuing our Phase III clinical trial in order to obtain long term data and plan to submit a Marketing Authorization Application to the European Medicines Agency for this indication. Our plans for 2005 include:

- Obtain NDA approval for rhIGF-I/rhIGFBP-3 in GHIS
- Initiate clinical trials to expand rhIGF-I/rhIGFBP-3 into additional niche indications
- Establish commercial activities consistent with FDA approval process
- Capitalize through debt/equity and partnership fees to sustain 2005/2006 operations
- Establish European partner for rhIGF-I/rhIGFBP-3 and global partner for rhIGFBP-3
- Aggressively defend patent lawsuits in the United States and United Kingdom

We have not been profitable and have accumulated deficits of approximately $213.7 million through December 31, 2004. 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.

Research and Development Activities

We are engaged in the research and development of proposed drug products for the treatment of metabolic diseases and endocrine disorders. All of our research and development expenditures, whether conducted by our own staff or by external scientists on our behalf and at our expense, are recorded as expenses as incurred and amounted to approximately $106 million dollars for the period since inception, in November 1999, through December 31, 2004, $18 million, $7 million and $23 million in the years ended December 31, 2002, 2003 and 2004, and $4.3 million in the three months ended March 31, 2005. Research and development expenses consist primarily of salaries and related expenses, costs to develop and manufacture products and amounts paid to contract research organizations, hospitals and laboratories for the provision of services and materials for drug development and clinical trials.

Our leading drug candidate, rhIGF-I/rhIGFBP-3, or SomatoKine®, is currently in Phase III clinical trials for the treatment of GHIS. We have filed an NDA for this drug in the GHIS indication, which was accepted for review by the FDA. We have also received priority review for SomatoKine®. The FDA initially notified us that the User Fee Goal Date was July 3, 2005, but later reset the User Fee Goal Date to October 3, 2005. There can be no assurance that the FDA will act by this date. SomatoKine® has also been granted orphan drug designation for the GHIS indication and other indications. Substantially all of our research and development expenditures for fiscal 2003 and 2004, and to date in fiscal 2005, have been related to SomatoKine®.

Our research and development efforts for other products are in their early stages and include primarily research and development regarding rhIGFBP-3 for the treatment of various cancers and INSM-18 for the treatment of various tumors. These products are either in pre-clinical stages or, Phase I and II clinical trials. All of our research and development expenditures related to these early-stage products and our efforts associated with SomatoKine® are significantly interrelated as they are all associated with drugs that modulate IGF-I activity in the human body. A significant finding in any one drug for a particular indication may provide benefits to our efforts across all of these

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products. All of these products also share a substantial amount of our common fixed costs such as salaries, facility costs, utilities and maintenance. Given the small portion of research and development expenses that are related to products other than SomatoKine® we have determined that very limited benefits would be obtained from implementing cost tracking systems that would be necessary to allow for cost information on a product-by-product basis.

In the near term, Insmed intends to focus substantially all of its research and development resources on the completion of phase III clinical trials for SomatoKine® in the GHIS indication and expansion of SomatoKine® into other indications. Our efforts to obtain FDA approval for SomatoKine® for the GHIS indication will be our main focus for the remainder of fiscal 2005. We estimate that our research and development expenditures to complete development of SomatoKine in this indication will be in the range of between $20 million to $23 million for the current fiscal year. Our plans to expand SomatoKine® into additional indications are expected to represent our main research and development focus beginning in 2006. Our thrust to develop our other early-stage products will continue but we expect those efforts to account for a much smaller portion of Insmed s research and development expenditures. These estimates are based on currently available information and, due to a number of factors, no assurance can be provided that this project will not take longer to complete or cost more than we have currently estimated. The full cost and completion dates, through commercialization, of these research and development efforts, are dependent on the results of our Phase III clinical trial, together with the review of our NDA by the FDA.

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

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

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

Moreover, all of our product candidates and particularly those that are in the pre-clinical or early clinical trial stage must overcome significant regulatory, technological, manufacturing and marketing challenges before they can be successfully commercialized. Some of these projects may never reach the clinical trial stage of research and development. As pre-clinical studies and clinical trials progress, we may determine that collaborative relationships will be necessary to help us further develop or to commercialize our product candidates, but such relationships may be difficult or impossible to arrange. Our projects or intended projects may also be subject to change from time to time as we evaluate our research and development priorities and available resources.

Any significant delays that occur or additional expenses that we incur may have a material adverse affect on our financial position and require us to raise additional capital sooner or in larger amounts than is presently expected. In addition, as a result of the risks and uncertainties related to the development and approval of our drug candidates and the additional uncertainties related to our ability to market and sell these products once approved for commercial sale, we are unable to provide a meaningful prediction regarding the period in which material net cash inflows from any of these projects are expected to become available.

Results of Operations

Three Months Ended March 31, 2005 compared to Three Months Ended March 31, 2004

Revenues for the three months ended March 31, 2005 were $57,000, compared with revenues of $61,000 for the equivalent period in 2004. The net loss for the three months ended March 31, 2005 was $5.8 million, or $0.13 per

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share which represents an increase of $1.0 million and $0.01 per share from the net loss of $4.8 million, or $0.12 per share reported for the corresponding period in 2004. Sequentially, first quarter 2005 revenues were $34,000 higher than the $23,000 reported in the fourth quarter of 2004. At March 31, 2005, cash and cash equivalents were $35.8 million, an increase of $26.6 million from December 31, 2004, as capital was raised through a convertible debt offering.

Revenues remained consistent for the first quarter of 2005 compared to the first quarter of 2004. Sequentially the $34,000 increase in revenues was due to an annual royalty which is normally received and reported in the first quarter of each year.

The $1.0 million increase in the net loss for the first quarter 2005 compared to the corresponding period in 2004 resulted from a $0.4 million increase in research and development spending, a $0.3 million increase in general and administration costs and a $0.3 million increase in interest expense.

The $0.4 million increase in research and development costs, stemmed primarily from increased regulatory costs during the first three months of 2005 in support of our lead product SomatoKine® in the Growth Hormone Insensitivity Syndrome (GHIS) indication. The $0.3 million increase in general and administrative expenditures is due to a rise in external service costs in support of our business program. The $0.3 million in interest expense resulted from $80,000 of interest payable on the convertible debt and $225,000 to cover the accretion of the debt discount and deferred offering costs for the period from March 15, 2005 when the convertible debt was issued, through to the end of the calendar quarter March 31, 2005. The debt discount, which is a non cash item, and deferred offering costs are calculated and amortized in accordance with GAAP. The combined total of $18.4 million for the debt discount and deferred offering costs is being amortized over 60 months, the term of the convertible notes.

Year Ended December 31, 2004 compared to Year Ended December 31, 2003

For the year ended December 31, 2004, we recorded a net loss of $27.2 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 $16.2 million from $7.1 million in 2003 to $23.3 million in 2004. This rise in spending resulted from a broader clinical trials program and an increase in manufacturing activity at our ITP facility and at our contract manufacturer Avecia to produce rhIGF-I/rhIGFBP-3 for our clinical trials,

General and administrative expenses increased $0.7 million from $3.6 million for 2003 to $4.3 million for 2004. The increase was due to higher external service and personnel costs in support of our business. Revenues decreased $13,000 from $150,000 in 2003 to $137,000 in 2004 due to a slight decline in royalties.

As of December 31, 2004, cash and cash equivalents decreased to $9.2 million from $29.5 million at December 31, 2003. As a result of a lower average cash balance and lower interest rates in 2004 compared to 2003, net interest income decreased $66,000 from $288,000 in 2003 to $222,000 million in 2004.

Accounts payable and accrued project costs increased $1.1 million from $2.4 million at December 31, 2003 to $3.5 million at December 31, 2004 as a result of increased clinical and manufacturing activity. Stockholders equity decreased $19.0 million mainly as a result of the net loss for 2004 of $27.2 million being partially offset by approximately $8.0 million in net proceeds received in connection with a private placement of

our common stock on November 8, 2004. The accumulated deficit at December 31, 2004 increased to approximately $213.8 million due to our 2004 net loss of $27.2 million.

Year Ended December 31, 2003 compared to Year Ended December 31, 2002

For the year ended December 31, 2003, we recorded a net loss of $10.3 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 $11.0 million from $18.1 million in 2002 to $7.1 million in 2003 as a result of decreased clinical trial activity.

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Clinical and contract manufacturing costs related to the development of rhIGF-I/rhIGFBP-3 decreased approximately $0.3 million from $3.5 million in 2002, to $3.2 million in 2003 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 increased $0.5 million from $3.0 million for 2002 to $3.5 million for 2003. The increase, although seen across all support services, was primarily due to higher external service costs.

In the third quarter of 2002, we recorded a restructuring charge of $2.5 million related to the previously announced discontinuation of our 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 of 2002 relating to the Celtrix acquisition in 2000.

Revenues decreased $1.8 million from $2.0 million in 2002 to $0.2 million in 2003. The decrease in revenues as compared with 2002 is due to the recognition of approximately $1.7 million of revenue from an international license fee for INS-1 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 was 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, 2003, cash and cash equivalents increased to $29.5 million from $27.3 million at December 31, 2002. As a result of a lower average cash balance and lower interest rates in 2003 compared to 2002, net interest income decreased $0.3 million from $0.6 million in 2003 to $0.3 million in 2003.

Accounts payable and accrued project costs decreased $0.8 million from $3.2 million at December 31, 2002 to $2.4 million at December 31, 2003 as a result of decreased clinical and manufacturing activity. Stockholders equity increased $2.8 as a result of approximately $13.0 million in proceeds received by us in connection with a private placement of our common stock on July 15, 2003, net of the loss in 2004. The accumulated deficit at December 31, 2003 increased to approximately $186.5 million due to our 2003 net loss of $10.3 million.

Liquidity and Capital Resources

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

Capital Requirements

Expenditures in the year ended December 31, 2004 were principally related to the research and development, increased clinical trial activity and manufacturing activities at our site in Boulder, Colorado, as well as administrative support activities. In the short-term, we will need to raise substantial additional funds to continue the development and approval process with respect to our lead drug products. In the longer-term, we will require substantial additional funds for the commercialization of those products. Our continuation as a going concern depends on our ability to obtain such additional financing and, ultimately, to generate positive cash flow and attain profitability. There can be no assurance that adequate funds will be available when we need them or on favorable

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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.

Planned expenditures in 2005 include the funding of our ongoing R & D activity, such as manufacturing and clinical trial costs, General and Administrative support costs plus initial commercialization efforts associated with the anticipated approval of our NDA.

Capital Resources

We have funded our operations to date primarily through public and private placements of equity securities. We plan to continue incurring losses as we expand our research and development and do not expect material revenues for at least the next several years. At December 31, 2004, our cash and cash investments were approximately $9.2 million and were invested in money market instruments. This is a decrease from $29.5 million at December 31, 2003, despite the conclusion, in November 2004, of a private placement of 6,455,551 shares of our common stock to a group of institutional investors at a price of $1.35 per share, which raised a total of approximately $8.7 million. The placement agent in the transaction received approximately $572,000 in fees and expenses (including fees paid to the placement agent s attorneys) resulting in net proceeds of approximately $8.0 million. We also issued warrants to purchase an additional 3,227,775 shares of our common stock with an exercise price of $2.00 per share.

On March 15, 2005, we entered into several purchase agreements with a group of institutional investors, pursuant to which we issued and sold to the investors approximately $35,000,000 aggregate principal amount of 5.5% convertible notes, which notes are convertible into our common stock, par value $0.01 per share, as well as warrants to purchase, in the aggregate, 14,864,883 shares of our common stock, at an exercise price of $1.36 per share. The principal of each note will mature and be payable in nine quarterly installments of approximately $3,890,000 commencing on March 1, 2008. Any outstanding notes must be repaid in cash or converted by March 1, 2010. Commencing on June 1, 2005, the holders of the notes will receive quarterly interest payments at a rate of 5.5% per annum. The holders of the notes may convert the notes into our common stock at a conversion price of $1.295 per share as adjusted in accordance with certain adjustments for stock splits, dividends and the like at any time prior to the close of business on March 1, 2010. The notes are convertible into, in the aggregate, 27,027,027 shares of our common stock. The warrants are immediately exercisable for 14,864,883 shares of our common stock at an exercise price of $1.36 per share. The warrants will expire on March 15, 2010. The holders of the notes have the right to require us to repurchase the notes with cash payments up on the occurrence of specified events of default and repurchase events. The investors also have the right to participate in future financings undertaken by us prior to March 16, 2006, subject to certain exceptions. In connection with issuance of the notes and warrants, we entered into registration rights agreements with the investors pursuant to which we agreed to file a Registration Statement under the Securities Act of 1933, registering for resale the shares of common stock issuable upon the conversion of the notes or exercise of the warrants.

With this additional funding the company believes it has sufficient capital resources to fund our operations through the next twelve months.

Our business strategy contemplates raising additional capital through equity sales. We also plan to enter into agreements with corporate partners in order to fund research and development and to provide milestone payments, license fees and equity investments to fund our operations.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that we believe is material to investors.

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Contractual Obligations

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

	Payments due by period (in thousands)		
Contractual Obligations	**Total**	**Less than 1 Year**	**1-4 Years**
Operating Lease Expenses	2,472	1,153	1,319
Total	2,472	1,153	1,319

Critical Accounting Policies

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. 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. For additional accounting policies, see Note 1 to our consolidated financial statements - Description of the Business and Summary of Significant Accounting Policies

Research and Development

Research and development costs are expensed as incurred. Research and development expenses consist primarily of salaries and related expenses, cost to develop and manufacture products and amounts paid to contract research organizations, hospitals and laboratories for the provision of services and materials for drug development and clinical trials.

We do not have separate accounting policies for internal or external research and development and we do not conduct any research and development for others. Our expenses related to clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with third party organizations that conduct and manage clinical trials on our behalf. These contracts set forth the scope of work to be completed at a fixed fee or amount per patient enrolled. Payments under these contracts depend on performance criteria such as the successful enrollment of patients or the completion of clinical trial milestones. Expenses are accrued based on contracted amounts applied to the level of patient enrollment and to activity according to the clinical trial protocol.

Our expenses relating to contract manufacturing of clinical material are based on agreements reached with the contract manufacturer. The contract identifies the amount of clinical material to be manufactured, the time for manufacture, and other development work to be completed in supporting the manufacturing of the clinical material. In general, the contract and the work to be completed are in phases, and we accrue expenses for these contracts based upon the initiation and timing of each phase.

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, as amended by FASB Statement No. 148, Accounting for Stock-Based Compensation Transition and Disclosure, are presented in Notes 1 and 2. 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

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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.

Quantitative And Qualitative Disclosures About Market Risk

We invest excess cash in investment grade, interest-bearing securities and, at December 31, 2004, had $9.2 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, 2004, are all less than three-months minimizes such risks. In addition, while a hypothetical 1.0% per annum decrease in market interest rates would reduce interest income in 2005, it would not result in a loss of the principal and the decline in interest income would be deemed immaterial.

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BUSINESS

Insmed Incorporated is a biopharmaceutical company focused on the development and commercialization of drug products for the treatment of metabolic diseases and endocrine disorders. Currently, our development activities focus on drugs that modulate IGF-I activity in the human body. We currently have 3 lead drug candidates, recombinant human insulin-like growth factor-I bound to recombinant human insulin-like growth factor binding protein-3 (rhIGF-I/rhIGFBP-3; also known as SomatoKine®) rhIGFBP-3 and INSM-18. We are actively developing these drugs to treat indications in the metabolic and oncology fields.

Scientific Background

Role of IGF-I and IGFBP-3 in Growth

Insulin-like growth factor-I (IGF-I) is required for normal growth, development and metabolism. It is produced locally in tissues throughout the body, and also circulates in the blood to be delivered to target tissues. The majority of circulating IGF-I, which is largely produced by the liver, is bound to IGF binding proteins (IGFBPs), principally IGFBP-3. The major role of IGFBP-3 is to regulate the tissue distribution and activity of IGF-I. IGF-I binds to IGFBP-3 with high affinity to form a binary complex, which in turns binds to an acid-labile subunit (ALS) to form a ternary complex. All three components of the ternary complex are growth hormone (GH)-dependent. IGF-I is the principal mediator of the growth-promoting properties of GH. GH-induced IGF-I, that is either produced locally or delivered via the circulation, stimulates cartilage and bone and the growth plates of long bones and is necessary for normal accrual of peak bone mass.

Insufficient blood levels of IGF-I (IGF-I deficiency) during childhood and adolescence result in growth failure and short stature. In some cases, this is the result of inadequate GH quantity or bioactivity. Children with low levels of GH (GH deficiency) can generally be treated with recombinant human GH (rhGH) replacement therapy, resulting in normalization of IGF-I production and catch-up growth in most patients. However, there are a number of conditions in which IGF-I deficiency can occur despite normal or even elevated levels of GH. These abnormalities are known collectively as growth hormone insensitivity syndrome (GHIS), and can result from either hereditary or acquired conditions. These forms of IGF-I deficiency are unresponsive to rhGH treatment.

IGF-I deficiency due to GHIS can be the result of genetic abnormalities involving the GH receptor or other genes in the GH signal transduction pathway or be the result of mutations in the IGF-I gene itself. Acquired conditions include the development of neutralizing antibodies to GH in response to rhGH treatment in children with deletions of the GH gene (GH deficiency type IA). Regardless of the cause of IGF-I deficiency, replacement therapy with rhIGF-I can correct the abnormality. Co-administration of rhIGF-I with rhIGFBP-3 can accomplish this in a more physiologic manner by delivering the IGF-I to tissues bound to its natural regulatory protein.

Role of IGF-I and IGFBP-3 in Glucose Metabolism

Insulin is the primary hormone responsible for controlling glucose metabolism. Although less potent than insulin, IGF-I is capable of stimulating hepatic and muscle glucose uptake. IGF-I can affect the set point for insulin action and, like insulin, block protein and lipid breakdown. IGF-I causes a decrease in circulating GH levels via negative feedback, which further affects glucose metabolism. Thus, the proper balance of insulin, GH and IGF-I is extremely important for normal glucose metabolism.

Short-term clinical studies with rhIGF-I/rhIGFBP-3 and longer-term studies with rhIGF-I reported in scientific literature demonstrate that IGF-I therapy can reduce insulin requirements, improve glycemic control, and increase insulin sensitivity in both type 1 and type 2 diabetes. Fujisawa Pharmaceutical Co., Ltd., with whom Insmed has entered into a license agreement (see Strategic Relationships), has received approval of rhIGF-I in Japan for the treatment of the most severe forms of diabetes, referred to as extreme insulin resistance. Extreme insulin resistance includes a number of chronic diseases distinguished by severe insensitivity to insulin due to inherited or acquired causes. Treatment with rhIGF-I/rhIGFBP-3 is intended to improved glycemic control and reduce insulin dose requirements in this patient population.

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Role of IGF-I and IGFBP-3 in Cancer

IGF-I plays an essential role in normal growth throughout fetal and childhood development. In adult life, IGF-I continues to function by regulating cellular metabolism, inducing cell division and protecting against cell death. IGFBP-3 is the most abundant naturally-occurring IGF-I binding protein in the circulation and controls the actions of IGF-I by regulating its tissue distribution. When bound to IGFBP-3, IGF-I is incapable of binding to the IGF-I receptor. IGFBP-3 also has independent actions of its own that can inhibit cell proliferation and stimulate cell death.

A number of epidemiological studies suggest that increased circulating levels of IGFBP-3 are associated with a decreased risk for the development of several common cancers, including those of the prostate, lung, rectum and bladder. Therefore, administration of rhIGFBP-3 may represent a novel therapeutic approach to a variety of human cancers. Insmed has initiated a clinical program with prominent oncologists to develop rhIGFBP-3 as a therapeutic agent. To date, we have evaluated the efficacy of rhIGFBP-3 alone and in combination with standard chemotherapeutic agents in pre-clinical models of breast, lung, prostate and colon cancers. Insmed is also initiating clinical studies of a compound known as INSM-18, which has novel effects on the activity of the IGF-I and other receptors that can lead to the inhibition of growth of various tumors. Insmed is currently planning the clinical development of this compound in collaboration with the University of California, San Francisco School of Medicine and is preparing to initiate an exploratory clinical study in patients with relapsed prostate cancer.

Primary Therapeutic Indications

Growth Failure Due to GHIS Resulting in IGF-I Deficiency

GHIS is a condition affecting a specific subset of patients suffering from growth failure because of a deficiency in IGF-I. This deficiency can be due to hereditary or acquired defects in the GH receptor or GH signal transduction. Characteristics of this condition include:

- normal or elevated serum GH levels
- inability to generate normal IGF-I levels after GH provocation
- reduced serum IGF-I and IGFBP-3 levels
- severe postnatal growth failure and markedly reduced adult height (120-140 cm)
- truncal adiposity
- delayed skeletal maturation

abnormal craniofacial development

Physicians use height standard deviation score, or height SDS, to indicate how many standard deviations a person s height is from the average of the normal population of the same age and sex. The American Academy of Pediatrics and the American Academy of Clinical Endocrinology define short stature as a height that is more than two standard deviations below the average. Children with severe GHIS typically have height SDS < -3. Similarly, in evaluating IGF-I deficiency, physicians can use an IGF-I SDS < -2 to define abnormally low serum IGF-I levels.

Extreme Insulin Resistance

Insulin resistance describes an abnormality whereby the body is incapable of responding appropriately to circulating insulin. This abnormality can occur in many forms and results in varying degrees of disease severity. Extreme insulin resistance can result from defects in the insulin receptor gene or other genes involved in insulin signal transduction. These conditions include:

Type A and Type B syndrome

Rabson-Mendenhall syndrome

Leprechaunism

Type A syndrome patients have high circulating concentrations of insulin with impaired glucose tolerance or diabetes. They also have hyperandrogenism, resulting in hirsutism, acne, abnormal menstruation, and infertility.

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High doses of insulin fail to provide adequate glycemic control in these patients and there is no satisfactory treatment currently available.

Type B syndrome is characterized by the presence of autoantibodies to the insulin receptor that interfere with proper receptor functioning. These patients have hyperinsulinism, erratic glycemic control, hyperandrogenism, and other autoimmune disorders. High doses of insulin fail to provide adequate glycemic control in these patients and there is no satisfactory treatment currently available. Rabson-Mendenhall syndrome and Leprechaunism are also characterized by high circulating concentrations of insulin with alternating episodes of hyperglycemia and hypoglycemia. They also have hyperandrogenism and growth failure. High doses of insulin fail to provide adequate glycemic control in these patients and there is no satisfactory treatment currently available.

Diabetes

Patients with type 1 diabetes are characterized by their inability to produce insulin. In these patients, insulin deficiency leads to glucose intolerance in childhood. In type 1 diabetes, down-regulation of GH receptors in the liver results in reduced circulating IGF-I levels, which can lead to GH hypersecretion. This in turn causes decreased insulin sensitivity and worsening of metabolic control. Treatment of type 1 diabetes with rhIGF-I/rhIGFBP-3 can reduce GH levels and improve insulin sensitivity and glycemic control, while decreasing insulin dose requirements.

Type 2 diabetes is characterized by insulin resistance. In addition to low circulating levels of IGF-I, these patients have an increased number of insulin/IGF-I hybrid receptors. Increased expression of these hybrid receptors positively correlates with a decrease in both insulin binding affinity and insulin sensitivity. Treatment of type 2 diabetics requiring insulin therapy with rhIGF-I/rhIGFBP-3 also leads to improved glycemic control while decreasing insulin dose requirement.

Cancer

The World Health Organization estimates that by 2020, the number of annual worldwide cancer related deaths is expected to reach 10 million. To date, the United States Food and Drug Administration (FDA) has approved over 110 oncology drugs for more than 25 indications. Up to two-thirds of these drugs are cytotoxic agents, many of which exhibit significant systemic toxicity and decrease the quality of life of the patient.

Identification of the signaling pathways that regulate tumor growth has led to novel strategies for the treatment of cancer. As a result, new agents that target growth factors and their receptors are emerging as promising new treatments. To this end, both IGFBP-3 and INSM-18 have emerged as promising novel treatments for a variety of cancer types. Both treatments interact with the IGF system to reduce tumor growth.

Business Strategy

Our focus is on the development and commercialization of products for the treatment of metabolic and endocrine diseases with unmet medical needs. Our initial goal is to obtain the approval of rhIGF-I/rhIGFBP-3 for the treatment of GHIS and establish proof-of-concept clinical data with rhIGFBP-3 in the treatment of breast or other cancers. Our long-term strategy is to capitalize on many other potential endocrine and metabolic indications with rhIGF-I/rhIGFBP-3 and additional cancer indications with rhIGFBP-3. Key elements of our strategy for achieving

these goals include:

Seek FDA and EMEA approval of rhIGF-I/rhIGFBP-3 replacement treatment for GHIS. We submitted a New Drug Application (NDA) on January 3, 2005 to the FDA for the use of rhIGF-I/rhIGFBP-3 in the treatment of GHIS, which was accepted for review by the FDA on March 4, 2005. After initially setting a User Fee Goal Date of July 3, 2005 for its priority review, the FDA reset the User Fee Goal Date for October 3, 2005. We are continuing our Phase III clinical trial in patients with GHIS in order to obtain long term data and plan to submit a Marketing Authorization Application to the European Medicines Agency (EMEA) for this indication. Children with this disorder have a significant unmet medical need because no effective treatment is currently available on the market. The proprietary information we have licensed from Pharmacia demonstrates that replacement therapy with rhIGF-I given twice daily will significantly improve height velocity in these severely growth disturbed patients. Data from our clinical studies demonstrates that we can achieve similar circulating concentrations of IGF-I and efficacy results following administration of rhIGF-I/rhIGFBP-3 as was achieved in the Pharmacia studies following administration of rhIGF-I.

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Furthermore, these blood levels and efficacy were achieved with one injection of rhIGF-I/rhIGFBP-3 per day as opposed to the two injections needed with rhIGF-I alone. In addition to having the advantage of once-a-day dosing, our animal and clinical data suggest less severe side effects with rhIGF-I/rhIGFBP-3 when compared with rhIGF-I.

Our strategy is to maintain a dual manufacturing source for our products. We currently manufacture rhIGF-I/rhIGFBP-3 at our manufacturing facility, Insmed Therapeutic Proteins (ITP), in Boulder, Colorado and plan to continue our manufacturing program with Avecia Limited, a third party contract manufacturer in the United Kingdom. Based on discussions with the FDA, we are conducting several studies, including analytical, pre-clinical and clinical to compare the drug substance previously manufactured at Avecia to the new drug substance produced at ITP. The results of this comparison will become part of our submissions to the regulatory authorities.

Expand the GHIS indication to other growth disorders related to IGF-I deficiency. A number of growth disorders related to IGF-I deficiency other than GHIS represent conditions with significant unmet medical needs. While seeking approval in GHIS, we plan to investigate these other indications and further develop those that will provide the best market opportunity for label expansion. We will then seek this label expansion through supplemental regulatory submissions. It is likely that we will conduct one or more clinical studies to support label expansion.

Develop rhIGF-I/rhIGFBP-3 in additional indications. We intend to initiate clinical studies of rhIGF-I/rhIGFBP-3 in additional indications. Based on the data from these studies, we will select the most promising indications for further development and commercialization. The indications we are considering are extreme insulin resistance, diabetes, myotonic dystrophy, HIV associated adipose redistribution syndrome, recovery from severe burn injury, recovery from osteoporotic hip fracture and retinopathy of prematurity.

Establish a sales and marketing organization for the United States. We intend to develop a sales and marketing force to target the approximately 400 active U.S.-based pediatric endocrinology centers where children with growth disorders are evaluated and treated. These physicians are primarily hospital-based and concentrated in major metropolitan areas and we believe that they will be best served by a focused marketing organization and specialized sales force. In addition, we intend to conduct continuing medical education programs, medical symposia, and regional speaker programs aimed at establishing awareness of rhIGF-I/rhIGFBP-3 in the medical community. We also intend to conduct post-marketing studies and establish a patient registry to provide further data on the safety and efficacy of rhIGF-I/rhIGFBP-3.

Establish a sales and marketing organization or obtain a Marketing Partner for Europe. We are exploring several opportunities in Europe to partner with an established sales and marketing organization. We expect to conduct continuing medical education programs, medical symposia, and regional speaker programs aimed at establishing awareness of rhIGF-I/rhIGFBP-3 in the European physician community. We also intend to conduct post-marketing studies and establish a patient registry to provide further data on the safety and efficacy of rhIGF-I/rhIGFBP-3.

Initiate clinical studies with rhIGFBP-3. We are currently conducting a Phase I clinical study to establish the pharmacokinetic profile of rhIGFBP-3 and plan to proceed to Phase II clinical studies in one or more of the following cancer types: breast, colorectal, lung and/or prostate.

Broaden endocrinology and oncology portfolio based on our expertise. Our longer-term strategy for growth is to pursue the development and commercialization of additional products for the treatment of significant unmet medical needs that complement our activities within the fields of metabolic and endocrine diseases and oncology.

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

Establish corporate partnerships in certain markets. We plan to establish corporate partnerships to develop, market and commercialize our products in markets outside of our core focus.

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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 focus is principally in developing and commercializing late-stage products. We conduct very little of our own preclinical laboratory research. However, we actively maintain ongoing discussions with academic research institutions and other companies regarding rhIGF-I/rhIGFBP-3, rhIGFBP-3 and other projects in endocrinology and oncology. We are currently conducting a Phase III clinical study with our lead product, rhIGF-I/rhIGFBP-3, and plan to investigate other potential indications with this product. We are also conducting pre-clinical studies with our other lead compound, rhIGFBP-3 and plan on conducting clinical studies with this product in the future. Our research and development expenses were approximately $4.3 million for the three months ended March 31, 2005, $23.3 million in 2004, $7.1 million in 2003, and $18.1 million in 2002.

Strategic Relationships

Fujisawa Pharmaceutical Co., Ltd.

In January 2004, Insmed was granted a non-exclusive license to patent rights pertaining to the use of IGF-I therapy for the treatment of extreme or severe insulin resistant diabetes from Fujisawa Pharmaceutical Co., Ltd. Under the terms of the agreement, Insmed obtained worldwide rights in territories (excluding Japan) where a valid patent claim exists, including the United States and Europe. We have made a commitment to use reasonable commercial efforts to make rhIGF-I/rhIGFBP-3 available on a named patient basis to patients with extreme insulin resistance.

Tzamal Pharmaceutical

In October 2004, we entered into a letter of intent promotion agreement with Tzamal Pharma, a subsidiary of Fox Pharma headquartered in Jerusalem Israel. The agreement calls for Tzamal to be our exclusive distributor in Israel and Palestinian autonomous territories, West Bank and Gaza. The agreement has a term of one year and on the anniversary of the agreement it may be renewed via a joint agreement between Insmed and Tzamal for another twelve months.

Pharmacia Inc.

Pharmacia, Inc. was granted marketing approval in several European and Scandinavian countries for rhIGF-I in the treatment of GHIS. In August 2002, we entered into an agreement with Pharmacia that grants us an exclusive worldwide license to Pharmacia s portfolio of regulatory filings and proprietary information pertaining to rhIGF-I for the treatment of GHIS. We have made a commitment to make rhIGF-I/rhIGFBP-3 available on a named patient basis to GHIS subjects that were previously being treated with rhIGF-I supplied by Pharmacia.

Avecia Limited

In July 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 the work performed under this agreement, we have paid process development and manufacturing costs associated with the production of rhIGF-I/rhIGFBP-3.

Patents and Proprietary Rights

Insmed Patent Portfolio

Proprietary protection is important to our business, and our policy is to protect our technology by filing patent applications for technology that we consider important. We 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 will issue in the United States or a foreign country. There also can be no assurance that a subsequent U.S. or foreign patent will later be held valid and enforceable.

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We hold 28 United States patents relating 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;
- 15 therapeutic use patents for rhIGF-I/rhIGFBP-3, IGF-I, rhIGFBP-3 or rhIGFBP-3 fragments for the treatment of various disease conditions; and
- 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.

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.

In addition, foreign counterparts to the above-referenced U.S. patents have issued or are pending issue in the major pharmaceutical markets, such as Europe, Canada and Japan.

With respect to Europe, Insmed recently decided to withdraw one of its patents, EP 451,194 (the 194 patent), which is directed to compositions and methods of using IGFBP-3. This patent expires in 2009. We do not believe that a competitor is developing IGFBP-3 or will engage in activities encompassed by this patent prior to 2009. As such, the costs of maintaining this patent outweigh its estimated value. Therefore, Insmed has withdrawn its approval of the text of the 194 patent. As a result of this action, we expect the European Patent Office will soon revoke the 194 patent.

As part of our development and manufacturing agreement with Avecia Limited, we are currently negotiating to obtain certain non-exclusive rights to Avecia s proprietary manufacturing technology. In January 2004, Insmed was granted a non-exclusive license to patent rights pertaining to the use of IGF-I therapy for the treatment of extreme or severe insulin resistant diabetes from Fujisawa Pharmaceutical Co., Ltd.

Reflecting our commitment to safeguarding proprietary information, we require our employees and consultants to sign confidentiality agreements. These agreements prohibit unauthorized disclosure of Insmed s proprietary information. Despite our efforts to protect our proprietary information, unauthorized parties may attempt to obtain and use our proprietary information. Policing unauthorized use of our proprietary information is difficult, and the steps we have taken might not prevent misappropriation, particularly in foreign countries where the laws may not protect our proprietary rights as fully as do the laws of the United States.

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

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

Third-Party Patents

Third parties, including Genentech Inc. and Chiron Corporation 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.

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We can provide no assurance, however, that one of these third parties will not assert a contrary position in the future, for instance in the context of an infringement action. Likewise, we cannot predict with certainty the outcome of such a proceeding. We note, however, that an adverse ruling could impact our ability to make, use or sell our products. In any event, in some cases, litigation or other proceedings may be necessary to defend Insmed against claims of patent infringement.

In this regard, we note that on December 20, 2004, Tercica, Inc. and Genentech Inc. filed a complaint against Avecia Limited and Insmed, Inc. in the United Kingdom at the High Court of Justice, Chancery Division, Patents Court alleging infringement of EP patent No. 571,417 (the 417 patent). The litigation regarding the 417 patent is ongoing and Insmed cannot predict with certainty the outcome of this proceeding. We note, however, that an adverse ruling could impact our ability to make, use or sell our products and would have a material adverse effect on our business, financial condition and results of operations.

In addition, Tercica, Inc. filed, on December 23, 2004, a complaint against Insmed in the United States District Court for the Northern District of California alleging infringement of U.S. patent Nos. 5,187,151 and 6,331,414. These patents are directed to certain methods of using IGF-I/IGFBP-3 and methods of producing human IGF-I, respectively. On February 16, 2005, Tercica, Inc. and Genentech, Inc. filed an Amended Complaint, adding allegations of infringement of U.S. patent No. 5,258,287 (the 287 patent). The claims of the 287 patent are directed to DNA encoding BP53 (i.e. IGFBP-3) and recombinant constructs, transformed host cells and methods for using same. The litigation regarding the 287 patent is ongoing and Insmed cannot predict with certainty the outcome of this proceeding. Insmed cannot predict with certainty the outcome of this proceeding. We note, however, that an adverse ruling could impact our ability to make, use or sell our products and would have a material adverse effect on our business, financial condition and results of operations.

In addition, Novartis AG and Chiron Corporation have rights to United States and foreign patents relating to the use of IGF-1 for the treatment of type 1 diabetes, and Novartis owns United States and foreign patents relating to the treatment of osteoporosis with IGF-1. Genentech, Inc. owns U.S. and foreign patents directed to using IGF-1 to increase the growth rate of certain patients with non-GH-deficient short stature and patients having partial growth hormone insensitivity syndrome. We do not expect that we will infringe these patents. We can give no assurances, however, that such patents can be avoided, invalidated or licensed. Thus, the patents could potentially have an adverse effect on our ability to make, use or sell rhIGF-I/rhIGFBP-3 for certain indications.

Manufacturing

We currently rely on our wholly owned subsidiary, Insmed Therapeutic Proteins, as well as contract manufacturers to produce rhIGF-I/rhIGFBP-3 and rhIGFBP-3. If we are unable to establish our own capacity and maintain relationships with third parties for manufacturing sufficient quantities of our product candidates and their components which meet our planned time and cost parameters, the development and timing of our clinical trials and/or product commercialization may be adversely affected.

Our product candidates must be manufactured in a facility by processes that comply with current good manufacturing practices (cGMP) and other similar regulations. Prior to receiving marketing approval from the FDA, it is likely that the FDA will inspect our manufacturing facilities to ensure that our contract manufacturers and/or Insmed Therapeutic Proteins are in compliance with cGMP. If we are not in compliance with cGMP, the FDA may make us halt manufacturing until we can bring the facilities into compliance. This could take a substantial period of time and could adversely affect the development and timing of our clinical trials and/or product commercialization.

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.

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To date, we have supplied all of our pre-clinical and clinical study requirements with rhIGF-I/rhIGFBP-3 previously produced by our subsidiary, Celtrix Pharmaceuticals Inc. or Avecia Limited, a contract manufacturer in Billingham, England.

In July 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 the work performed under this agreement, we have paid process development and manufacturing costs associated with the production of rhIGF-I/rhIGFBP-3.

We are currently manufacturing rhIGF-I/rhIGFBP-3 at Insmed Therapeutic Proteins in Boulder, Colorado. Celtrix Pharmaceuticals Inc. no longer produces rhIGF-I/rhIGFBP-3. We cannot guarantee that Insmed Therapeutic Proteins and Avecia will be able to produce the rhIGF-I/rhIGFBP-3 or rhIGFBP-3 necessary for future pre-clinical and clinical trials or commercialization.

Marketing and Sales

We currently have no sales, marketing or distribution capability. However, we intend to develop a sales and marketing force to target the approximately 400 active U.S.-based pediatric endocrinologists who treat children with growth disturbance. Because these pediatric endocrinologists are primarily hospital-based and concentrated in major metropolitan areas, we believe that a focused marketing organization and specialized sales force can effectively serve them. In addition, we intend to conduct continuing medical education programs, medical symposia, and regional speaker programs aimed at establishing awareness of rhIGF-I/rhIGFBP-3 in the physician community. We also intend to conduct post-marketing studies and establish a patient registry to provide further data on the safety and efficacy of rhIGF-I/rhIGFBP-3.

We are exploring several opportunities for sales and marketing in Europe including the establishment of our own sales and marketing organization, acquisition of an existing sales and marketing organization and partnering with an established sales and marketing organization.

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.

Currently, no drug in the United States and Europe is approved and marketed as replacement therapy for the treatment of GHIS. We are aware of only one other company, Tercica, Inc., that is pursuing development of a product for this indication. On February 28, 2005 Tercica announced that it had submitted a NDA for the use of rhIGF-I in the long term treatment of growth failure in children with a severe form of primary IGF deficiency. We

believe this indication would include patients with GHIS. We believe Tercica may also be planning to develop rhIGF-I for some of the same indications that we plan to pursue with rhIGF-I/rhIGFBP-3.

GH may also be a competitive product for the treatment of some patients with growth disorders associated with IGF-I deficiency. The major suppliers of commercially available GH are Genentech, Eli Lilly, Novo Nordisk, Pfizer and Serono.

In addition, we believe that Genentech, Merck, Novo Nordisk and Pfizer have previously conducted research and development of orally available small molecules that cause the release of GH, known as GH secretagogues. We are not aware of any continued clinical development of these molecules by these companies. We believe that Rejuvenon Corporation may have licensed certain rights to Novo Nordisk s GH secretagogues, which are in pre-clinical development. We are also aware that Theratechnologies is developing various peptides that stimulate the release of hormones that could be used in the treatment of some of the indications we plan to pursue with rhIGF-I/rhIGFBP-3.

Many companies are seeking to develop products and therapies for the treatment of diabetes. Our competitors include multinational pharmaceutical companies, specialized biotechnology firms, and universities and other research institutions. Our largest competitors include Bristol-Myers Squibb Company, Eli Lilly, GlaxoSmithKline, Merck, Novartis, Novo Nordisk, Takeda Chemical Industries and Amylin Pharmaceuticals. Various products are currently available to treat type 2 diabetes, such as insulin and oral hypoglycemic drugs.

In addition, several companies are developing various new approaches to improve the treatments of type 1 and type 2 diabetes. Amylin Pharmaceuticals has conducted and is continuing to conduct clinical trials for two products, Symlin and Exenatide, for the treatment of type 2 diabetes. Tercica has indicated that it plans to pursue the development of rhIGF-I in the treatment of severe forms of diabetes.

Many companies are pursuing the development of products for the treatment of cancer. Our competitors include multinational pharmaceutical companies, specialized biotechnology firms, and universities and other research institutions. Although we are unaware of any companies developing rhIGFBP-3 for cancer, we are aware of companies who are developing products that are intended to target the same pathway that we are targeting with rhIGFBP-3.

It is possible that there are other companies with products currently in development or that exist on the market that may compete directly with rhIGF-I/rhIGFBP-3 or rhIGFBP-3.

Government Regulation

Government authorities in the United States and other countries extensively regulate the research, development, testing, manufacture, promotion, marketing and distribution of drug products. Drugs are subject to rigorous regulation by the FDA and similar regulatory bodies in other countries. 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 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

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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. The performance goals and procedures of the FDA Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), as agreed to under the reauthorization of the prescription drug user fee program in the Food and Drug Administration Modernization Act of 1997, indicate the FDA is striving to review and act on 90% of standard NDA submissions filed during years 2003 through 2007 within 10 months of receipt and priority NDA submissions within 6 months of submission. 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 our 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.

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

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States Orphan drug designation must be requested before submitting a NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same disease, except in very limited circumstances, for seven years. This exclusivity, however, also could block the approval of our products for

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seven years if a competitor is granted orphan designation and receives NDA approval of the same drug for the same indication or disease before we do. We have received orphan designation for the treatment of severe burn injury, growth disturbances due to GHIS, and extreme insulin resistance. We also intend to file for orphan drug designation for other indications which meet the criteria for orphan exclusivity. Obtaining FDA approval to market a product with orphan drug exclusivity may not provide us with a material commercial advantage.

The FDA Modernization Act of 1997 included a pediatric exclusivity provision that was extended by the Best Pharmaceuticals for Children Act of 2003. Pediatric exclusivity is designed to provide an incentive to manufacturers for conducting research about the safety of their products in children. Pediatric exclusivity, if granted, provides an additional six months of market exclusivity in the United States for new or currently marketed drugs, if certain pediatric studies requested by FDA are completed by the applicant. We believe our current plans to study rhIGF-I/rhIGFBP-3 in children may qualify rhIGF-I/rhIGFBP-3 for the additional six months of pediatric exclusivity, although there can be no assurances that FDA will grant such additional exclusivity. The current pediatric exclusivity provision is scheduled to end on October 1, 2007 and there can be no assurances that it will be reauthorized.

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 risks similar to those associated with FDA approval as described above.

Properties

We occupy 46,000 square feet of office and laboratory space in Glen Allen, Virginia and 30,000 square feet of manufacturing and warehouse space in Boulder, Colorado. Our annual cash cost for the Virginia space including utilities and services in 2004 was approximately $1.1 million under an operating lease that contains annual escalations of 1.75% and expires in October 2006. Our annual cash cost for the Colorado space including utilities and services in 2004 was approximately $0.6 million under an operating lease that contains an annual escalation of 3% and expires in February 2008. 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.

Employees

As of December 31, 2004, we had 55 full-time employees. Of these employees, 14 were engaged in research and development, 29 were engaged in manufacturing and 12 were engaged in general management, finance and administration. None of our employees are covered by any collective bargaining agreement. We consider relations with our employees to be good.

Legal Proceedings

Proceedings in the United Kingdom

On December 20, 2004, Tercica, Inc. and Genentech Inc. filed a complaint against Avecia Limited and Insmed, Inc. in the United Kingdom at the High Court of Justice, Chancery Division, Patents Court alleging infringement of EP patent No. 571,417 (the 417 patent). The 417 patent has claims directed to particular uses of a combination of IGFBP-3 and IGF-I. In the complaint, Tercica asked the court for an injunction to restrain allegedly infringing activity, for a declaration that the 417 patent is valid and infringed, for an order requiring the delivery or destruction of allegedly infringing articles and materials and for an inquiry into possible economic damages.

On February 11, 2005, Avecia and Insmed filed a Defense and Counterclaim to Tercica s suit. In its Defense, Avecia and Insmed asserted, among other things, that the 417 patent is invalid and that the Claimant failed to properly register its license. In its Counterclaim, Avecia and Insmed also asked the court to revoke the 417 patent.

On May 20, 2005, the High Court of Justice issued rulings in the patent infringement case brought by Tercica against Insmed and Avecia. and in a related patent revocation action brought by Insmed and Avecia against

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Genentech. The Court denied the motions, indicating that the issue of validity could not be decided on summary judgment and at this early stage of the case, and awarded Tercica and Genentech their costs of £70,000 solely in connection with the denied motions.

Insmed cannot predict with certainty the outcome of this proceeding. We note however, that an adverse ruling could impact our ability to make, use or sell our products.

Proceedings in the United States

Tercica filed, on December 23, 2004, a complaint against Insmed in the United States District Court for the Northern District of California alleging infringement of U.S. patent Nos. 5,187,151 and 6,331,414. These patents are directed to certain methods of using IGF-I/IGFBP-3 and methods of producing human IGF-I, respectively. On February 16, 2005, Tercica and Genentech filed an Amended Complaint, adding allegations of infringement of U.S. patent No. 5,258,287 (the 287 patent). The claims of the 287 patent are directed to DNA encoding BP53 (i.e. IGFBP-3) and recombinant constructs, transformed host cells and methods for using same.

On February 18, 2005, Insmed filed a motion to dismiss the Amended Complaint. In the motion, Insmed asserted that all alleged activities fall within the statutory safe-harbor provided by 35 U.S.C. § 271(e)(1), commonly called the clinical trial exemption. This exemption prevents patent infringement actions from being filed against activities reasonably related to obtaining FDA approval of a product, such as when the product is still being tested in clinical trials. Insmed further asserted, among other things, that Tercica and Genetech have failed to state a claim for the requested relief, have not sued the proper party, have failed to name all the proper plaintiffs and have failed to establish the existence of a sufficiently real and substantial controversy between the parties. Insmed requested immediate dismissal or Summary Judgment against the plaintiff s allegation on these grounds.

On April 15, 2005, the United States District Court for the Northern District of California granted Insmed s Motion to Dismiss the First Amended Complaint filed by Tercica and Genentech alleging patent infringement against Insmed. The Court granted Tercica and Genentech leave to file another amended complaint within thirty days and Tercica and Genentech filed a Second Amended Complaint on April 22, 2005.

On May 6, 2005, Insmed filed a Motion to Dismiss the second cause of action and to dismiss in part the third cause of action in the plaintiff s Second Amended Complaint relating to U.S. Patent No. 5,258,287 contending that Plaintiff s have failed to join all the owners of the patent as plaintiffs. Insmed has requested immediate dismissal of this particular patent on these grounds. Discovery requests have been served by the parties and a Case Management Conference, originally set for May 13, 2005 has been rescheduled by the court to June 10, 2005, the same date currently scheduled to hear Insmed s Motion to Dismiss.

Insmed cannot predict with certainty the outcome of this proceeding. We note however, that an adverse ruling could impact our ability to make, use or sell our products.

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MANAGEMENT

Executive Officers and Directors

Set forth below is the name, age, position and a brief account of the business experience of each of our executive officers and directors.

Name	Age	Position(s)
Geoffrey Allan, Ph.D.	51	President, Chief Executive Officer, Chairman of the Board, Director
Melvin Sharoky, M.D. (1)(2)(3)	54	Director
Randall W. Whitcomb, M.D. (4)	50	Director
Kenneth G. Condon, C.P.A., C.F.P., M.B.A. (1)(2)	57	Director
Steinar J. Engelsen, M.D. (1)(2)	54	Director
Graham K. Crooke, MB.BS	46	Director
Ronald D. Gunn, M.B.A., M.S.	44	Executive Vice President and Chief Operating Officer
Kevin P. Tully, C.G.A.	51	Principal Financial Officer, Treasurer and Controller
Philip J. Young	47	Chief Business Officer and Executive Vice President

(1) Member of Audit Committee

(2) Member of Compensation Committee

(3) Member of Nominations and Governance Committee

Geoffrey Allan, Ph.D. age 51. Dr. Allan has served as our President, Chief Executive Officer and Chairman of the Board since our inception in November 1999. Dr. Allan has been President and a director of Insmed Pharmaceuticals Inc., our predecessor, since January 1994 and has 24 years of experience in pharmaceutical drug development. Prior to joining Insmed Pharmaceuticals, Dr. Allan served as Vice President, Drug Development at Whitby Research, Inc., a pharmaceutical company. Before his association with Whitby Research, Dr. Allan was the Head of the Cardiovascular Section at Wellcome Research Laboratories. Dr. Allan received his Ph.D. in Pharmacology from Cornell University Medical College.

Melvin Sharoky, M.D. age 54. Dr. Sharoky has been a director of Insmed since his election on May 16, 2001. Since January 1, 2002, he has been President and CEO of Somerset Pharmaceuticals, Inc., a research and development pharmaceutical company which markets Eldepryl® for the treatment of patients with late stage Parkinson s disease having previously served as President of Somerset Pharmaceuticals from July 1995 to June 30, 2001. From June 30, 2001 to January 1, 2002, Dr. Sharoky was retired. From July 1995 through January 1998, Dr. Sharoky was President of Watson Pharmaceuticals, Inc., a leading specialty pharmaceutical company, and from February 1993 to January 1998 he was also President and Chief Executive Officer of its wholly-owned subsidiary, Circa Pharmaceuticals, Inc., which develops, manufactures and markets

solid dosage generic pharmaceutical products to wholesale distributors. Dr. Sharoky joined Circa Pharmaceuticals in July 1988 as Medical Director, served as Senior Vice President and Director of Research and Development from April 1991 to August 1992, and as Executive Vice President and Director of Research and Development from August 1992 to January 1993. Prior to this, from February 1986 to June 1988 he was Vice President and Chief Medical Officer of Pharmakinetics Laboratories, Inc. Dr. Sharoky serves on the board of directors of Andrx Corporation, a specialty pharmaceutical company. Dr. Sharoky received a B.A. in biology from the University of Maryland in Baltimore County and an M.D. from the University of Maryland School of Medicine.

Randall W. Whitcomb, M.D. age 50. Dr. Whitcomb has been a director of Insmed since November 15, 2001. Since 2001, Dr. Whitcomb has been Chief Medical Officer at Quatrx Pharmaceuticals, Inc., a privately-held, drug development company focusing on proteins in the cell nucleus that act as receivers for key hormones that regulate certain metabolic and developmental processes in the body. From 1992 through 2000, he held various management positions with Parke-Davis Pharmaceutical Research, Inc., a division of Warner Lambert Company, finally serving

as Vice President of Drug Development with particular responsibility for the development and approval of products for women s health care and diabetes. After the merger of Warner Lambert into Pfizer, Inc., Dr. Whitcomb was Vice-President Global Project Management for Pfizer Global Research and Development. From 1987 through 1992 he was on the faculty of Massachusetts General Hospital and Harvard Medical School. He received his B.A. degree from Tabor College and his M.D. degree from the University of Kansas.

Kenneth G. Condon C.P.A., C.F.P., M.B.A. age 57. Mr. Condon has been a director of Insmed since our inception in November 1999 and of Insmed Pharmaceuticals since 1997. Mr. Condon serves as Chief Financial Officer of Boston University, a position he has held from 1975 to present. He is also a Trustee of Newbury College. He was formerly Chairman of the Board of BayFunds, a $1.8 billion mutual fund family; a former director of BayBank Harvard Trust; a former member of the BankBoston Advisory Board; a former director of the BayBank Trust Board; a former director of Seragen, Inc., a biotechnology firm; a former director, Chapter Secretary, Treasurer and President of the Financial Executives Institute of Massachusetts; and Director, Treasurer of the Boston Municipal Research Bureau. Before 1975, Mr. Condon was a Senior Accountant with the CPA firm of Arthur Andersen & Co. in Boston. He received his B.A. degree in Economics and Mathematics from Tufts University, and an M.B.A. in Finance from the Wharton School of Finance, University of Pennsylvania. Mr. Condon is both a Certified Public Accountant and a Certified Financial Planner.

Steinar J. Engelsen, M.D. age 54. Dr. Engelsen has been a director of Insmed since our inception in November 1999 and of Insmed Pharmaceuticals since 1998. Since November 1996, Dr. Engelsen has been a partner of Teknoinvest Management AS, a venture capital firm based in Norway. From 1989 until October 1996, Dr. Engelsen held various management positions within Hafslund Nycomed AS, a pharmaceutical company based in Europe, and affiliated companies. He was responsible for therapeutic research and development, most recently serving as Senior Vice President, Research and Development of Nycomed Pharma AS from January 1994 until October 1996. In addition, from January to November 2000, Dr. Engelsen was acting chief executive officer of Centaur Pharmaceuticals, Inc., a biopharmaceutical company. Dr. Engelsen also served as chairman of the board of directors of Centaur. Dr. Engelsen received a M.Sc. in nuclear chemistry and an M.D. from the University of Oslo, and is a Certified European Financial Analyst.

Graham K. Crooke, MB, BS age 46. Dr. Crooke has been a director of Insmed since our inception in November 1999 and of Insmed Pharmaceuticals since 1996. In April 2000, Dr. Crooke became a partner of Asset Management Company, a venture capital firm focusing on investments in early stage information technology and life sciences companies. Previously, from September 1997 through March 2000, Dr. Crooke was a partner at Ticonderoga Capital, a venture capital firm, where he focused on biotechnology and healthcare service investments. From April 1992 until September 1997, Dr. Crooke was a vice president of Dillon Read Venture Capital, a venture capital firm and predecessor to Ticonderoga. Prior to that, Dr. Crooke worked with the healthcare practice of Booz, Allen & Hamilton, Inc., a management consulting firm, was a product manager at Molecular Devices Corporation, a developer of bioanalytical measurement systems, and, from 1984 to 1986, practiced medicine at major teaching hospitals in Western Australia. He received his medical degree from the University of Western Australia and an M.B.A. from the Stanford Graduate School of Business.

Ronald D. Gunn, M.B.A., M.S. age 44. In February 2004, Mr. Gunn was appointed Executive Vice President and Chief Operating Officer. From June 2003 until his appointment as Executive Vice President and Chief Operating Officer, Mr. Gunn served as Executive Vice President. Since our inception in November 1999 until his election as Executive Vice President, Mr. Gunn served as our Vice President, Business Development. From January 1999 to November 1999, Mr. Gunn served as Vice President, Business Development and previously as Director of Business Development and of Clinical Operations at Insmed Pharmaceuticals. Mr. Gunn joined our predecessor in 1996 and has more than 18 years of experience in pharmaceutical drug development. Prior to joining Insmed, Mr. Gunn served as Clinical Affairs Officer with Finnish bioscience company, Leiras, Inc. Mr. Gunn received his M.S. and M.B.A. from Virginia Commonwealth University.

Kevin P. Tully, C.G.A. - age 51. In January 2002, Mr. Tully became our Treasurer, Controller and Principal Financial Officer. From August 2001 until his election as Treasurer, he served as Senior Director, Finance and Administration. Mr. Tully joined Insmed in March 2001 as Director of Finance and has over 30 years of experience across Europe and the Americas covering finance, marketing and manufacturing. Prior to joining Insmed, Mr. Tully served as Vice President of Finance Europe, and Vice President, Finance and Administration Americas for

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Albright and Wilson Ltd., an international chemical producer. Mr. Tully received his O.N.C. in Business and Administration from St. Helens College in England and is a Certified General Accountant.

Philip J. Young age 47. In April 2004, Mr. Young was appointed Executive Vice President of Commercial Operations and Chief Business Officer of Insmed Incorporated. Prior to joining Insmed, Mr. Young served as President and Chief Operations Officer for AGY Therapeutics and Chief Executive Officer of GanTech International. From 1998-2000, Mr. Young was Vice President and General Manager of Neurex Pharmaceuticals, where he was responsible for developing and managing the commercial and clinical strategies for new product launches and expanding label indications. Prior to Neurex, Mr. Young was Business Director and General Manager of the Peptide Hormones Division at Pharmacia (Pfizer) where under his leadership strategies were developed which led to the successful launch of Genotropin for pediatric and adult growth hormone deficiency. Mr. Young also served for seven years at Genentech where he was the Product Manager of Growth Hormone Products.

Director Compensation

Our non-employee directors receive an annual director s fee of $15,000 plus $2,000 and reimbursement of expenses for each meeting of the Board attended in person, $1,000 for each Compensation and Nominations and Governance Committee meeting attended in person, $1,500 for each Audit Committee attended in person and $500 for each meeting attended telephonically. In addition, each non-employee director receives an option to purchase 25,000 shares of Insmed Common Stock upon initial election to the Board and options to purchase 17,500 shares of Insmed Common Stock annually, which options vest one year from the date of grant if the director attends at least 75% of the Board meetings in the preceding fiscal year. Directors who are officers or employees of Insmed do not receive any additional compensation for their services as directors.

Board Committees

Our Bylaws establish four standing Committees of the Board: the Executive Committee, Audit Committee, Compensation Committee, and Nominations and Governance Committee.

Executive Committee. Our Executive Committee consists of the independent directors, Mr. Condon and Drs. Engelsen, Sharoky, Crooke and Whitcomb, and the Chairman of the Board, Dr. Geoffrey Allan. Executive Committee meetings are held at least two times a year and are planned following a regularly scheduled in-person meeting of the Board. Executive sessions do not include any of our employee directors, and the Chair of the meetings rotates from meeting to meeting among the Chairmen of the Nominations and Governance Committee, the Audit Committee and the Compensation Committee.

Audit Committee. Our Audit Committee currently consists of Mr. Condon (Chairman), and Drs. Engelsen and Sharoky. During 2004, the Audit Committee held six meetings. Mr. Condon and Dr. Sharoky attended all of the meetings and Dr. Engelsen attended five of the meetings. The Audit Committee (i) recommends the selection of independent accountants and auditors, (ii) reviews the scope of the accountants audit and approves any non-audit services to be performed by the independent accountants and (iii) reviews annual audits and accounting practices. The Board has adopted a written charter for the Audit Committee, which is available on our website at www.insmed.com.

Insmed Common Stock is listed on the Nasdaq National Market and, as such, we are governed by the listing standards of the National Association of Securities Dealers, Inc. (the NASD). Rule 4350(d)(2)(A) of the NASD s listing standards requires that our Audit Committee be comprised of at least three members, each of whom must be an independent director as defined in Rule 4200(a)(15) of the listing standards of the NASD. The Board has determined that all three of our Audit Committee members, Mr. Condon and Drs. Engelsen and Sharoky, are independent directors as defined by the listing standards of the NASD.

The Board has determined that Mr. Condon is an audit committee financial expert as that term is defined in the rules promulgated by the Securities and Exchange Commission pursuant to the Sarbanes-Oxley Act of 2002.

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The Board has determined that each of the members of the Audit Committee is able to read and understand fundamental financial statements, including our balance sheet, consolidated statement of operations and consolidated statement of cash flows, and has accounting or related financial management expertise, as such terms are interpreted by the Board.

The Audit Committee s pre-approval policies and procedures are detailed in the Audit Committee Report, which is included in this Proxy Statement.

Compensation Committee. Our Compensation Committee currently consists of Dr. Sharoky (Chairman), Mr. Condon and Dr. Engelsen. During fiscal year ended December 31, 2004, the Compensation Committee held five meetings and Drs. Engelsen and Sharoky and Mr. Condon attended all of the meetings. The Compensation Committee reviews and makes recommendations to the Board regarding the compensation and benefits of all of our officers and reviews policy matters relating to compensation and benefits of our employees. The Board has adopted a written charter for the Compensation Committee, a copy of which is available on our website at www.insmed.com. The Board has determined that each of the members of our Compensation Committee is independent as defined in Rule 4200 (a) (15) of the Nasdaq listing standards of the NASD and our Corporate Governance Guidelines.

Nominations and Governance Committee. Our Nominations and Governance Committee currently consists of Drs. Whitcomb (Chairman) and Sharoky. During the fiscal year ended December 31, 2004, the Nominations and Governance Committee held two meetings and Drs. Whitcomb and Sharoky attended all of the meetings. The Nominations and Governance Committee (i) assists the Board by identifying and recruiting individuals qualified to become Board members and recommending to the Board the director nominees for the next annual meeting of shareholders; (ii) recommends to the Board director nominees for each committee; (iii) oversees the governance of Insmed including recommending to the Board Corporate Governance Guidelines; (iv) leads the Board in its annual review of the Board s performance and oversee the evaluation of each of the Board s Committees; and (v) oversees the management continuity planning process. The Board has adopted a written charter for the Nominations and Governance Committee, a copy of which is available on our website at www.insmed.com.

Compensation Committee Interlocks And Insider Participation

The following persons served on our Compensation Committee during the fiscal year ended December 31, 2004: Dr. Sharoky (Chairman), Mr. Condon and Dr. Engelsen. Neither Dr. Sharoky, Mr. Condon nor Dr. Engelsen is or has ever been an officer or employee of Insmed or any of our subsidiaries.

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Executive Compensation

Summary Compensation Table. The following table sets forth information for the fiscal years ended December 31, 2004, 2003 and 2002, respectively, with respect to certain compensation paid by us to our named executive officers, as such term is defined in Item 402(a)(3) of Regulation S-K. Other than the executive officers listed below, none of our current executive officers received total cash compensation from us in excess of $100,000 for any of the fiscal years ended December 31, 2004, 2003 and 2002.

		ANNUAL COMPENSATION ($)(1)			LONG TERM COMPENSATION (1)			
Name and Principal Position	Fiscal Year	Salary (2)	Bonus (3)	Other Annual Compensation (4)	Restricted Stock Awards ($)	Securities Underlying Options/ SARs(#)	Long Term Incentive Plan Payout ($)	All Other Compensation ($)(5)
Geoffrey Allan, Ph.D.	2004	395,200	98,800	21,717				2,075
Chairman of the Board, Chief	2003	395,200	197,600	18,941		150,000		2,075
Executive Officer and President	2002	395,200		15,432		300,000		1,353
Ronald D. Gunn, M.B.A., M.S. (6)	2004	261,875	65,469					597
Executive Vice President and	2003	190,900	57,270	203		100,000		438
Chief Operating Officer	2002	176,800						370
Andreas Sommer, Ph.D. (7)	2004	260,000	39,000	5,057				2,170
Chief Scientific Officer	2003	260,000	26,000	4,165		100,000		2,170
	2002	260,000		5,471				2,170
Kevin P. Tully, CGA (8)	2004	176,800	44,200					851
Treasurer, Controller and	2003	176,800	35,360	203		100,000		851
Principal Financial Officer	2002	164,642				100,000		555
Philip J. Young (9)	2004	173,295	43,324	239,063		250,000		548
Chief Business Officer and Executive Vice President, Commercial Operations								

(1) Except as disclosed in the table, there was no other cash compensation, long-term incentive plan or restricted stock award that required disclosure.

(2) Includes amounts earned but deferred at the election of the executive, such as salary deferrals under Insmed s 401(k) plan.

(3) Amounts in this column reflect the aggregate annual bonuses that were earned for such fiscal year.

(4) Dr. Allan s other annual compensation for the periods indicated reflects the personal use of a vehicle provided by Insmed and, for 2003, includes $203 given to all employees by Insmed as a holiday gift. Dr. Sommer s other annual compensation for the periods indicated includes compensation related to the cost of a medical reimbursement program provided by Insmed and, for 2003, includes $203 given to all employees by Insmed as a holiday gift. Mr. Gunn s and Mr. Tully s other annual compensation for 2003 relates to a holiday gift given to all employees by Insmed. Mr. Young s other annual compensation related to relocation expenses paid by Insmed on his behalf.

(5) Dr. Allan s, Mr. Gunn s, Dr. Sommer s, Mr. Tully s and Mr. Young s other compensation for 2002, 2003 and 2004 relates to life insurance premiums for coverage in excess of $50,000.

(6) Mr. Gunn was named Executive Vice President and Chief Operating Officer effective February 1, 2004.

(7) Dr. Sommer joined Insmed on August 1, 2000. He was named an executive officer effective March 4, 2004 but was not named as an executive officer at the annual meeting of Insmed s Board in May 2005.

(8) Mr. Tully was named an executive officer effective January 30, 2002.

(9) Mr. Young joined Insmed on April 7, 2004 and was named an executive officer on May 5, 2004.

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Option Grants in Fiscal Year Ended December 31, 2004

The following table shows the stock options granted to Insmed s chief executive officer, each executive officer, each non-employee director and all other employees (other than executive officers) during the fiscal year ended December 31, 2004. Insmed did not grant any stock appreciation rights (SARs) during the fiscal year ended December 31, 2004.

	INDIVIDUAL GRANTS				POTENTIAL REALIZABLE VALUE AT ASSUMED ANNUAL RATES OF STOCK PRICE APPRECIATION FOR OPTION TERM	
Name	Number of Securities Underlying Options Granted (#)	% Of Total Options Granted to Employees in Fiscal Year	Exercise or Base Price($/sh.)	Expiration Date	5% ($)	10% ($)
Geoffrey Allan, Ph.D.						
Ronald D. Gunn, M.B.A., M.S.						
Andreas Sommer, Ph.D.						
Kevin P. Tully, CGA						
Philip J. Young	150,000(1)	15.4%	3.00	4/7/2010	153,043	347,202
	100,000(2)	10.2%	1.30	8/10/2013	71,673	176,533

(1) Options vest and become exercisable in equal annual increments over a four year period.

(2) These shares will vest in 25,000 shares increments upon attaining certain milestones established by Insmed relating to the commercialization of one of our principal drug products, SomatoKine®, provided that these milestone-based options will vest on August 10, 2011 (seven years from Date of Grant), if not sooner vested.

Name	Number of Securities Underlying Options Granted (#)	Exercise or Base Price($/sh.)
All executive officers	380,000	2.22
All non-employee directors	87,500	2.70
All employees (excluding Executive Officers)	438,500	1.94

Aggregated Option Exercises in Fiscal Year Ended December 31, 2004 and Fiscal Year-End Option Values

The following table shows the stock options exercised by the named executive officers during the fiscal year ended December 31, 2004 and the number and value of all unexercised options held by the named executive officers at December 31, 2004.

Name	Shares Acquired on Exercise (#)	Value Realized ($)	Number of Securities Underlying Unexercised Options at Fiscal Year-End(#)		Value of Unexercised In-the-Money Options at Fiscal Year-End($)	
			Exercisable	Unexercisable	Exercisable	Unexercisable
Geoffrey Allan, Ph.D.			601,554	435,947	145,005	109,845
Ronald D. Gunn, M.B.A., M.S.			198,425	206,251	59,874	73,230
Andreas Sommer, Ph.D.			248,749	193,751	21,770	73,230
Kevin P. Tully, CGA			113,749	116,251	61,403	91,597
Philip J. Young				250,000		90,000

Stock Plans

2000 Amended and Restated Stock Incentive Plan. The 2000 Stock Incentive Plan (the 2000 Stock Plan) first became effective in 2000 and was amended and restated on May 11, 2005. As of December 31, 2004, 4,864,425 shares of common stock were authorized for issuance and options to purchase 4,086,685 shares of common stock were outstanding at a weighted average exercise price of $3.70 per share under this plan. and included the addition of 3,000,000 share of common stock to the pool of shares available for issuance pursuant to options granted in accordance with this plan.

The administrator has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2000 Stock Plan. The administrator may delegate to one or more officers of Insmed the authority to grant certain awards to employees who are not executives

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officers of Insmed. Persons eligible to participate in the 2000 Stock Plan will be those employees, non-employee directors and other service providers of Insmed and its affiliates as selected from time to time by the administrator.

The 2000 Stock Plan permits the granting of (i) options to purchase Insmed common stock intended to qualify as incentive stock options under Section 422 of the Code and (ii) options that do not so qualify. Options granted under the 2000 Stock Plan will be non-qualified options if they (i) fail to qualify as incentive options, (ii) are granted to a person not eligible to receive incentive options under the Code, or (iii) otherwise so provide. Non-qualified options may be granted to any persons eligible to receive incentive options and to non-employee directors and service providers. The option exercise price of each option will be determined by the administrator but may not be less than 100% of the fair market value of Insmed s common stock on the date of grant.

The term of each option will be fixed by the administrator and generally may not exceed ten years from the date of grant. The administrator will determine at what time or times each option may be exercised and, subject to the provisions of the 2000 Stock Plan, the period of time, if any, after retirement, death, disability or termination of employment during which options may be exercised. Options may be made exercisable in installments and the exercisability of options may be accelerated by the administrator.

Upon exercise of options, the option exercise price must be paid in full either in cash or a cash equivalent acceptable to the Administrator or by delivery of shares of common stock. Subject to applicable law, the exercise price may also be delivered to Insmed by a broker pursuant to irrevocable instructions to the broker from the optionee.

To qualify as incentive options, options must meet additional federal tax requirements, including a $100,000 limit on the value of shares subject to incentive options that first become exercisable by a participant in any one calendar year, and a shorter term and higher minimum exercise price in the case of certain large shareholders.

The administrator may grant performance share awards to participants entitling the recipient to receive shares of common stock or, in the administrator s discretion, an equivalent cash payment or a combination of both shares and cash, upon the achievement of individual or company performance goals (as summarized in the Proposal section above) and such other conditions as the administrator shall determine.

The administrator may grant awards of Insmed common stock to participants, subject to conditions determined by the administrator, which condition may include the achievement of individual or company performance goals. Each stock award will specify a number of shares of Insmed common stock that may be awarded to the participant determined by the administrator upon satisfaction of certain specified conditions.

2000 Stock Plan authorizes the administrator to make appropriate adjustments to outstanding awards to reflect stock dividends, stock splits and similar events. In the event of a merger, consolidation, sale of Insmed or similar event, the administrator will make appropriate adjustments in the limits specified in the 2000 Stock Plan and to outstanding awards. The administrator may also adjust outstanding awards to take into consideration certain other material changes if the administrator determines that such adjustments are appropriate.

The 2000 Stock Plan provides that in the event of an acquisition (as defined in the plan) in which the Insmed s shareholders will receive cash consideration, Insmed may make or provide for a cash payment to participants holding options equal to the difference between the per share cash consideration and the exercise price of the options. The administrator has the discretion to determine the treatment of other awards under the 2000 Stock Plan, including whether options and other awards will become exercisable and/or vested, in the event of a change in control of

Insmed.

The Board may at any time amend or discontinue the 2000 Stock Plan and the administrator may at any time amend or cancel any outstanding award for the purpose of satisfying changes in the law or for any other lawful purpose. However, no such action may adversely affects any rights under any outstanding award without the holder s consent. Any amendments that materially change the terms of the 2000 Stock Plan, including any amendments that increase the number of shares reserved for issuance under the plan, expand the types of awards available, permit stock option repricing under, materially expand the eligibility to participate in, or materially extend

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the term of, the plan, will be subject to approval by shareholders. Amendments shall also be subject to approval by our shareholders if and to the extent determined by the administrator to be required by the Internal Revenue Code to preserve the qualified status of incentive options or to ensure that compensation earned under the 2000 Stock Plan qualifies as performance-based compensation under Section 162(m) of the Code.

2000 Employee Stock Purchase Plan. The 2000 Employee Stock Purchase Plan (the Stock Purchase Plan) was originally adopted as of April 5, 2000 for a term of ten years and that terms was extended on May 11, 2005 when the plan was amended. The Stock Purchase Plan is administered by the Compensation Committee and provides for the issuance of 500,000 shares of Insmed common stock to participating employees.

The Stock Purchase Plan provides that all Insmed employees whose customary employment is for more than 20 hours per week are eligible to participate in the Stock Purchase Plan, provided, however, that grants may not be made to any persons who would own 5% or more of Insmed s voting stock following the grant. The Stock Purchase Plan provides for two purchase periods each year, the first commencing on January 2 of each year and continuing through June 30 of such year, and the second commencing on July 1 of each year and continuing through December 31 of such year. Eligible employees may elect to become participants in the Stock Purchase Plan by enrolling prior to December 15th for the first purchase period or June 15th for the second purchase period. Shares are purchased through the accumulation of payroll deductions of not less than 1% nor more than 15% of each participant s compensation. The maximum number of shares of Insmed common stock that can be purchased under the Stock Purchase Plan during any six-month purchase period is that number having a fair market value of $12,500 on the first day of the purchase period pursuant to which the shares are purchased. Subject to such maximum limit, the number of shares to be purchased is determined by dividing the participant s balance in the plan account on the last day of the purchase period by the purchase price per share for the stock. The purchase price per share will be the lower of 85% of the fair market value of Insmed common stock as of either the first or last day of the purchase period.

Equity Compensation Plan Information

The following table presents information as of December 31, 2004, 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(2)	4,864,425(3)	$ 3.70	879,749 (4)(5)(6)
Equity Compensation Plans Not Approved by Shareholders (7):	0	n/a	0
None			
Total:	4,864,425	$ 3.70	879,749 (6)

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

(2) Includes the 2000 Stock Incentive Plan and 2000 Employee Stock Purchase Plan.

(3) Does not include shares issuable under the 2000 Employee Stock Purchase Plan because purchase price (and therefore the number of shares to be purchased) will not be determined until the end of the purchase period.

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(4) 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.

(5) On May 11, 2005, an additional 3,000,000 shares were authorized for issuance under the 2000 Stock Incentive Plan, but these shares are not included in the table.

(6) This amount includes 102,009 shares of common stock issuable pursuant to Insmed s 2000 Employee Stock Purchase Plan but excludes an additional 250,000 approved for issuance under the 2000 Employee Stock Purchase Plan on May 11, 2005.

(7) Insmed does not have any equity compensation plans that have not been approved by its shareholders.

Change In Control Arrangements

We have entered into Change in Control Agreements with Dr. Allan, Mr. Gunn, Dr. Sommer, Mr. Tully and Mr. Young, which entitled those executive officers to receive additional benefits in the event of their termination following a change in control of Insmed. We believe that the existence of these potential benefits will benefit Insmed by discouraging turnover and causing such executives to be more able to respond to the possibility of a change in control without being influenced by the potential effect of a change in control on his job security.

For purposes of these agreements, the term change in control generally includes:

(a) the acquisition by another person of beneficial ownership of 40% or more of Insmed Common Stock;

(b) a proxy contest that results in the replacement of 50% or more of the members of Insmed s Board;

(c) a merger after which Insmed s stockholders own less than 60% of the surviving corporation s stock; or

(d) approval by Insmed s stockholders of a complete liquidation or dissolution of Insmed.

If, during the one-year period following a change in control, Insmed or its successor terminates the executive s employment other than for cause or the executive voluntarily terminates employment for after the executive s compensation or duties are changed in any material respect from what they were immediately prior to the change in control, the executive shall receive a lump-sum cash payment equal to the sum of the executive s highest annual salary rate while an employee of Insmed plus a prorated maximum potential bonus. All stock options then held by the executive remain exercisable for the term of the option period set forth in his option agreement(s) and any restricted stock held by the executive remains subject to the restrictions set forth in his restricted stock agreement. In addition, Insmed shall continue to provide to the executive health, dental, long-term disability, life insurance, continuation of D&O insurance, and the other fringe benefits that the executive received prior to termination.

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Compensation Committee Report

This report of the Compensation Committee (the Committee) of the Board describes the objectives of Insmed s executive compensation program, the various components of the program, and explains the basis on which compensation determinations for the fiscal year ended December 31, 2004 were made by the Committee.

Overall Objectives of Executive Compensation Programs

The Committee s guiding philosophy is to establish executive compensation policies that are linked to the sustained creation of shareholder value. The following objectives serve as the guiding principles for all compensation decisions:

- provide a competitive total compensation opportunity that will enable Insmed to attract, retain and motivate highly qualified executives;
- align compensation opportunities with shareholder interests by making the executive compensation program highly sensitive to Insmed s performance, which is defined in terms of milestones associated with achieving long-term profitability and creating shareholder value; and
- provide a strong emphasis on equity-based compensation and equity ownership, creating a direct link between shareholder and management interests.

Compensation Program Components

The Committee believes that the total compensation opportunity available to members of management should consist of base salary, annual bonuses and stock options, with each component geared to the median of the market for all positions in the aggregate. Individuals may be compensated above or below the median of the marketplace based on Insmed s performance and on considerations of individual performance and experience. The Committee considers all elements of the program when setting compensation levels.

The Committee periodically meets individually with members of management in order to assess progress toward meeting objectives set by the Board for both annual and long-term compensation.

The Committee utilizes compensation surveys to aid in the determination of competitive levels of executive pay. The surveys include companies that are larger and smaller than Insmed. Some surveys are limited to companies in the biotechnology business. The Committee also utilizes executive compensation information compiled from the proxy statements of other biotechnology companies. References to the market in this report refer to these survey and proxy data.

Base Salaries

Base salaries are determined in accordance with the responsibilities of each officer, median market data for the position and the officer s performance achieving corporate goals. The Committee considers each of these factors but does not assign a specific value to each factor. Furthermore, a subjective element is acknowledged in evaluating the officer s overall span of responsibility and control. Total compensation for Insmed s officers is believed to be generally in line with the median of the market as described above.

Annual Bonuses

The Committee reviews annual bonuses in conjunction with senior management. The compensation committee has the authority to grant annual bonuses of up to 50% of the CEO s annual salary and up to 35% of individual officers annual salaries. Awards are based on an evaluation of the performance, level of responsibility and leadership of the individual in relation to overall corporate results. For the fiscal year ended December 31, 2004, annual bonuses of 15% to 25% were awarded to officers based on the attainment by individuals of specific objectives necessary for Insmed to achieve its business plan.

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Stock Options and Restricted Awards

The Committee believes strongly that equity based awards are an integral part of total compensation for officers and certain key managers with significant responsibility for Insmed s long-term results. Stock options that are tied to corporate performance provide an effective means of delivering incentive compensation and also foster stock ownership on the part of management.

The Stock Incentive Plan:

- authorizes the granting of stock options, SARs, performance shares, restricted stock and other incentive awards, all of which may be made subject to the attainment of performance goals established by the Committee;
- provides for the enumeration of the business criteria on which an individual s performance goals are to be based; and
- establishes the maximum share grants or awards (or, in the case of incentive awards, the maximum compensation) that can be paid to a Stock Incentive Plan participant.

In the fiscal year ended December 31, 2004, incentive awards of stock options and performance shares were made in accordance with the performance-based focus of the Stock Incentive Plan.

Discussion of 2004 Compensation for the Chief Executive Officer

Dr. Geoffrey Allan s base salary as Chief Executive Officer was not increased in the fiscal year ended December 31, 2004, and remained at $395,200, the same level as fiscal years ended December 31, 2003 and 2002. The Committee intends base salary to provide Dr. Allan with a level of stability and certainty each year and intends that this particular component of compensation not be affected to any significant degree by company performance factors. The committee awarded Dr. Allan a bonus for 2004 of $98,800 in recognition of the leadership that Dr. Allan has shown in managing the business, raising equity and focusing on maximizing long-term value for our shareholders.

Deductibility of Compensation

The Committee has carefully considered Section 162(m) of the Internal Revenue Code of 1986, as amended, which provides certain criteria for the tax deductibility of compensation in excess of $1 million paid to our executive officers. The Committee believes it is in Insmed s best interests and that of its shareholders to comply with the requirements of Section 162(m), but the Committee intends to preserve the flexibility to reward executives consistent with Insmed s pay philosophy for each compensation element. The Committee intends that grants of options, awards of performance shares, restricted stock and other incentive awards under the Stock Incentive Plan comply with the requirements of Section 162(m).

THE COMPENSATION COMMITTEE

Melvin Sharoky, M.D., Chairman

Kenneth G. Condon, C.P.A., C.F.P., M.B.A.

Steinar Engelsen, M.D.

March 11, 2005

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Performance Graph

The following graph compares cumulative returns for Insmed, the Nasdaq Market Index and the Nasdaq Pharmaceutical Index since June 1, 2000, the day Insmed Common Stock began trading publicly. The comparison assumes $100 was invested on June 1, 2000 and dividends were reinvested.

Date	Insmed	NASDAQ Market Index	NASDAQ Pharmaceutical Index
June 1, 2000	$ 100.00	$ 100.00	$ 100.00
December 29, 2000	21.02	72.57	113.65
June 29, 2001	54.48	64.13	105.34
December 31, 2001	23.15	58.05	96.52
June 28, 2002	8.48	44.13	60.03
December 31, 2002	2.72	40.42	59.36
June 30, 2003	16.30	49.20	83.53
December 31, 2003	18.00	60.89	89.52
June 30, 2004	13.58	62.55	107.27
December 31, 2004	13.33	66.74	111.77

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PRINCIPAL STOCKHOLDERS

The following table sets forth the beneficial ownership of Insmed Common Stock as of May 31, 2005 by all directors, executive officers named in the Summary Compensation Table contained in this Proxy Statement and each person who beneficially owns more than 5% of our outstanding common stock. The table also shows the beneficial ownership of all directors and executive officers as a group. The address of each of our directors and executive officers is c/o Insmed Incorporated, 4851 Glen Allen, Virginia 23060.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission, and includes factors such as voting and investment power with respect to shares. Unless otherwise indicated below, to our knowledge, all persons named in the table have sole voting and investment power with respect to their shares of common stock, except to the extent authority is shared by spouses under applicable law. Percentage ownership is based on 45,011,743 shares of common stock outstanding as of May 31, 2005.

Beneficial ownership of Insmed Common Stock by the 5% stockholders set forth below, after giving effect to the sales of shares pursuant to this prospectus, is provided in the section in this prospectus entitled Selling Stockholders.

Name of Beneficial Owner	Aggregate Number of Shares Beneficially Owned (1)	Percent of Class
Directors and Executive Officers		
Geoffrey Allan, Ph.D. (2)	1,727,750	3.8%
Kenneth G. Condon, C.P.A., C.F.P., M.B.A. (3)	521,776	1.2%
Graham K. Crooke, MB.BS (4)	894,400	2.0%
Steinar J. Engelsen, M.D. (5)	105,625	*
Ronald D. Gunn, M.B.A., M.S. (6)	310,695	*
Melvin Sharoky, M.D. (7)	389,600	*
Andreas Sommer, Ph.D. (8)	327,223	*
Kevin P. Tully, C.G.A.(9)	239,160	*
Randall W. Whitcomb, M.D. (10)	113,500	*
Philip J. Young (11)	42,179	*
All directors and executive officers as a group (10 persons)	4,671,908	10.0%
5% Stockholders		
Alexandra Global Master Fund Ltd. (12) (13)	4,945,796	9.9%
Citco Building, Wickams Cay P.O. Box 662 Road Town Tortola, British Virgin Islands		
Alexandra Investment Management, LLC (12) (13)	4,945,796	9.9%
767 Third Avenue, 39th Floor		

New York, New York 10017		
Mikhail A Filimonov (12) (13)	4,945,796	9.9%
767 Third Avenue, 39th Floor New York, New York 10017		
Dimitri Sogoloff (12) (13)	4,945,796	9.9%
767 Third Avenue, 39th Floor New York, New York 10017		
Felix J. Baker (12)	4,945,796	9.9%
667 Madison Avenue New York, New York 10021		
Julian C. Baker (12)	4,945,796	9.9%
667 Madison Avenue New York, New York 10021		
Baker Biotech Fund I, L.P. (12)	2,906,916	6.1%
667 Madison Avenue New York, New York 10021		
Baker Biotech Fund II, L.P (12)	2,643,977	5.5%
667 Madison Avenue New York, New York 10021		
Sagamore Hill Capital Management L.P. (12)	2,992,279	6.2%
10 Glenville Street, 3rd Floor Greenwich, CT 06831		
Sagamore Hill Managers LLC (12)	2,992,279	6.2%
10 Glenville Street, 3rd Floor Greenwich, CT 06831		
Steven H. Bloom (12)	2,992,279	6.2%
10 Glenville Street, 3rd Floor Greenwich, CT 06831		
Morgan Stanley & Co., Inc. (12)	2,393,822	5.0%
2000 Westchester Avenue Purchase, NY 10577		

* Indicates less than 1%

(1) Shares subject to options that are exercisable within 60 days of March 11, 2005, are deemed to be outstanding and to be beneficially owned by the person holding such options for the purpose of computing the percentage ownership of such person, and of the directors and

executive officers as a group, but are not treated as outstanding for the purpose of computing the percentage ownership of any other person.

(2) Includes 726,286 shares issuable upon exercise of options.

(3) Mr. Condon, a director of Insmed, currently has the right to purchase 57,500 shares upon exercise of options. The number of shares listed opposite Mr. Condon s name also includes 444,463 shares owned by Boston University Nominee Partnership, of which he is a partner, and 15,750 shares owned by Trustees of Boston University.

(4) Dr. Crooke, a director of Insmed, has the right to purchase 157,500 shares upon exercise of options. The number of shares listed opposite Dr. Crooke s name also includes 686,990 shares owned by Concord Partners III, LP (formerly Dillon Read Venture Partners III LP). Dr. Crooke has an ownership interest (but not a management interest) in Concord Associates III, LLC which is the sole general partner of Concord Partners III, LP.

(5) Dr. Engelsen, a director of Insmed, currently has the right to purchase 57,500 shares upon exercise of options.

(6) Includes 270,621 shares issuable upon exercise of options.

(7) Dr. Sharoky, a director of Insmed, currently has the right to purchase 62,500 shares upon exercise of options. The number of shares listed opposite Dr. Sharoky s name includes 210 shares which are owned by his minor son 620 shares which are owned by his minor daughter and 3,600 shares which are owned by his spouse.

(8) Includes 320,622 shares issuable upon exercise of options.

(9) Includes 132,082 shares issuable on exercise of options.

(10) Dr. Whitcomb, a director of Insmed, currently has the right to purchase 62,500 shares upon exercise of options. The number of shares listed opposite Dr. Whitcomb s name includes 21,000 shares that are owned by the Randall W. Whitcomb Living Trust. Dr. Whitcomb and his spouse, Rita K. Whitcomb, are trustees of the Randall W. Whitcomb Living Trust.

(11) Includes 37,500 shares issuable on exercise of options.

(12) Information is derived from a Schedule 13G filed with the Securities and Exchange Commission on March 24, 2005. Amount includes shares issuable upon conversion of convertible notes and exercise of warrants.

(13) Alexandra Investment Management, LLC, Mikhail A Filimonov and Dimitri Sogoloff have shared voting power with respect to 4,945,796 shares of Insmed common stock owned by Alexandra Global Master Fund Ltd., which shares may be beneficially owned by each of them.

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CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

There are no family relationships among any of our directors, executive officers or nominees. The Audit Committee reviewed all transactions required to be disclosed in our filings with the Securities and Exchange Commission pursuant to Item 404 of Regulation S-K for potential conflict of interest situations. All such transactions must be approved by the Audit Committee. There were no such transactions during the fiscal years ended December 31, 2004, 2003 and 2002.

SELLING STOCKHOLDERS

The table below lists the selling stockholders and other information regarding their ownership of our common stock as of May 31, 2005. The number of shares owned by the selling stockholders is determined by rules promulgated by the Securities and Exchange Commission for beneficial ownership and is not necessarily indicative of ownership for any other purposes. Notwithstanding the preceding sentence, and although the terms of the convertible notes and the 2005 warrants include limitations on the conversion and exercise of the convertible notes and warrants which limit certain selling stockholders ownership of common stock to 9.9% of our outstanding shares of common stock, all shares of common stock issuable upon conversion of the convertible notes and exercise of the 2005 warrants, 2004 warrants and 2003 warrants held by the selling stockholders are included in the numbers set forth in the table below.

The second and third columns of the table list the number and percent of shares of common stock beneficially held by each selling stockholder as of March 15, 2005, taking into account its ownership of shares of common stock assuming the conversion or exercise of the convertible notes and 2005 warrants, 2004 warrants and 2003 warrants, as applicable, but without giving effect to any limitations on conversion or exercise thereof. The fourth column shows the number of shares of common stock being offered by this prospectus by the selling stockholders. The fifth and sixth columns show the number and percent of shares of common stock to be beneficially held by each selling stockholder after the offering of shares under this prospectus (assuming the sale of all of the shares offered by the selling stockholders pursuant to this prospectus).

Pursuant to registration rights agreements, we have registered on behalf of the selling stockholders the 58,334,520 shares covered by the registration statement of which this prospectus forms a part. We have registered the shares to permit the selling stockholders and their pledgees, donees, transferees or other successors-in-interest that receive their shares from the selling stockholders as a gift, partnership distribution or other non-sale related transfer after the date of this prospectus to resell the shares. The registered shares consist of;

- 6,670,020 shares of common stock held by the selling stockholders;
- 27,027,013 shares of common stock issuable upon conversion of the convertible notes, plus 1,486,467 shares potentially issuable to the investors in respect of interest accruing on the notes from time to time;
- 14,864,883 shares of common stock issuable upon exercise of the 2005 warrants, plus 1,858,096 shares potentially issuable to the investors as a result of anti-dilution adjustments to the 2005 warrants; and
- 4,771,821 shares of common stock issuable upon the exercise of the 2004 warrants and 2003 warrants.

Except as otherwise disclosed below, none of the selling stockholders has, or within the past three years has had, any positions, office or other material relationship with us. Each of the selling security holders has represented to us that it is not acting as an underwriter in this offering, that it purchased its shares and warrants in the ordinary course of business, and at the time of such purchase, it had no agreements or understandings, directly or indirectly, with any person to distribute the securities.

The selling stockholders are not making any representations that the shares covered by this prospectus will be offered for sale. The selling stockholders may from time to time offer and sell pursuant to this prospectus any or all of the shares of common stock being registered. Because the selling stockholders may offer all or some portion of the shares of common stock listed in the table and may sell all, part or none of the shares of common stock listed

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pursuant to this prospectus or otherwise, no estimate can be given as to the number of shares of common stock that will be held by the selling stockholders upon termination of the offering. See Plan of Distribution below.

	Number of Shares Owned Before Offering(#)		Number of Shares Offered Pursuant to the Prospectus(+)	Number of Shares Owned After Offering	
Investor	Number	Percent	Number	Number	Percent
Alexandra Global Master Fund Ltd.(1)	9,336,834	17.3%	8,976,834	360,000	*
Baker Bros. Investments, L.P.(2)	294,271	*	292,046	2,225	*
Baker/Tisch Investments, L.P.(3)	303,065	*	281,274	21,791	*
Baker Biotech Fund I, L.P.(4)	2,906,916	6.1%	2,886,950	19,966	*
Baker Biotech Fund II, L.P.(5)	2,643,977	5.5%	2,643,977		*
Baker Biotech Fund III, L.P.(6)	2,274,131	4.8%	2,274,131		*
Caduceus Capital Master Fund Limited(7)	2,154,440	4.6%	2,154,440		*
Caduceus Capital II, L.P.(8)	1,077,220	2.3%	1,077,220		*
UBS Eucalyptus Fund, L.L.C.(9)	1,831,274	3.9%	1,831,274		*
HFR SHC Aggressive Master Trust(10)	323,166	*	323,166		*
Tang Capital Partners, L.P.(11)	2,316,602	4.9%	2,316,602		*
Steelhead Investments Ltd.(12)	1,986,201	4.2%	1,986,201		*
Morgan Stanley & Co. Inc.(13)	2,393,822	5.0%	2,393,822		*
SF Capital Partners Ltd.(14)	1,795,367	3.8%	1,795,367		*
Sagamore Hill Hub Fund Ltd.(15)	2,992,278	6.2%	2,992,278		*
Capital Ventures International(16)	2,263,367	4.8%	2,263,367		*
Walker Smith Capital, L.P.(17)	123,297	*	123,297		*
Walker Smith International Fund, Ltd.(18)	892,433	2.0%	892,433		*
Walker Smith Capital (QP), L.P.(19)	583,526	1.3%	583,526		*
SRB Greenway Offshore Operating Fund, L.P.(20)	53,861	*	53,861		*
SRB Greenway Capital, L.P.(21)	81,749	*	81,749		*
SRB Greenway Capital (QP), L.P.(22)	582,537	1.3%	582,537		*
WS Opportunity Fund International, Ltd.(23)	146,741	*	146,741		*
WS Opportunity Fund, L.P.(24)	102,216	*	102,216		*
WS Opportunity Fund (QP), L.P.(25)	110,116	*	110,116		*
Xmark Opportunity Fund, Ltd.(26)	1,511,315	3.2%	1,511,315		*
Xmark Opportunity Fund, L.P.(27)	1,030,871	2.2%	1,030,871		*
Koyah Leverage Partners, L.P.(28)	354,492	*	119,692	234,800	*
Koyah Microcap Partners Master Fund, L.P.(29)	321,237	*	179,537	141,700	*
Portside Growth and Opportunity Fund(30)	1,719,788	3.7%	1,719,788		*
Smithfield Fiduciary LLC(31)	810,727	1.8%	448,842		*
Omicron Master Trust(32)	789,582	1.7%	789,582		*
Iroquois Capital LP(33)	783,641	1.7%	783,641		*
RHP Master Fund, Ltd.(34)	572,627	1.3%	572,627		*
Cimarron Overseas Equity Master Fund, L.P.(35)	239,383	*	239,383		*
Frank Kung(36)	97,133	*	96,833	250	*
Compound & Co., nominee for Jennison Health Sciences Fund, a series of the Jennison Sector Funds, Inc.(37)	2,100,000	4.6%	2,100,000		4.6%
Deephaven Small Cap Growth Fund LLC(38)	842,592	1.8%	842,592		*
Elliott International, L.P.(39)	546,000	1.2%	546,000		*
Gryphon Master Fund, L.P.(40)	481,481	1.1%	481,481		*
Elliott Associates, L.P.(41)	364,000	*	364,000		*
Langley Partners, L.P.(42)	338,000	*	338,000		*
Otape Investments LLC(43)	240,740	*	240,740		*
Castle Creek Healthcare Partners LLC(44)	240,740	*	240,740		*
	195,000	*	195,000		*

AIG DKR Soundshore Private Investors Holding Fund Lt.(45)					
Redwood Partners, LLC(46)	120,369	*	120,369		*
Spectra Capital Management(47)	120,369	*	120,369		*
Stonestreet LP(48)	120,369	*	120,369		*
WEC Partners LLC(49)	120,369	*	120,369		*
Truk Opportunity Fund, LLC(50)	97,500	*	97,500		*
Crown Investment Partners, LP(51)	78,000	*	78,000		*
Gemini Master Fund Ltd.(52)	65,000	*	65,000		*
JAS Securities, LLC(53)	60,184	*	60,184		*
TCMP3 Partners L.P.(54)	60,184	*	60,184		*
Greenwich Growth Fund Ltd.(55)	48,148	*	48,148		*
Wolverine Trading LLC(56)	48,148	*	48,148		*
Maybach Capital Inc.(57)	24,073	*	24,073		*
Total	**54,111,469**	**54.2%**	**53,330,737**	**780,732**	**1.7%**

Although the terms of the notes and warrants include limitations on the conversion and exercise of the notes and warrants which limit each selling stockholder s ownership of common stock to 9.9% of our outstanding shares of common stock, all shares of common stock issuable upon conversion of the notes and exercise of the warrants held by the selling stockholders are included in the numbers set forth in the table.

+ We have also registered an additional 1,486,467 shares, in the aggregate, potentially issuable to the selling stockholders in respect of interest accruing on the convertible notes from time to time, and 1,858,096 shares, in the aggregate, potentially issuable to the selling stockholders as a result of anti-dilution adjustments to the warrants. Those additional shares may also be offered pursuant to this prospectus to the extent that they are issued to the selling stockholders in accordance with the terms of the convertible notes and the related warrants.

* Indicates less than 1%

(1) Includes 8,976,834 shares of common stock issuable upon conversion and exercise of convertible notes and warrants. Alexandra Investment Management, LLC, a Delaware limited liability

company (Alexandra), serves as investment adviser to Alexandra Global Master Fund Ltd., a British Virgin Islands company (Master Fund). By reason of such relationship, Alexandra may be deemed to share dispositive power over the shares of common stock stated as beneficially owned by Master Fund. Alexandra disclaims beneficial ownership of such shares of common stock. Messrs. Mikhail A. Filimonov (Filimonov) and Dimitri Sogoloff (Sogoloff) are managing members of Alexandra. By reason of such relationships, Filimonov and Sogoloff may be deemed to share dispositive power over the shares of common stock stated as beneficially owned by Master Fund. Filimonov and Sogoloff disclaim beneficial ownership of such shares of common stock.

(2) Includes 292,046 shares of common stock issuable upon conversion and exercise of convertible notes and warrants.

(3) Includes 281,274 shares of common stock issuable upon conversion and exercise of convertible notes and warrants.

(4) Includes 2,886,950 shares of common stock issuable upon conversion and exercise of convertible notes and warrants.

(5) Includes 2,643,977 shares of common stock issuable upon conversion and exercise of convertible notes and warrants.

(6) Includes 2,274,131 shares of common stock issuable upon conversion and exercise of convertible notes and warrants.

(7) Includes 2,154,440 shares of common stock issuable upon conversion and exercise of convertible notes and warrants.

(8) Includes 1,077,220 shares of common stock issuable upon conversion and exercise of convertible notes and warrants.

(9) Includes 1,831,274 shares of common stock issuable upon conversion and exercise of convertible notes and warrants.

(10) Includes 323,166 shares of common stock issuable upon conversion and exercise of convertible notes and warrants.

(11) Includes 3,590,734 shares of common stock issuable upon conversion and exercise of convertible notes and warrants.

(12) Includes 1,986,201 shares of common stock issuable upon conversion and exercise of convertible notes and warrants. Steelhead Investments Ltd. is under common control with HBK Global Securities L.P., a registered broker-dealer. HBK Global Securities L.P. is not currently expected to participate in any sale of shares of common stock offered pursuant to this prospectus.

(13) Includes 2,393,822 shares of common stock issuable upon conversion and exercise of convertible notes and warrants. Morgan Stanley & Co. Inc. is a broker-dealer and will be participating in the sale of shares of common stock offered pursuant to this prospectus.

(14) Includes 1,795,367 shares of common stock issuable upon conversion and exercise of convertible notes and warrants. SF Capital Partners Ltd. is affiliated with two NASD broker-dealers, Reliant Trading and Shepherd Trading Limited, neither of whom are currently expected to participate in the sale of shares of common stock offered pursuant to this prospectus.

(15) Includes 2,992,278 shares of common stock issuable upon conversion and exercise of convertible notes and warrants.

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(16) Includes 1,736,771 shares of common stock issuable upon conversion and exercise of convertible notes and warrants. Capital Ventures International is affiliated with one or more NASD broker-dealers, none of whom are currently expected to participate in the sale of shares of common stock offered pursuant to this prospectus. Capital Ventures International acquired Insmed securities in the ordinary course of its business and had no prior arrangement with any other party to distribute said securities.

(17) Includes 86,297 shares of common stock issuable upon conversion and exercise of convertible notes and warrants.

(18) Includes 593,733 shares of common stock issuable upon conversion and exercise of convertible notes and warrants.

(19) Includes 408,486 shares of common stock issuable upon conversion and exercise of convertible warrants.

(20) Includes 53,861 shares of common stock issuable upon conversion and exercise of convertible notes and warrants.

(21) Includes 81,749 shares of common stock issuable upon conversion and exercise of convertible notes and warrants.

(22) Includes 582,537 shares of common stock issuable upon conversion and exercise of convertible notes and warrants.

(23) Includes 146,741 shares of common stock issuable upon conversion and exercise of convertible notes and warrants.

(24) Includes 102,216 shares of common stock issuable upon conversion and exercise of convertible notes and warrants.

(25) Includes 110,116 shares of common stock issuable upon conversion and exercise of convertible notes and warrants.

(26) Includes 1,511,315 shares of common stock issuable upon conversion and exercise of convertible notes and warrants.

(27) Includes 1,030,871 shares of common stock issuable upon conversion and exercise of convertible notes and warrants.

(28) Includes 119,692 shares of common stock issuable upon conversion and exercise of convertible notes and warrants. Some limited partners of Koyah Microcap Partners Master Fund, L.P. may have broker-dealer affiliations, however, no broker-dealers are currently expected to participate in the sale of shares of common stock offered pursuant to this prospectus.

(29) Includes 179,537 shares of common stock issuable upon conversion and exercise of convertible notes and warrants. Some limited partners of Koyah Leverage Partners, L.P. may have broker-dealer affiliations, however, no broker-dealers are currently expected to participate in the sale of shares of common stock offered pursuant to this prospectus.

(30) Includes 1,098,455 shares of common stock issuable upon conversion and exercise of convertible notes and warrants.

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Ramius Capital Group, LLC (Ramius Capital) is the investment adviser of Portside Growth and Opportunity Fund (Portside) and consequently has voting control and investment discretion over securities held by Portside. Ramius Capital disclaims beneficial ownership of the shares held by Portside, Peter A. Cohen, Morgan B. Stark, Thomas W. Strauss and Jeffrey M. Solomon are the sole managing members of C4S & Co., LLC, the sole managing member of Ramius Capital. As a result, Messrs Cohen, Stark, Strauss and Solomon may be considered beneficial owners of any shares deemed to be beneficially owned by Ramius Capital. Messrs. Cohen, Stark, Strauss and Solomon disclaim beneficial ownership of these shares. The investment advisor to Portside Growth and Opportunity Fund is Ramius Capital Group, LLC. Ramius Securities LLC, a NASD member, is an affiliate of Ramius Capital Group, LLC. However, Ramius Securities, LLC will not sell any shares purchased in this offering by Portside Growth and Opportunity Fund and will receive no compensation whatsoever in connection with sales of shares purchased in this transaction.

(31) Includes 634,027 shares of common stock issuable upon conversion and exercise of convertible notes and warrants. Highbridge Capital Management, LLC is the trading manager of Smithfield Fiduciary LLC and consequently has voting control and investment discretion over securities held by Smithfield. Glenn Dubin and Henry Swieca control Highbridge. Each of Highbridge, Glenn Dubin and Henry Swieca disclaims beneficial ownership of the securities held by Smithfield. Smithfield Fiduciary LLC is a wholly owned indirect subsidiary of Highbridge Capital Company, a broker-dealer and NASD member, however, Highbridge Capital Company is not expected to participate in the sale of shares of common stock offered pursuant to this prospectus.

(32) Includes 723,472 shares of common stock issuable upon conversion and exercise of convertible notes and warrants. Omicron Capital, L.P., a Delaware limited partnership (Omicron Capital), serves as investment manager to Omicron Master Trust, a trust formed under the laws of Bermuda (Omicron), Omicron Capital, Inc., a Delaware corporation (OCI), serves as general partner of Omicron Capital, and Winchester Global Trust Company Limited (Winchester) serves as the trustee of Omicron. By reason of such relationships, Omicron Capital and OCI may be deemed to share dispositive power over the shares of our common stock owned by Omicron, and Winchester may be deemed to share voting and dispositive power over the shares of our common stock owned by Omicron. Omicron Capital, OCI and Winchester disclaim beneficial ownership of such shares of our common stock. No other person has sole or shared voting or dispositive power with respect to the shares of our common stock being offered by Omicron, as those terms are used for the purposes of Regulation 13D-G under the Securities Exchange Act of 1934, as amended. Omicron and Winchester are not affiliates of one another, as that term is used for purposes of the Securities Exchange Act of 1934, as amended, or of any other person named in this prospectus as a selling stockholder. No person or group (as that term is used in Section 13(d) of the Securities Exchange Act of 1934, as amended, or the SEC s Regulation 13D-G) controls Omicron and Winchester.

(33) Includes 783,641 shares of common stock issuable upon conversion and exercise of convertible notes and warrants.

(34) Includes 572,627 shares of common stock issuable upon conversion and exercise of convertible notes and warrants. RHP Master Fund, Ltd. is a party to an investment management agreement with Rock Hill Investment Management, L.P., a limited partnership of which the general partner is RHP General Partner, LLC. Pursuant to such agreement, Rock Hill Investment Management directs the voting and disposition of shares owned by RHP Master Fund. Messrs. Wayne Bloch and Peter Lockhart own all of the interests in RHP General Partner. The aforementioned entities and individuals disclaim beneficial ownership of Insmed s common stock owned by the RHP Master Fund.

(35) Includes 239,383 shares of common stock issuable upon conversion and exercise of convertible notes and warrants issued on March 15, 2005.

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(36) Includes 96,833 shares of common stock issuable upon conversion and exercise of convertible notes and warrants.

(37) Includes 700,000 shares of Common Stock issuable upon exercise of warrants. Jennison Associates LLC serves as investment advisor with power to direct investments and power to vote the shares owned by this entity, and may be deemed to be the indirect beneficial owner of the shares held by this entity. Jennison Associates LLC expressly disclaims beneficial ownership of such shares.

(38) Includes 194,444 shares of common stock issuable upon exercise of warrants.

(39) Includes 126,000 shares of common stock issuable upon exercise of warrants.

(40) Includes 111,111 shares of common stock issuable upon exercise of warrants.

(41) Includes 84,000 shares of common stock issuable upon exercise of warrants.

(42) Includes 78,000 shares of common stock issuable upon exercise of warrants.

(43) Includes 55,555 shares of common stock issuable upon exercise of warrants.

(44) Includes 55,555 shares of common stock issuable upon exercise of warrants.

(45) Includes 45,000 shares of common stock issuable upon exercise of warrants.

(46) Includes 27,777 shares of common stock issuable upon exercise of warrants.

(47) Includes 27,777 shares of common stock issuable upon exercise of warrants.

(48) Includes 27,777 shares of common stock issuable upon exercise of warrants.

(49) Includes 27,777 shares of common stock issuable upon exercise of warrants.

(50) Includes 22,500 shares of common stock issuable upon exercise of warrants.

(51) Includes 18,000 shares of common stock issuable upon exercise of warrants.

(52) Includes 15,000 shares of common stock issuable upon exercise of warrants.

(53) Includes 13,888 shares of common stock issuable upon exercise of warrants.

(54) Includes 13,888 shares of common stock issuable upon exercise of warrants.

(55) Includes 11,111 shares of common stock issuable upon exercise of warrants.

(56) Includes 11,111 shares of common stock issuable upon exercise of warrants.

(57) Includes 5,555 shares of common stock issuable upon exercise of warrants.

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DESCRIPTION OF CAPITAL STOCK

General

This summary of the characteristics of our capital stock is qualified in all respects by reference to our articles of incorporation and amended and restated bylaws, and by the provisions of applicable Virginia law.

We have authority to issue a maximum of 500,000,000 shares of common stock, par value $.01 per share, and 200,000,000 shares of preferred stock, par value $.01 per share. As of May 31, 2005, there were approximately 45,011,743 shares of Common Stock outstanding, excluding any shares issuable upon conversion or exercise of the Securities. We have authorized the issuance of an additional shares of common stock in connection with this offering. No shares of preferred stock are outstanding.

Common Stock

Each share of our common stock entitles the holder to one vote in the election of directors and on all other matters submitted to a vote of shareholders. Holders of our common stock have no conversion or redemption rights and no preemptive or other rights to subscribe for our common stock. Shareholders have no right to cumulate votes in the election of directors. Holders of Insmed Incorporated common stock are entitled to receive dividends when, as and if declared by our board of directors out of funds legally available for distribution. Upon our liquidation, holders of common stock will be entitled, subject to the rights of the holders of any outstanding Insmed preferred stock, to receive pro rata all assets, if any, of Insmed available for distribution after payment of necessary expenses and all prior claims.

Insmed Incorporated is listed on the Nasdaq National Market under the trading symbol INSM.

Preferred Stock

We may issue the preferred stock, from time to time in one or more series, and our board of directors, without further approval of the shareholders, is authorized to fix the dividend rights and terms, redemption rights and terms, liquidation preferences, conversion rights, voting rights and sinking fund provisions applicable to each such series of preferred stock. If we issue a series of preferred stock in the future that has voting rights or preferences over the common stock with respect to the payment of dividends or upon liquidation, dissolution or winding up, this issuance may adversely affect the rights of the holders of our common stock offered hereby. We may amend from time to time our articles of incorporation to increase the number of authorized shares of preferred stock. This type of amendment would require the approval of the holders of a majority of the outstanding shares of each series of preferred stock, if any, that the amendment adversely affects, voting separately by group and the approval of a majority of all the voting capital stock of Insmed Incorporated, voting as a single voting group. The issuance of shares of preferred stock could be utilized, under certain circumstances, in an attempt to prevent an acquisition of our company. As of the date of this prospectus, we have no shares of preferred stock outstanding.

Warrants

On July 11, 2003, we issued warrants to purchase 1,544,046 million shares of common stock with an exercise price of $4.10 per share.

On November 8, 2004, we issued warrants to purchase 3,277,775 million shares of common stock that are now exercisable at $0.71 per share.

On March 15, 2005, we issued warrants to purchase 14,864,883 shares of common stock with an exercise price of $1.36 per share.

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Convertible Notes

On March 15, 2005, we issued and sold to certain institutional investors 5.5% convertible notes due 2008-2010 in an aggregate principal amount of $35,000,000, as well as warrants to purchase, in the aggregate, 14,864,883 shares of common stock, raising a total of approximately $32,800,000. The principal amount of the notes will mature and become payable in nine quarterly installments of approximately $3,890,000 commencing on March 1, 2008. All outstanding notes shall be repaid in cash or converted by March 1, 2010. The notes may not be prepaid, in whole or in part, or redeemed by the Registrant except under certain limited circumstances as provided for in the terms of the notes. Commencing on June 1, 2005, the holders of the notes will receive quarterly interest payments at a rate of 5.5% per annum. The holders of the notes may convert the notes into common stock at any time prior to the close of business on March 1, 2010, at a conversion price of $1.295 per share. The notes are subject to adjustments based on splits, dividends and similar extraordinary event affecting the common stock. The notes are convertible into, in the aggregate, 27,027,013 shares of common stock.

Registration Rights

In connection with each of the private placements described above, we and the respective investors entered into Registration Rights Agreements, pursuant to which, we agreed to file a Registration Statement, on Form S-3 (or another appropriate form) with the Securities and Exchange Commission subsequent to the closing of the transaction for purposes of registering the resale of the shares of common stock issued in the private placement. We also agreed to use its reasonable best efforts to have such Registration Statement declared effective as soon as practicable after being filed with the SEC and to file additional Registration Statements under certain circumstances.

Important Provisions of Virginia Corporate Law, Our Articles of Incorporation and Bylaws

The following is a summary of certain important provisions of Virginia corporate law, our articles of incorporation and our amended and restated bylaws in effect as of the date of this prospectus, and is qualified in its entirety by reference to Virginia law and to these documents, copies of which may be obtained from our company.

Our Articles of Incorporation and Bylaws. The Virginia Stock Corporation Act and our articles of incorporation and bylaws govern shareholder rights and related matters. Provisions of our articles of incorporation and bylaws, which are summarized below, may make it more difficult to change the composition of our board of directors and may discourage or make more difficult any attempt by a person or group to obtain control of our company.

Board of Directors. Under our articles of incorporation and bylaws, the board will consist of seven directors. We have three classes of directors. One- third of the directors will be in each class, and one class of directors would be up for election at each annual meeting. Directors are elected by a plurality of the votes cast by the holders of shares entitled to vote in the election of directors at a meeting of shareholders at which a quorum is present. Under Virginia law, vacancies, whether by resignation, death or removal or because of an increase in the size of the board, may be filled by the remaining members of the board of directors although less than a quorum. A director elected to fill a vacancy will serve until the next shareholders meeting at which directors are elected. Virginia law provides that directors may be removed with or without cause by the vote of a majority of the shares of the voting groups that elected such director entitled to vote at an election of directors. However, our articles of incorporation do require cause, as well as an affirmative vote of 75% of the outstanding shares of capital stock entitled to vote, to remove a director.

Advance Notice Requirements for Shareholder Proposals. Our amended and restated bylaws require a shareholder desiring to bring a proposal before an annual meeting of shareholders to give proper written notice to our Secretary. Notice will be deemed proper if, in case of the 2001 annual meeting, it is delivered by November 6, 2000, and in case of subsequent annual meetings, it is delivered not later than 90 days nor more than 120 days before the first anniversary of the date of mailing of our proxy statement in connection with the last preceding year s annual meeting. The written notice delivered to the Secretary must include the information, and be in the proper form, as specified in our bylaws.

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Limitations on Liability. Virginia law permits a corporation to provide indemnification of reasonable expenses for officers, directors, employees or agents of the corporation (or any such person serving in such capacities for another entity at the request of the corporation) who are parties or are threatened to be made parties to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation), against expenses, judgments, fines and amounts paid in settlement that are actually and reasonably incurred. Virginia law permits indemnification in all instances, except in the case of willful misconduct or knowing violation of the criminal law. Our articles of incorporation provide for the indemnification of liabilities of each person incurred by reason of serving as a director, officer, employee or agent or by reason of serving as a director, officer, trustee, or in some similar capacity, of another corporation in all instances, except where the indemnitee engaged in willful misconduct or a knowing violation of the criminal law. Virginia law does not permit indemnification in the following circumstances:

proceedings by and in the right of the corporation, in which the director is liable to the corporation; and

transactions from which a director received an improper personal benefit.

We currently have directors and officers liability insurance to provide our directors and officers with insurance coverage arising from claims based on breaches of duty, negligence, errors and other wrongful acts.

Advance Notice Requirements for Nomination of Directors. Our bylaws require a shareholder desiring to nominate a director for election at an annual meeting of shareholders to give proper written notice to our Secretary. Notice will be deemed proper if, notice is given not later than 90 days nor more than 120 days prior to the first anniversary date of the previous year s annual meeting. The written notice delivered to the Secretary must include the information, and be in the proper form, as specified in our bylaws.

Meetings of Shareholders. Our bylaws permit the President, a majority of the board of directors, or the Chairman of the Board to call a special meeting of shareholders. The bylaws specifically deny the shareholders the right to convene a special meeting of shareholders.

Amendment of Articles of Incorporation or Bylaws. Subject to Virginia law, our articles of incorporation generally may be amended by the affirmative vote of the holders of a majority of the outstanding votes entitled to be cast by each voting group entitled to vote. However, certain provisions of the articles of incorporation may only be amended or repealed by the affirmative vote of the holders of 75% of the outstanding votes entitled to be cast by each voting group entitled to vote. The bylaws may be amended or repealed by the affirmative vote of a majority of the board of directors, unless otherwise required by our articles of incorporation or Virginia law. If shareholder voting is required for an amendment to our bylaws, 75% of the then outstanding stock voting together as a single voting group must vote in the affirmative to approve the amendment.

Mergers and Share Exchanges. Unless otherwise specified, any merger or share exchange must be approved by an affirmative vote of more than two-thirds of all the issued and outstanding shares of stock of each voting group entitled to vote; provided, however, that shareholder action by the acquiring corporation in a share exchange is normally not required.

Anti-takeover Provisions of the Virginia Stock Corporation Act. Virginia law contains two statutory provisions that may have the effect of delaying or discouraging a hostile takeover. Under the first statutory provision, if a person acquires 10% or more of the stock of a Virginia corporation without the prior approval of the corporation s board of directors, the person is deemed an interested shareholder and may not engage in certain transactions with the corporation, including a merger and a sale or exchange of greater

than 5% of the corporation s net worth, for a period of three years, and then only with the specified supermajority shareholder vote, disinterested director approval or fair price and procedural protections. The three year prohibition on an affiliated transaction does not apply if before the affiliated transaction, a majority of the disinterested directors and holders of at least two-thirds of the outstanding voting shares other than shares beneficially owned by the interested person approve the transaction. Virginia law permits a corporation to exempt itself from this statutory provision by placing a statement to that effect in its articles of incorporation. Furthermore, this statutory provision regarding affiliated transactions does not apply to corporations with fewer than 300 shareholders. Our articles of incorporation do not specifically address the Virginia statute regarding affiliated transactions; therefore, we are subject to this provision.

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Under the second statutory provision, Virginia law requires an interested person who acquires a threshold percentage of stock in the target corporation to obtain the approval of disinterested shareholders before the interested person may exercise its voting rights with respect to the acquired shares. Under the Virginia statute, certain notice and informational filings and special shareholder voting and meeting procedures must be followed prior to consummation of the purchase of stock that will provide the interested shareholder with the power to vote in excess of 20%, 33% or 50% of the outstanding voting stock of the company. Assuming compliance with notice and information filing requirements, the purchased stock will not provide the interested purchaser with any voting rights with respect to the stock until a majority of the outstanding disinterested shares vote to restore the voting rights to the purchased stock. Our articles of incorporation provide that this second statutory provision does not apply to our company; therefore, we are not subject to this provision.

Transfer Agent and Registrar

The transfer agent and registrar for the shares of our common stock is Wachovia Bank, N.A.

SHARES ELIGIBLE FOR FUTURE RESALE

The warrants and convertible notes issued by us to date, which are described above in Description of Capital Stock Warrants and Description of Capital Stock Convertible Notes , are presently exercisable for and convertible into as many as 50,004,280 shares of common stock, representing approximately 111% of our outstanding common stock as of May 31, 2005.

The conversion or exercise of some or all of the notes and warrants will significantly dilute the ownership interests of existing stockholders. Any future sales in the public market of the common stock issuable upon such conversion or exercise could adversely affect prevailing market prices of our common stock or our future ability to raise capital through an offering of equity securities.

PLAN OF DISTRIBUTION

The shares of common stock offered hereby may be sold from time to time by the selling stockholders for their own accounts. We will receive none of the proceeds from this offering. We will bear substantially all costs and expenses incident to the offering and sale of the shares to the public, including legal fees and disbursements of counsel, blue sky expenses, accounting fees and filing fees, but excluding any brokerage commissions, discounts or similar charges.

Resale of the shares by the selling stockholders are not subject to any underwriting agreement. The shares of common stock covered by this prospectus may be sold by the selling stockholders or by their permitted pledgees, donees, transferees, beneficiaries, distributees or successors-in-interest selling shares received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other non-sale related transfer. In addition, certain of the selling stockholders are corporations or partnerships which may, in the future, distribute their shares to their stockholders or partners, respectively. Those shares may later be sold by those stockholders or partners. The selling stockholders will act independently of us in making decisions with respect to the timing, manner and size of each sale. The shares offered by each selling stockholder may be sold from time to time:

at market prices prevailing at the time of sale,

at prices relating to such prevailing market prices, or

at negotiated prices.

Such sales may be effected in the over-the-counter market, on the Nasdaq National Market, or on any exchange on which the shares may then be listed. We will supply the selling stockholders with reasonable quantities of this prospectus. The shares may be sold by one or more of the following:

One or more block trades in which a broker or dealer so engaged will attempt to sell all or a portion of the shares held by the selling stockholders as agent but may position and resell a portion of the block as principal to facilitate the transaction,

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purchases by a broker or dealer as principal and resale by such broker or dealer for its account pursuant to this prospectus,

ordinary brokerage transactions and transactions in which the broker solicits purchasers, or

in negotiated transactions; and through other means.

To the extent permitted by law, the selling stockholders may enter into hedging transactions when selling the shares. For example, the selling stockholders may:

sell shares short and redeliver such shares to close out their short positions; enter into transactions involving short sales by the brokers or dealers,

enter into option or other types of transactions that require the selling stockholders to deliver shares to a broker or dealer, who then resells or transfer the shares under this prospectus, or

loan or pledge the shares to a broker or dealer, who may sell the loaned shares or, in the event of default, sell the pledged shares.

There is no assurance that any of the selling stockholders will sell any or all of the shares offered by them.

The selling stockholders may effect sales through customary brokerage channels, either through broker-dealers acting as agents or brokers, or through broker-dealers acting as principals, who may then resell the shares, or at private sales or otherwise, at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at negotiated prices. The selling stockholders may effect such transactions by selling shares to or through broker-dealers, and such broker-dealers may receive compensation in the form of underwriting discounts, concessions, commissions or fees from the selling stockholders and/or purchasers of the shares for whom such broker-dealers may act as agent or to whom they sell as principal, or both (which compensation to a particular broker-dealer might be in excess of customary commissions). The selling stockholders may further agree to indemnify any broker-dealer or agent against certain liabilities related to the selling of the common stock, including liabilities arising under the Securities Act of 1933. The selling stockholders and any underwriters, broker-dealers or agents that participate in the sale of the common stock into which the notes are convertible and for which the warrants are exercisable may be underwriters within the meaning of Section 2(11) of the Securities Act. One Selling Stockholder, Morgan Stanley & Co. Inc., is deemed to be an underwriter with respect to the common stock it sells pursuant to this prospectus. Any discounts, commissions, concessions or profit that any underwriter earns on any resale of the common stock may be underwriting discounts or commissions under the Securities Act. Underwriters within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act. To the extent required, this prospectus may be amended or supplemented from time to time to describe a specific plan of distribution.

We have agreed to keep the registration statement of which this prospectus forms a part effective until the earlier of (i) June 15, 2010, (ii) the date on which the selling stockholders may sell all of the shares of common stock offered pursuant to this prospectus without restriction by the volume limitations of Rule 144(e) of the Securities Act, (iii) the date on which the selling stockholders have sold all of the shares of common stock offered pursuant to this prospectus under a registration statement and (iv) the occurrence of a business combination involving Insmed in which the existing Insmed stockholders do not own at least 51% of the shares of the entity resulting from the business combination, unless following the business combination Insmed continues to exist and its common stock continues to be approved for quotation on the Nasdaq Small Cap Market, the Nasdaq National Market or other stock price quotation service in the United States. Pursuant to the terms of our Stock and Warrant Purchase Agreements with the selling stockholders, we may temporarily suspend the rights of the selling stockholders to resell their shares pursuant to this prospectus under certain circumstances.

We will inform the selling stockholders of the need for delivery of copies of this prospectus in connection with sales under the registration statement.

Some states require that any shares sold in that state only be sold through registered or licensed brokers or dealers. In addition, some states require that the shares have been registered or qualified for sale in that state, or that there exists an exemption from the registration or qualification requirements and that the exemption has been complied with.

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Any shares covered by the prospectus that qualify for resale pursuant to Rule 144 under the Securities Act of 1933, as amended, may be sold under Rule 144 rather than pursuant to this prospectus. In addition to selling the shares of common stock, the selling stockholders may transfer the shares by gift, distribution or other transfer not involving market makers or established trading markets.

LEGAL MATTERS

The validity of the common stock offered hereby will be passed upon for us by Woods Rogers PLC.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements included in this prospectus as of December 31, 2004 and management s assessment of the effectiveness of internal control over financial reporting as of December 31, 2004 included by reference therein, as set forth in their report. Our financial statements and management s assessment of internal control are included in reliance on Ernst & Young LLP s reports, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements, and other information with the Securities and Exchange Commission (the SEC). You may read and copy any documents we file at the SEC s Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the Public Reference Room. Our SEC filings are also available to the public on our web site at www.insmed.com at the SEC s web site at www.sec.gov.

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FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Insmed Incorporated

We have audited the accompanying consolidated balance sheets of Insmed Incorporated (the Company) as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2004. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Insmed Incorporated at December 31, 2004 and 2003, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Insmed Incorporated s internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 15, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia

March 15, 2005

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INSMED INCORPORATED

CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 31, 2004	December 31, 2003
Assets		
Current assets:		
Cash and cash equivalents	**$ 9,222**	$ 29,526
Restricted cash	**285**	
Other current assets	**174**	225
Total current assets	9,681	29,751
Long-term assets:		
Restricted cash long-term portion	**3,303**	
Property and equipment, net	**27**	61
Total assets	$ 13,011	$ 29,812
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	**$ 2,621**	$ 660
Accrued project costs	**884**	1,747
Payroll liabilities	**1,183**	205
Restructuring reserve	**360**	334
Total current liabilities	**5,048**	2,946
Long-term liabilities:		
Asset retirement obligation	443	
Restructuring reserve long-term portion	285	646
Total liabilities	**5,776**	3,592
Stockholders equity:		
Common stock, $.01 par value; authorized shares 500,000,000; issued and outstanding shares 44,893,496 in 2004 and 38,394,994 in 2003	**449**	384
Additional capital	**220,515**	212,362
Accumulated deficit	**(213,729)**	(186,526)
Net stockholders equity	**7,235**	26,220
Total liabilities and stockholders equity	$ 13,011	$ 29,812

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INSMED INCORPORATED

Condensed Consolidated Statements of Operations

(in thousands, except per share data)

	Twelve Months Ended December 31,		
	2004	**2003**	**2002**
Revenues	**$ 137**	$ 150	$ 1,955
Operating expenses:			
Research and development	**23,320**	7,140	18,077
General and administrative	**4,242**	3,596	2,984
Operational restructuring charge			2,533
Goodwill impairment charge			15,385
Total operating expenses	**27,562**	10,736	38,979
Operating loss	**(27,425)**	(10,586)	(37,024)
Interest income	**222**	288	607
Net loss	**$ (27,203)**	$ (10,298)	$ (36,417)
Basic and diluted net loss per share	**$ (0.69)**	$ (0.29)	$ (1.10)
Shares used in computing basic and diluted net loss per share	**39,160**	35,600	33,066

See accompanying notes.

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INSMED INCORPORATED

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

YEARS ENDED DECEMBER 31, 2004, 2003, AND 2001

(in thousands, except share amounts)

	Common Stock	Additional Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
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
Issuance of 53,171 shares of common stock upon exercise of stock options	1	53			54
Issuance of 36,439 shares of common stock from Employee Stock Purchase Plan		27			27
Issuance of 5,146,846 shares of common stock and 1,544,046 warrants for cash, net of offering costs of $972,593	51	12,872			12,923
Recognition of stock compensation expense for consultants	1	118			119
Stock re-purchase from Taisho	(1)	(52)			(53)
Comprehensive earnings:					
Net loss			(10,298)		(10,298)
Comprehensive loss					(10,298)
Balance at December 31, 2003	384	212,362	(186,526)		26,220
Issuance of 6,091 shares of common stock upon exercise of stock options		3			3
Issuance of 36,860 shares of common stock from Employee Stock Purchase Plan		69			69
Issuance of 6,455,551 shares of common stock and 3,227,775 warrants for cash, net of offering costs of $602,472	65	8,048			8,113
Recognition of stock compensation expense for consultants		33			33
Comprehensive earnings:					
Net loss			(27,203)		(27,203)
Comprehensive loss					(27,203)
Balance at December 31, 2004	$ 449	$ 220,515	$ (213,729)	$	$ 7,235

See accompanying notes.

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INSMED INCORPORATED

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Twelve Months Ended December 31,	
	2004	**2003**
Operating activities		
Net loss	**$ (27,203)**	$ (10,298)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	**34**	96
Stock issued for services	**33**	119
Changes in operating assets and liabilities:		
Due from Taisho Pharmaceutical Co., Ltd.		199
Other assets	**51**	390
Accounts payable	**1,961**	(281)
Accrued project costs	**(863)**	(536)
Payroll liabilities	**978**	(153)
Restructuring reserve	**(335)**	(298)
Asset retirement obligation	**443**	
Net cash used in operating activities	**(24,901)**	(10,762)
Financing activities		
Proceeds from issuance of common stock	**8,185**	12,951
Cash restricted to support letters of credit	**(3,588)**	
Net cash provided by financing activities	**4,597**	12,951
(Decrease) Increase in cash and cash equivalents	**(20,304)**	2,189
Cash and cash equivalents at beginning of period	**29,526**	27,337
Cash and cash equivalents at end of period	**$ 9,222**	$ 29,526

See accompanying notes.

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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 manifests 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 and INSM-18. 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. INSM-18 binds to and inhibits one of the key enzymes involved in the downstream signaling pathway for IGF-I.

Insmed has three lead drug candidates: rhIGF-I/rhIGFBP-3, which is expected to began Phase III Clinical testing for GHIS in 2005, rhIGFBP-3 is currently undergoing Phase I and Pre-Clinical trials in the oncology area and INSM-18 will enter clinical trials in 2005. The Company is actively developing rhIGF-I/rhIGFBP-3 to treat GHIS and diabetes, and are concurrently continuing Phase I and 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 Therapeutic Proteins, 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.

On April 14, 2004 the Company announced that it had acquired a lease to operate a recombinant protein manufacturing facility located in Boulder, Colorado. The Company intends to use the facility for the commercial manufacture of its Phase III development product, rhIGF-I/rhIGFBP-3. Insmed provided a Letter of Credit to the landlord of the Boulder facility in the amount of $1.6 million for prepayment of the outstanding lease term of 4 years and a Letter of Credit to Baxter Healthcare Corporation for $2.0 million to cover facility restoration expenses on termination of the lease. These amounts are supported by segregated cash and cash equivalents and classified as restricted cash on the balance sheet.

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,	
	2004	**2003**
	(in thousands)	
Furniture and office equipment	$ 511	$ 511
	511	511
Accumulated depreciation	(484)	(450)
Property and equipment, net	$ 27	$ 61

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INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2004 and 2003 due to the short-term maturities of these instruments.

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 FASB Statement 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

(in thousands, except per share data)

	Year Ended December 31,		
	2004	**2003**	**2002**
Net Loss	$ (27,203)	$ (10,298)	$ (36,417)
Net Loss Per Share (Basic and Diluted)	$ (0.69)	$ (0.29)	$ (1.10)
Stock based employee compensation cost (under APB 25)			

Pro-forma Fair value stock compensation expense	(1,851)	(2,001)	(2,731)
Pro-Forma Net Income	(29,054)	(13,131)	(39,148)
Pro-Forma Net Loss Per Share (Basic and Diluted)	$ (0.74)	$ (0.37)	$ (1.18)

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 89% in 2004, 127% in 2003, and 106% in 2002, a risk-free interest rate of 3.83% in 2004, 3.0% in 2003, and 3.0% in 2002, no dividends, and a weighted-average expected life of the option of 5 years in 2004, 4.93 years in 2003 and 5.7 years in 2002. Compensation expense for fixed awards with pro-rata vesting is recognized under the straight-line method.

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.

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INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Research and Development

Research and development costs are expensed as incurred. Research and development expenses consist primarily of salaries and related expenses, cost to develop and manufacture products and amounts paid to contract research organizations, hospitals and laboratories for the provision of services and materials for drug development and clinical trials.

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.

Net Loss Per Share

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

Segment Information

The Company currently operates in one business segment, which is the development and commercialization of pharmaceutical products for the treatment of metabolic and endocrine diseases associated with insulin resistance. 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

On December 16, 2004, the Financial Accounting Standards Board (FASB) issued a revision of Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment (Statement 123(R)), which is a revision of FASB Statement No. 123, Accounting for Stock-Based Compensation. Statement 123(R) supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees, and amends FASB Statement No. 95, Statement of Cash Flows. Generally, the approach in Statement 123(R) is similar to the approach described in Statement 123. Statement 123(R) will be adopted by Insmed Incorporated on July 1, 2005.

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INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

As permitted by Statement 123, Insmed Incorporated currently accounts for share-based payments to employees using Opinion 25 s intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options. However, Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values over the expected period of service.

The full impact of adoption of Statement 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had Insmed Incorporated adopted Statement 123(R) in prior periods, the impact of that standard would have approximated the impact of Statement 123 as described in the disclosure of pro forma net income and earnings per share in Note 1 to the consolidated financial statements. Statement 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. Insmed Incorporated expects the financial impact of Statement 123(R) to closely approximate the values that have been discussed in the footnotes on Stock Based Compensation.

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 the then recently completed Phase II clinical trials. At December 31, 2004, approximately $0.4 million of the related restructuring costs remain accrued in the current portion of the restructuring reserve and $0.3 million in the long-term portions of the restructuring reserve. These balances are expected to closely approximate the remaining costs to be incurred by the Company for lease obligations. Lease termination costs are anticipated to extend through 2006.

2. Stockholders Equity

Common Stock

On November 19, 2004 Insmed Incorporated concluded a private placement of 6,455,551 shares of common stock to a group of institutional investors at a price of $1.35 per share, raising a total of approximately $8.7 million received in gross proceeds. The placement agent in the transaction received approximately $572,000 in fees and expenses (including fees paid to the placement agent s attorneys) resulting in net proceeds to the Company of approximately $8.0 million. The Company also issued warrants to purchase an additional 3,227,775 shares of common stock with an exercise price of $2.00 per share.

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

expense in the accompanying consolidated statements of operations.

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INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Stock Warrants and Options

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. Options may be granted at the discretion of the board of directors, compensation committee or a delegate. The weighted-average fair value of options granted during 2004, 2003, and 2002 was $2.12, $1.72, and $1.36 respectively. A summary of stock option activity is as follows:

Description	2004	Weighted Average Exercise Price	2003	Weighted Average Exercise Price	2002	Weighted Average Exercise Price
Options outstanding at January 1	3,900,516	$ 4.06	3,250,227	$ 4.49	3,143,561	$ 6.11
Granted	976,000	2.12	1,349,000	1.72	1,984,750	1.98
Exercised	(6,091)	0.50	(53,171)	1.01	(198,282)	0.64
Cancelled	(6,000)	2.20	(645,540)	1.59	(1,679,802)	5.01
Options outstanding at December 31	4,864,425	$ 3.68	3,900,516	$ 4.06	3,250,227	$ 4.49

The following table summarizes options outstanding at December 31, 2004:

Range of Exercise Prices		Options Outstanding			Options Exercisable	
		Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$ 0.172	$ 1.00	690,811	5.32	0.74	352,365	0.72
$ 1.06	$ 2.92	1,985,433	6.65	1.98	413,003	1.99
$ 3.00	$ 8.25	1,737,793	4.04	4.35	900,787	4.81
$ 8.30	$ 32.12	450,389	2.61	13.09	450,389	13.09
		4,864,425	5.15	3.70	2,116,544	5.34

A total of 11,463,585 shares of common stock were reserved at December 31, 2004 in connection with stock options, stock warrants, and the employee stock purchase plan.

3. Income Taxes

The deferred tax assets of approximately $104.2 million and $93.8 million at December 31, 2004 and 2003, 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, 2004 and 2003, the Company had net operating loss carryforwards for income tax purposes of approximately $261.0 million and $232.8 million, respectively, expiring in various years beginning in 2005 through 2024. Utilization of these carryforwards will be significantly limited due to changes in the ownership of the Company s common stock.

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INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	2004	2003
	(in thousands)	
Deferred tax assets		
General Business Credits	4,224	4,224
Other	1,106	1,174
NOL Carryforwards	99,064	88,385
Total deferred tax assets	104,394	93,783
Deferred tax liabilities		
Other	(224)	(2)
Total deferred tax liabilities	(224)	(2)
Tax deferred asset/(liability)	104,170	93,781
Valuation allowance	(104,170)	(93,781)
Net deferred tax asset/(liability)		

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

	2004	2003
Statutory federal tax rate	34%	34%
State income taxes net of federal benefit	4	4
Research and development credit		(45)
Other	0	0
Change in valuation allowance	(38)	6
Total Expense	0%	0%

4. Leases

The Company leases office and laboratory space in Glen Allen, Virginia 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 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 restructuring charge relating to this lease during the third quarter of 2003. The Company also leases a manufacturing facility and warehouse in Boulder, Colorado under an operating lease agreement expiring in February 2008. The lease provides for monthly rent of approximately $30,000 with a 3% escalation per year. The Company also leases a vehicle and office equipment. Future minimum payments on all these leases at December 31, 2004 approximate $1,153,000, $861,000, $365,000, $79,700 and $12,500 in 2005, 2006, 2007, 2008, and 2009 respectively. Rent expense for all operating leases approximated $869,000 in 2004, $535,000 in 2003, and $702,000 in 2002.

5. 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, 2004 there were 250,000 shares authorized for issuance under the plan and 147,991 have been issued.

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INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

6. License and Collaborative Agreements

Tzamal Pharmaceutical

In October 2004, we entered into a letter of intent promotion agreement with Tzamal Pharma, a subsidiary of Fox Pharma headquartered in Jerusalem Israel. The agreement calls for Tzamal to be our exclusive distributor in Israel and Palestinian autonomous territories, West Bank and Gaza. The agreement has a term of one year and on the anniversary of the agreement it may be renewed via joint agreement between Insmed and Tzamal for another twelve months.

Fujisawa Pharmaceutical Co., Ltd.

In January 2004, Insmed was granted a non-exclusive license to patent rights pertaining to the use of IGF-I therapy for the treatment of extreme or severe insulin resistant diabetes from Fujisawa Pharmaceutical Co., Ltd. Under the terms of the agreement, Insmed obtained worldwide rights in territories (excluding Japan) where a valid patent claim exists, including the United States and Europe. We have made a commitment to use reasonable commercial efforts to make rhIGF-I/rhIGFBP-3 available on a named patient basis to patients with extreme insulin resistance.

Pharmacia

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

Avecia Limited

In July 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 have paid for process development and manufacturing costs associated with production of rhIGF-I/rhIGFBP-3.

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 in 2002. 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

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INSMED INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

result of this termination the Company recognized the remaining amount of the deferred license fee of $1.7 million in the 2002. In April of 2003 the Company repurchased the 93,413 shares of Insmed Incorporated stock that was being held by Taisho.

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 discontinued the development of products covered under this license and terminated this agreement on June 29, 2004.

7. Legal Proceedings

On December 20, 2004, Tercica, Inc. filed a complaint against Avecia Limited and Insmed Incorporated in the United Kingdom at the High Court of Justice, Chancery Division, Patents Court alleging infringement of EP patent No. 571,417 (the 417 patent). The 417 patent has claims directed to particular uses of a combination of IGFBP-3 and IGF-I. In the complaint, Tercica, Inc. asked the court for an injunction to restrain allegedly infringing activity, for a declaration that the 417 patent is valid and infringed, for an order requiring the delivery or destruction of allegedly infringing articles and materials and for an inquiry into possible economic damages.

On February 11, 2005, Avecia and Insmed Incorporated filed a Defense and Counterclaim to Tercica Inc. s suit. In its Defense, Avecia and Insmed Incorporated asserted, among other things, that the 417 patent is invalid and that the Claimant failed to properly register its license. In its Counterclaim, Avecia and Insmed also asked the court to revoke the 417 patent.

Insmed Incorporated cannot predict with certainty the outcome of this proceeding. We note, however, that an adverse ruling could impact our ability to make, use or sell our products.

Tercica, Inc. and Genentech, Inc. filed, on December 23, 2004, a complaint against Insmed Incorporated in the United States District Court for the Northern District of California alleging infringement of U.S. patent Nos. 5,187,151 and 6,331,414. These patents are directed to certain methods of using IGF-I/IGFBP-3 and methods of producing human IGF-I, respectively. On February 16, 2005, Tercica, Inc. and Genentech, Inc. filed an Amended Complaint, adding allegations of infringement of U.S. patent No. 5,258,287 (the 287 patent). The claims of the 287 patent are directed to DNA encoding BP53 (i.e. IGFBP-3) and recombinant constructs, transformed host cells and methods for using same.

On February 18, 2005, Insmed Incorporated filed a motion to dismiss the Amended Complaint. In the motion, Insmed Incorporated asserted that all alleged activities fall within the statutory safe-harbor provided by 35 U.S.C. § 271(e)(1), commonly called the clinical trial exemption. This exemption prevents patent infringement actions from being filed against activities reasonably related to obtaining FDA approval of a product, such as when the product is still being tested in clinical trials. Insmed Incorporated further asserted, among other things, that Plaintiffs have failed to state a claim for the requested relief, have not sued the proper party, have failed to name all the proper plaintiffs and have failed to establish the existence of a sufficiently real and substantial controversy between the parties. Insmed requested immediate dismissal or Summary Judgment against the plaintiff s allegation on these grounds.

Insmed Incorporated cannot predict with certainty the outcome of this proceeding, however, an adverse ruling could impact our ability to make, use or sell our products.

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8. Quarterly Financial Data (Unaudited)

	Fiscal Quarter								
	First	First		Second		Third		Fourth	
	2005	2004	2003	2004	2003	2004	2003	2004	2003
Revenues	57	$ 61	$ 62	$ 29	$ 34	$ 24	$ 27	$ 23	$ 27
Operating Loss	(5,523)	(4,835)	(2,301)	(9,060)	(3,313)	(7,647)	(2,468)	(5,883)	(2,504)
Net Loss	(5,764)	(4,759)	(2,209)	(9,011)	(3,240)	(7,596)	(2,398)	(5,837)	(2,451)
Net Loss Per Share (Basic and Diluted)	(0.13)	$ (0.12)	$ (0.07)	$ (0.23)	$ (0.10)	$ (0.20)	$ (0.06)	$ (0.14)	$ (0.06)

9. Subsequent Events

On March 15, 2005, we entered into several purchase agreements with a group of institutional investors, pursuant to which we issued and sold to the investors approximately $35,000,000 aggregate principal amount of 5.5% convertible notes, which notes are convertible into our common stock, par value $0.01 per share, as well as warrants to purchase, in the aggregate, 14,864,883 shares of our common stock, at an exercise price of $1.36 per share. The principal of each note will mature and be payable in nine quarterly installments of approximately $3,890,000 commencing on March 1, 2008. Any outstanding notes must be repaid in cash or converted by March 1, 2010. Commencing on June 1, 2005, the holders of the notes will receive quarterly interest payments at a rate of 5.5% per annum. The holders of the notes may convert the notes into our common stock at a conversion price of $1.295 per share as adjusted in accordance with certain adjustments for stock splits, dividends and the like at any time prior to the close of business on March 1, 2010. The notes are convertible into, in the aggregate, 27,027,027 shares of our common stock. The warrants are immediately exercisable for 14,864,883 shares of our common stock at an exercise price of $1.36 per share. The warrants will expire on March 15, 2010. The holders of the notes have the right to require us to repurchase the notes with cash payments up on the occurrence of specified events of default and repurchase events. The investors also have the right to participate in future financings undertaken by us prior to March 16, 2006, subject to certain exceptions. In connection with issuance of the notes and warrants, we entered into registration rights agreements with the investors pursuant to which we agreed to file a Registration Statement under the Securities Act of 1933, registering for resale the shares of common stock issuable upon the conversion of the notes or exercise of the warrants.

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INSMED INCORPORATED

Condensed Consolidated Balance Sheets

(in thousands)

	March 31, 2005	December 31, 2004
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	**$ 35,771**	$ 9,222
Restricted Cash	**285**	285
Other current assets	**100**	174
Total current assets	**36,156**	9,681
Long-term assets:		
Restricted Cash - long term	**3,118**	3,303
Deferred financing costs	**1,827**	
Property and equipment, net	**24**	27
Total assets	**$ 41,125**	$ 13,011
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	**$ 1,541**	$ 2,621
Accrued project costs	**759**	884
Payroll liabilities	**1,407**	1,183
Interest payable	**80**	
Restructuring reserve	**360**	360
Total current liabilities	**4,147**	5,048
Long-term liabilities:		
Convertible Debt	**35,000**	
Debt discount	**(16,369)**	
Net convertible debt	**18,631**	
Asset retirement obligation	**591**	443
Restructuring reserve-long-term portion	**207**	285
Total liabilities	**23,576**	5,776
Stockholders equity:		
Common stock; $.01 par value; authorized share 500,000,000; issued and outstanding shares, 44,987,287 in 2005 and 44,893,496 in 2004	**450**	449
Additional capital	**236,592**	220,515
Accumulated deficit	**(219,493)**	(213,729)

Net stockholders equity	**17,549**	7,235
Total liabilities and stockholders equity	**$ 41,125**	$ 13,011

See accompanying notes to the condensed consolidated financial statements.

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INSMED INCORPORATED

Condensed Consolidated Statements of Operations

(in thousands, except per share data - unaudited)

	Three Months Ended March 31,	
	2005	**2004**
Revenues	**$ 57**	$ 61
Operating expenses:		
Research and development	**4,287**	3,855
General and administrative	**1,293**	1,041
Total operating expenses	**5,580**	4,896
Operating loss	(5,523)	(4,835)
Interest income	**64**	76
Interest expense	**(305)**	
Net loss	**$ (5,764)**	$ (4,759)
Basic and diluted net loss per share	**$ (0.13)**	$ (0.12)
Shares used in computing basic and diluted net loss per share	**44,986**	38,395

See accompanying notes to the condensed consolidated financial statements.

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INSMED INCORPORATED

Consolidated Statements of Cash Flows

(in thousands - unaudited)

	Three Months Ended March 31,	
	2005	**2004**
Operating activities		
Net loss	**$ (5,764)**	$ (4,759)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	**226**	14
Changes in operating assets and liabilities:		
Other assets	**74**	(159)
Accounts payable	**(1,080)**	1,114
Accrued project costs	**(125)**	(907)
Payroll liabilities	**224**	154
Restructuring reserve	**(78)**	(76)
Asset Retirement Obligations	**148**	
Interest payable	**80**	
Net cash used in operating activities	**(6,295)**	(4,619)
Financing activities		
Proceeds from issuance of convertible debt with detachable stock warrants	**35,000**	
Proceeds from issuance of common stock	**87**	
Costs incurred in conjunction with issuance of debt	**(2,428)**	
Cash restricted to restricted letters of credit	**185**	
Net cash provided by financing activities	**32,844**	
Increase (decrease) in cash and cash equivalents	**26,549**	(4,619)
Cash and cash equivalents at beginning of period	**9,222**	29,526
Cash and cash equivalents at end of period	**$ 35,771**	$ 24,907

See accompanying notes to the condensed consolidated financial statements.

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Insmed Incorporated

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States and applicable Securities and Exchange Commission regulations for interim financial information. These financial statements do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. It is presumed that users of this interim financial information have read or have access to the audited financial statements contained in the Annual Report on Form 10-K of Insmed Incorporated (the Company) for the fiscal year ended December 31, 2004. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for fair presentation have been included. Operating results for the interim periods presented are not necessarily indicative of the results that may be expected for the full year.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

2. Summary of Significant Accounting Policies

Research and Development Costs

Research and development costs consist primarily of compensation and other expenses related to research and development personnel, costs associated with pre-clinical testing and clinical trials of our product candidates, including the costs of manufacturing the product candidates, and facilities expenses. Research and development costs are expensed as incurred. The Company does not have separate accounting policies for internal or external research and development and we do not conduct any research and development for others.

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. 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.

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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

(in thousands - except per share data)

	For the Three Months Ended	
	March 31, 2005	March 31, 2004
Net Loss	(5,764)	(4,759)
Net Loss Per Share (Basic and Diluted)	(0.13)	(0.12)
Stock based employee compensation cost (under APB 25)		
Pro-forma Fair value stock compensation expense	(560)	(480)
Pro-forma Net Income	(6,324)	(5,239)
Pro-forma Net Loss Per Share (Basic and Diluted)	(0.14)	(0.14)

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 89%, a risk-free interest rate of 4.17%, no dividends, and a weighted-average expected life of the option of 5 years.

3. Recent Accounting Pronouncements

On December 16, 2004, the Financial Accounting Standards Board (FASB) issued a revision of Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment (Statement 123(R)). Statement 123(R) supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees, and amends FASB Statement No. 95, Statement of Cash Flows. Generally, the approach in Statement 123(R) is similar to the approach described in Statement 123. Statement 123(R) will be adopted by Insmed Incorporated on January 1, 2006.

The full impact of the adoption of Statement 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had the Company

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adopted Statement 123(R) in prior periods, the impact of that standard would have approximated the impact of Statement 123 as described in the disclosure of pro forma net income and earnings per share in Note 2 to the consolidated financial statements. Statement 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. Insmed Incorporated expects the financial impact of Statement 123(R) to closely approximate the values that have been discussed in the footnotes on Stock Based Compensation.

4. Operational Restructuring

As a result of the September 10, 2002 decision to discontinue the INS-1 development program the Company approved a restructuring plan to focus on its remaining drug candidates. In the third quarter of 2002, the Company recorded a restructuring charge of $2.5 million. At March 31, 2005, approximately $0.4 million and $0.2 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. Lease termination costs are anticipated to extend through 2006.

5. Convertible Debt Financing

On March 15, 2005, we entered into several purchase agreements with a group of institutional investors, pursuant to which we issued and sold to the investors approximately $35,000,000 aggregate principal amount of 5.5% convertible notes, which notes are convertible into our common stock, par value $0.01 per share, as well as warrants to purchase, in the aggregate, 14,864,883 shares of our common stock, at an exercise price of $1.36 per share. The principal of each note will mature and be payable in nine quarterly installments of approximately $3,890,000 commencing on March 1, 2008. Any outstanding notes must be repaid in cash or converted by March 1, 2010. Commencing on June 1, 2005, the holders of the notes will receive quarterly interest payments at a rate of 5.5% per annum. The holders of the notes may convert the notes into our common stock at a conversion price of $1.295 per share as adjusted in accordance with certain adjustments for stock splits, dividends and the like at any time prior to the close of business on March 1, 2010. The notes are convertible into, in the aggregate, 27,027,027 shares of our common stock. The warrants are immediately exercisable for 14,864,883 shares of our common stock at an exercise price of $1.36 per share. The warrants will expire on March 15, 2010. The holders of the notes have the right to require us to repurchase the notes with cash payments up on the occurrence of specified events of default and repurchase events. The investors also have the right to participate in future financings undertaken by us prior to March 16, 2006, subject to certain exceptions. In connection with issuance of the notes and warrants, we entered into registration rights agreements with the investors pursuant to which we agreed to file a Registration Statement under the Securities Act of 1933, registering for resale the shares of common stock issuable upon the conversion of the notes or exercise of the warrants.

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PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the various expenses to be incurred in connection with the sale and distribution of the securities being registered hereby (except for any underwriting discounts and commissions), all of which will be borne by Insmed. All amounts shown are estimates except the SEC registration fee.

SEC registration fee	$ 4,659
Accounting fees and expenses	12,500
Legal fees and expenses	40,000
Miscellaneous	10,000
Total	$ 52,159

Item 14. Indemnification of Directors and Officers.

The Virginia Stock Corporation Act (the VSCA) permits, and the Registrant s Articles of Incorporation require, indemnification of the Registrant s directors and officers in a variety of circumstances, which may include indemnification for liabilities under the Securities Act of 1933, as amended (the Securities Act). Under Sections 13.1-697 and 13.1-702 of the VSCA, a Virginia corporation generally is authorized to indemnify its directors and officers in civil or criminal actions if they acted in good faith and believed their conduct to be in the best interests of the corporation and, in the case of criminal actions, had no reasonable cause to believe that the conduct was unlawful. The Registrant s Articles of Incorporation require indemnification of directors and officers with respect to certain liabilities, expenses and other amounts imposed upon them because of having been a director or officer, except in the case of willful misconduct or a knowing violation of criminal law.

In addition, the Registrant carries insurance on behalf of directors, officers, employees or agents that may cover liabilities under the Securities Act. The Registrant s Articles of Incorporation also provide that, to the full extent the VSCA (as it presently exists or may hereafter be amended) permits the limitation or elimination of the liability of directors and officers, no director or officer of the Registrant shall be liable to the Registrant or its stockholders for monetary damages with respect to any transaction, occurrence or course of conduct. Section 13.1-692.1 of the VSCA presently permits the elimination of liability of directors and officers in any proceeding brought by or in the right of a company or brought by or on behalf of stockholders of a company, except for liability resulting from such person s having engaged in willful misconduct or a knowing violation of the criminal law or any federal or state securities law, including, without limitation, any unlawful insider trading or manipulation of the market for any security. Sections 13.1-692.1 and 13.1-696 to -704 of the VSCA are hereby incorporated by reference herein.

Item 15. Recent Sales of Unregistered Securities.

Set forth in chronological order is information regarding unregistered securities issued and warrants and options granted by the Registrant during the three years prior to the date of this Registration Statement.

On July 11, 2003, the Registrant sold approximately 5.1 million newly issued shares of common stock to a group of institutional investors at a price of $2.70 per share, raising a total of approximately $13.9 million in gross proceeds. As part of that private placement, the Registrant issued warrants to purchase an additional 1.54 million shares of common stock with an exercise price of $4.10 per share.

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On November 4, 2004, the Registrant sold approximately 6.5 million newly issued shares of common stock to a group of institutional investors at a price of $1.35 per share, raising a total of approximately $8.7 million in gross proceeds. As part of that private placement, the Registrant issued warrants to purchase an additional 3.25 million shares of common stock which now have an exercise price of $1.71 per share.

On March 15, 2005, the Registrant issued and sold to certain institutional investors 5.5% convertible notes due 2008-2010 in an aggregate principal amount of $35,000,000 and warrants to purchase, in the aggregate, 14,864,883 shares of common stock, raising a total of approximately $32,800,000. The warrants are immediately exercisable and have an exercise price of $1.36 per share, but will expire if not exercised on or prior to March 15, 2010. The principal amount of the notes will mature and become payable in nine quarterly installments of approximately $3,890,000 commencing on March 1, 2008. All outstanding notes shall be repaid in cash or converted by March 1, 2010. The notes may not be prepaid, in whole or in part, or redeemed by the Registrant except under certain limited circumstances as provided for in the terms of the notes. Commencing on June 1, 2005, the notes will bear interest at a rate of 5.5% per annum. Interest on the notes is payable quarterly commencing on March 1, 2008 and ending on March 1, 2010. The holders of the notes may convert the notes into common stock at any time prior to the close of business on March 1, 2010, at a conversion price of $1.295 per share. The notes are subject to adjustments based on splits, dividends and similar extraordinary event affecting the common stock. The notes are convertible into, in the aggregate, 27,027,013 shares of common stock.

Item 16. Exhibits.

Exhibit Number	Description
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)).
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)).
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).
3.4	Articles of Amendment for Reverse Split (previously filed as Exhibit 3.4 to Insmed Incorporated s Annual Report on Form 10-K for the year ended December 31, 2002).
4.1	Description of Capital Stock (contained in the Registrant s Articles of Incorporation previously filed as Annex H to the Joint Proxy Statement/Prospectus contained in Part I of the Registrant s Registration Statement on Form S-4 (Registration No. 333-30098) on February 11, 2000).
4.2	Specimen stock certificate representing common stock, $.0l par value per share, of the Registrant (previously filed as Exhibit 4.2 to the Registrant s Registration Statement on Form S-4 (Registration No. 333-30098) on February 11, 2000).
4.3	Article VI of the Articles of Incorporation of the Registrant (previously filed as Exhibit 4.1 to the Registrant s Registration Statement on Form S-4 (Registration No. 333-30098) on February 11, 2000).
4.4	Rights Agreement, dated as of May 16, 2001, between the Registrant and First Union National Bank, as Rights Agent (which includes as (i) Exhibit A the form of Articles of Amendment to the Registrant s Articles of Incorporation, as amended, (ii) Exhibit B the form of Rights Certificate, and

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	(iii) Exhibit C the Summary of the Rights to Purchase Preferred Stock) (previously filed as Exhibit 4.4 to the Registrant s Registration Statement on Form 8-A filed with the Securities and Exchange Commission on May 17, 2001).
4.5	Form of Rights Certificate (previously filed as Exhibit B to the Rights Agreement, dated as of May 16, 2001, between the Registrant and First Union National Bank, as Rights Agent, filed as Exhibit 4.4 to the Registrant s Registration Statement on Form 8-A filed with the Securities and Exchange Commission on May 17, 2001).
4.6	Form of Purchase Agreement, dated March 15, 2005, between the Registrant and each of the investors in the March 2005 private placement of notes and warrants to purchase common stock.
4.7	Form of 5.5% Note Due 2008-2010, dated March 15, 2005, between the Registrant and each of the investors in the March 2005 private placement of notes and warrants to purchase common stock.
4.8	Form of Warrant, dated March 15, 2005, between the Registrant and each of the investors in the March 2005 private placement of notes and warrants to purchase common stock.
4.9	Form of Registration Rights Agreement, dated March 15, 2005, between the Registrant and each of the investors in the March 2005 private placement of notes and warrants to purchase common stock.*
4.10	Amendment No. 1 to Rights Agreement, dated as of March 15, 2005, by and between the Registrant and Wachovia Bank, N.A. (f/k/a First Union National Bank) as Rights Agent*
5.1	Opinion of Woods Rogers PLC.**
10.1	Insmed Incorporated 2000 Employee Stock Purchase Plan (previously filed as Exhibit 10.2 to Insmed Incorporated s Registration Statement on Form S-4 (Registration No. 333-30098)).
10.2	Insmed Incorporated Amended and Restated 2000 Stock Incentive Plan (previously filed as Exhibit A to Insmed Incorporated s Definitive Proxy Statement filed on May 11, 2005).
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)).
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)).
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)).
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)).
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)).

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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)).
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)).
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)).
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)).
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).
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).
10.14	Termination Agreement, dated as of February 3, 2003, between Insmed Pharmaceuticals, Inc. and Taisho Pharmaceutical Co., Ltd (previously filed as Exhibit 10.14 to Insmed Incorporated s Annual Report on Form 10-K for the year ended December 31, 2003).
10.15+	Agreement, dated as of July 25, 2003, between Insmed Incorporated and Avecia Limited (previously filed as Exhibit 10.15 to Insmed Incorporated s Annual Report on Form 10-K for the year ended December 31, 2003).
10.16+	License and Supply Agreement, dated as of August 28, 2003, between Insmed Incorporated and Pharmacia AB (previously filed as Exhibit 10.16 to Insmed Incorporated s Annual Report on Form 10-K for the year ended December 31, 2003).
10.17	Agreement, dated as of March 3, 2004, between Insmed Incorporated and Geoffrey Allan, Ph.D. (previously filed as an Exhibit to Insmed Incorporated s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 12, 2004).
10.18++	License Agreement, dated as of January 19, 2004, between Insmed Incorporated and Fujisawa Pharmaceutical Co., Ltd (previously filed as an Exhibit to Insmed Incorporated s Annual Report on Form 10-K filed with the Securities and Exchange Commission on September 23, 2004).
10.19	Form of Change of Control Agreement entered into between Insmed Incorporated and certain of its executive officers (previously filed as Exhibit 10.19 to Insmed Incorporated s Annual Report on Form 10-K for the year ended December 31, 2004).
10.20	Insmed Incorporated Officer s Bonus Plan (previously filed as Exhibit 10.20 to Amendment No. 2 to the Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on April 7, 2005).
10.21	Second Amendment to Insmed Incorporated Employee Stock Purchase Plan (previously filed as Exhibit B to Insmed Incorporated s Definitive Proxy Statement filed on May 11, 2005)

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10.22	Form of Director Option Grant pursuant to the Insmed Incorporated Amended and Restated 2000 Stock Incentive Plan (previously filed as Exhibit 10.1 to Insmed Incorporated s Current Report on Form 8-K filed with the Securities and Exchange Commission on June 10, 2005).
23.1	Consent of Ernst & Young LLP.
23.2	Consent of Woods Rogers PLC.**
24.1	Power of Attorney.**

* Filed as an Exhibit to the Registrant s Current Report on Form 8-K filed March 16, 2005 with the Securities and Exchange Commission.

** Filed as an Exhibit to the Registrant s Registration Statement on Form S-3 filed with the Securities and Exchange Commission on March 30, 2005.

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

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

Item 17. Undertakings.

(a) The undersigned Registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement;

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the Registration Statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the Registration Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective Registration Statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the Registration Statement or any material change to such information in the Registration Statement; provided, however, that paragraphs (a)(1)(i) and (a) (1)(ii) do not apply if the Registration Statement is on Form S-3, Form S-8 or Form F-3, and the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the Registrant pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the Registration Statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new Registration Statement relating to the

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securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(b) The undersigned Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the Registrant s annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan s annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the Registration Statement shall be deemed to be a new Registration Statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-1 and has duly caused this Amendment No. 1 to Registration Statement on Form S-3 on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized in Reston, Virginia, on June 10, 2005.

INSMED INCORPORATED

By: /s/ KEVIN P. TULLY, C.G.A.
Kevin P. Tully, C.G.A.
Principal Financial Officer, Treasurer and

Controller

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the date indicated.

Signature	Title	Date
/s/ Geoffrey Allan, Ph.D. Geoffrey Allan, Ph.D.	Chairman of the Board, President and Chief Executive Officer (Principal Executive officer)	June 10, 2005
/s/ Kevin P. Tully, C.G.A. Kevin P. Tully, C.G.A.	Treasurer and Controller (Principal Financial and Accounting Officer)	June 10, 2005
* Kenneth G. Condon	Director	June 10, 2005
* Graham K. Crooke, MB.BS	Director	June 10, 2005
* Steinar J. Engelsen, M.D.	Director	June 10, 2005
* Melvin Sharoky, M.D.	Director	June 10, 2005
*	Director	June 10, 2005

Randall W. Whitcomb, M.D.

* /s/ Kevin P. Tully
Kevin P. Tully
Attorney-in-Fact

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EXHIBIT INDEX

Exhibit Number	Description
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)).
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)).
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).
3.4	Articles of Amendment for Reverse Split (previously filed as Exhibit 3.4 to Insmed Incorporated s Annual Report on Form 10-K for the year ended December 31, 2002).
4.1	Description of Capital Stock (contained in the Registrant s Articles of Incorporation previously filed as Annex H to the Joint Proxy Statement/Prospectus contained in Part I of the Registrant s Registration Statement on Form S-4 (Registration No. 333-30098) on February 11, 2000).
4.2	Specimen stock certificate representing common stock, $.01 par value per share, of the Registrant (previously filed as Exhibit 4.2 to the Registrant s Registration Statement on Form S-4 (Registration No. 333-30098) on February 11, 2000).
4.3	Article VI of the Articles of Incorporation of the Registrant (previously filed as Exhibit 4.1 to the Registrant s Registration Statement on Form S-4 (Registration No. 333-30098) on February 11, 2000).
4.4	Rights Agreement, dated as of May 16, 2001, between the Registrant and First Union National Bank, as Rights Agent (which includes as (i) Exhibit A the form of Articles of Amendment to the Registrant 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 the Registrant s Registration Statement on Form 8-A filed with the Securities and Exchange Commission on May 17, 2001).
4.5	Form of Rights Certificate (previously filed as Exhibit B to the Rights Agreement, dated as of May 16, 2001, between the Registrant and First Union National Bank, as Rights Agent, filed as Exhibit 4.4 to the Registrant s Registration Statement on Form 8-A filed with the Securities and Exchange Commission on May 17, 2001).
4.6	Form of Purchase Agreement, dated March 15, 2005, between the Registrant and each of the investors in the March 2005 private placement of notes and warrants to purchase common stock.
4.7	Form of 5.5% Note Due 2008-2010, dated March 15, 2005, between the Registrant and each of the investors in the March 2005 private placement of notes and warrants to purchase common stock.
4.8	Form of Warrant, dated March 15, 2005, between the Registrant and each of the investors in the March 2005 private placement of notes and warrants to purchase common stock.

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4.9	Form of Registration Rights Agreement, dated March 15, 2005, between the Registrant and each of the investors in the March 2005 private placement of notes and warrants to purchase common stock.*
4.10	Amendment No. 1 to Rights Agreement, dated as of March 15, 2005, by and between the Registrant and Wachovia Bank, N.A. (f/k/a First Union National Bank) as Rights Agent*
5.1	Opinion of Woods Rogers PLC.**
10.1	Insmed Incorporated 2000 Employee Stock Purchase Plan (previously filed as Exhibit 10.2 to Insmed Incorporated s Registration Statement on Form S-4 (Registration No. 333-30098)).
10.2	Insmed Incorporated Amended and Restated 2000 Stock Incentive Plan (previously filed as Exhibit A to Insmed Incorporated s Definitive Proxy Statement filed on May 11, 2005).
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)).
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)).
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)).
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)).
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)).
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)).
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)).
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)).
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)).
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).

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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).
10.14	Termination Agreement, dated as of February 3, 2003, between Insmed Pharmaceuticals, Inc. and Taisho Pharmaceutical Co., Ltd (previously filed as Exhibit 10.14 to Insmed Incorporated s Annual Report on Form 10-K for the year ended December 31, 2003).
10.15+	Agreement, dated as of July 25, 2003, between Insmed Incorporated and Avecia Limited (previously filed as Exhibit 10.15 to Insmed Incorporated s Annual Report on Form 10-K for the year ended December 31, 2003).
10.16+	License and Supply Agreement, dated as of August 28, 2003, between Insmed Incorporated and Pharmacia AB (previously filed as Exhibit 10.16 to Insmed Incorporated s Annual Report on Form 10-K for the year ended December 31, 2003).
10.17	Agreement, dated as of March 3, 2004, between Insmed Incorporated and Geoffrey Allan, Ph.D. (previously filed as an Exhibit to Insmed Incorporated s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 12, 2004).
10.18++	License Agreement, dated as of January 19, 2004, between Insmed Incorporated and Fujisawa Pharmaceutical Co., Ltd (previously filed as an Exhibit to Insmed Incorporated s Annual Report on Form 10-K filed with the Securities and Exchange Commission on September 23, 2004).
10.19	Form of Change of Control Agreement entered into between Insmed Incorporated and certain of its executive officers (previously filed as Exhibit 10.19 to Insmed Incorporated s Annual Report on Form 10-K for the year ended December 31, 2004).
10.20	Insmed Incorporated Officer s Bonus Plan (previously filed as Exhibit 10.20 to Amendment No. 2 to the Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on April 7, 2005).
10.21	Second Amendment to Insmed Incorporated Employee Stock Purchase Plan (previously filed as Exhibit B to Insmed Incorporated s Definitive Proxy Statement filed on May 11, 2005)
10.22	Form of Director Option Grant pursuant to the Insmed Incorporated Amended and Restated 2000 Stock Incentive Plan (previously filed as an Exhibit to Insmed Incorporated s Current Report on Form 8-K filed with the Securities and Exchange Commission on June 10, 2005).
23.1	Consent of Ernst & Young LLP.
23.2	Consent of Woods Rogers PLC.**
24.1	Power of Attorney.**

* Filed as an Exhibit to the Registrant s Current Report on Form 8-K filed March 16, 2005 with the Securities and Exchange Commission.

** Filed as an Exhibit to the Registrant s Registration Statement on Form S-3 filed with the Securities and Exchange Commission on March 30, 2005.

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

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