INSMED INC
Form S-3
February 03, 2006
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As filed with the Securities and Exchange Commission on February 3, 2006

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM S-3

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)

Geoffrey Allan, Ph.D.

President and Chief Executive Officer

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

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If the only securities being registered pursuant on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ¨

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 number of the earlier effective registration statement for the same offering. ¨ _____

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 this Form is a registration statement pursuant to General Instruction I.D. or a post effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ¨

If this Form is a post effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, 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 Unit (3)	Proposed Maximum Aggregate Offering Price (4)(5)	Amount of Registration Fee (4)
Common Stock $0.01 par value (6) Preferred Stock $0.01 par value Warrants	$ 75,000,000(7)		$ 75,000,000(7)	$ 8,025

(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 (the Securities Act), that may be issued to prevent dilution resulting from stock splits, stock dividends or similar transactions affecting the shares being offered.

(2) Subject to note 7 below, there is being registered hereunder an indeterminate number of shares of common stock, preferred stock and warrants to purchase common stock or preferred stock of the registrant as may be sold from time to time by the registrant. Pursuant to Rule 457(i) under the Securities Act, the shares being registered hereunder include such indeterminate number of shares of common stock, preferred stock and warrants as may be issuable upon conversion or exchange of any preferred stock or warrants issued under this registration statement.

(3) The proposed aggregate offering price per unit will be determined from time to time by the registrant in connection with the issuance by the registrant of the securities registered hereunder and is not specified as to each class of security pursuant to General Instruction II. D. of Form S-3 under the Securities Act.

(4) Calculated in accordance with Rule 457(o) under the Securities Act.

(5) Includes consideration to be received by us for registered securities that are issuable upon exercise, conversion or exchange of other registered securities.

(6) 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

(7) In no event will the aggregate offering price of all securities issued from time to time pursuant to this registration statement exceed $75,000,000. The securities sold hereunder may be sold separately or as units with other securities registered hereunder.

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 this registration statement shall become effective on such date as the 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. We 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 it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to completion, dated February 3, 2006

INSMED INCORPORATED

$75,000,000

Common Stock

Preferred Stock

Warrants

This prospectus relates to common stock, preferred stock and warrants that we may sell from time to time in one or more offerings up to an aggregate public offering amount of $75,000,000 (or its equivalent in foreign or composite currencies) on terms to be determined at the time of sale. We will provide specific terms for any sale of the securities in one or more supplements to this prospectus. You should read this prospectus and any applicable supplement, as well as the documents incorporated or deemed to be incorporated by reference in this prospectus, carefully before you invest. This prospectus may not be used to offer and sell securities unless accompanied by a prospectus supplement for the securities.

Our common stock is listed on The Nasdaq National Market under the trading symbol INSM. Each prospectus supplement to this prospectus will contain information, where applicable, as to any listing on The Nasdaq National Market or any securities market or exchange of the securities covered by the prospectus supplement.

These securities may be sold directly by us, through dealers or agents designated from time to time, to or through underwriters or through a combination of these methods. See Plan of Distribution in this prospectus. We may also describe the plan of distribution for any particular offering of these securities in any applicable prospectus supplement. If any agents, underwriters or dealers are involved in the sale of any securities in respect of which this prospectus is being delivered, we will disclose their names and the nature of our arrangements with them in a prospectus supplement. The net proceeds that we expect to receive from any such sale will also be included in a prospectus supplement.

An investment in our securities involves a high degree of risk. You should consider carefully the Risk Factors beginning on page 4 of this prospectus. We may also include additional risk factors in an applicable prospectus supplement under the heading Risk Factors. You should review that section of the prospectus supplement for a discussion of matters that investors in our securities should consider.

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 , 2006

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You should rely on the information contained in this prospectus, any prospectus supplement or any document incorporated herein or therein to which we have referred you. We have not authorized anyone to provide you with information that is different. This prospectus and any prospectus supplement may be used only where it is legal to sell these securities. The information contained in this prospectus or any prospectus supplement is accurate only as of the date on the front of these documents, regardless of the time of delivery of this prospectus or of any sale of our securities.

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PROSPECTUS SUMMARY

This summary highlights important features of this offering and the information included or incorporated by reference in this prospectus. This summary may not contain all of the information that is important to you. You should read the entire prospectus and the applicable prospectus supplement carefully, including Risk Factors beginning on page 4 of this prospectus, before deciding to invest in our securities.

About this Prospectus

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC, using a shelf registration process. Under this shelf process, we may sell any combination of the securities described in this prospectus in one or more offerings up to a total public offering price of $75,000,000 (or its equivalent in foreign or composite currencies). This prospectus provides you with a general description of the securities we may offer.

Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the securities being offered and the terms of that offering. The prospectus supplement may also add to, update or change information contained in this prospectus. You should read both this prospectus and any prospectus supplement together with the additional information described under the heading Where You Can Find More Information carefully before making an investment decision.

Unless the context otherwise requires, in this prospectus, Insmed, we, us and our refer to Insmed Incorporated and its subsidiaries.

About Insmed

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-1 activity in the human body. We currently have one drug that has been approved for commercial sale by the United States Food and Drug Administration (FDA), IPLEX (mecasermin rinfabate (rDNA origin) injection), and two other lead drug candidates, rhIGFBP-3 and INSM-18. We are also developing these drugs to treat indications in the metabolic and oncology fields.

On December 12, 2005, the FDA approved IPLEX (mecasermin rinfabate (rDNA origin) injection) for the treatment of growth failure in children with severe primary IGF-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH. We have been granted Orphan Drug Designation by the FDA and European Medicines Agency for the Evaluation of Medicinal Products (EMEA) for IPLEX in the treatment of severe growth disturbance due to growth hormone insensitivity syndrome (GHIS) (i.e., Laron s Syndrome). As an orphan drug, IPLEXs entitled to seven years of marketing exclusivity for the treatment of Primary IGFD in the United States and should approval be granted by the EMEA, IPLEX may be granted 10 years of marketing exclusivity in the European territory. Our worldwide Phase III clinical trial for this indication will continue for an additional two years and will assess immunogenicity.

We believe the commercial opportunities for IPLEX reach beyond the indication of Primary IGFD and that initial approval of IPLEX may offer us an opportunity to enter, in the future when we have conducted full clinical studies, other potentially large markets. These markets include other growth disturbances related to IGF-1 deficiency, severe insulin resistance, diabetes, myotonic dystrophy, HIV associated adipose redistribution syndrome, severe burns, hip fracture and retinopathy of prematurity. It is our intention to initiate clinical studies in a variety of these indications with IPLEX. 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.

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Insmed has also initiated clinical study of a small molecule compound known as INSM-18, which has novel effects on the activity of the IGF-1 and other receptors that can lead to the inhibition of growth of various tumors. Insmed is currently conducting the study and 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. Our internet address is www.insmed.com. We make available on our Internet website free of charge a link to our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports as soon as practicable after we electronically file such material with the SEC. Information contained on our website is not incorporated into this prospectus and is not a part of this prospectus.

The Securities We May Offer

We may offer shares of our common stock, preferred stock and warrants to purchase common stock or preferred stock with a total value of up to $75,000,000 from time to time under this prospectus at prices and on terms to be determined by market conditions at the time of offering. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities, including, to the extent applicable:

- designation or classification;
- aggregate offering price;
- rates and times of payment of dividends or other payments, if any;
- redemption, conversion, preemption, exchange, settlement or sinking fund terms, if any;
- conversion, exchange or settlement prices or rates, if any, and, if applicable, any provisions for changes to or adjustments in the conversion, exchange or settlement prices or rates and in the securities or other property receivable upon conversion, exchange or settlement;
- ranking;
- restrictive covenants, if any;

voting or other rights, if any; and

important federal income tax considerations.

The prospectus supplement also may add, update or change information contained in this prospectus or in documents we have incorporated by reference into this prospectus.

This prospectus may not be used to offer or sell any securities unless accompanied by a prospectus supplement.

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We may sell the securities directly or through underwriters, dealers or agents. We, and our underwriters, dealers or agents, reserve the right to accept or reject all or part of any proposed purchase of securities. If we do offer securities through underwriters, dealers or agents, we will include in the applicable prospectus supplement:

- the names of those underwriters or agents;
- applicable fees, discounts and commissions to be paid to them;
- details regarding over-allotment options, if any; and
- the net proceeds to us.

Common Stock. We may issue shares of our common stock from time to time. Holders of our common stock are entitled to one vote per share for the election of directors and on all other matters that require shareholder approval. Subject to any preferential rights of any then outstanding preferred stock, in the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in the assets remaining after payment of liabilities and the liquidation preferences of any then outstanding preferred stock. Our common stock does not carry any preemptive rights enabling a holder to subscribe for, or receive shares of, any class of our common stock or any other securities convertible into shares of any class of our common stock, or any redemption rights.

Preferred Stock. We may issue shares of our preferred stock from time to time, in one or more series. Under our certificate of incorporation, our board of directors has the authority, without further action by shareholders, to designate up to 200,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges, qualifications and restrictions granted to or imposed upon the preferred stock, including dividend rights, conversion rights, voting rights, rights and terms of redemption, liquidation preference and sinking fund terms, any or all of which may be greater than the rights of the common stock. To date, of the 200,000,000 authorized shares of preferred stock, our board of directors has designated 500,000 shares as Series A Junior Participating Preferred Stock.

We will fix the rights, preferences, privileges, qualifications and restrictions of the preferred stock of each series that we sell under this prospectus and applicable prospectus supplements in the certificate of designation relating to that series. We will incorporate by reference into the registration statement of which this prospectus is a part the form of any certificate of designation that describes the terms of the series of preferred stock we are offering before the issuance of the related series of preferred stock. We urge you to read the prospectus supplements related to the series of preferred stock being offered, as well as the complete certificate of designation that contains the terms of the applicable series of preferred stock.

Warrants. We may issue warrants for the purchase of common stock and/or preferred stock in one or more series, from time to time. We may issue warrants independently or together with common stock and/or preferred stock, and the warrants may be attached to or separate from those securities.

The warrants will be evidenced by warrant certificates issued under one or more warrant agreements, which are contracts between us and an agent for the holders of the warrants. In this prospectus, we have summarized certain general features of the warrants. We urge you, however, to read the prospectus supplements related to the series of warrants being offered, as well as the complete warrant agreements and warrant certificates that contain the terms of the warrants. Forms of warrant agreements and warrant certificates relating to warrants for the purchase of

common stock and preferred stock have been filed as exhibits to the registration statement of which this prospectus is a part, and complete warrant agreements and warrant certificates containing the terms of the warrants being offered will be incorporated by reference into the registration statement of which this prospectus is a part from reports we file with the SEC.

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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 or incorporated by reference into 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.

Until recently we have been focused solely 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 September 30, 2005, our accumulated deficit was $242 million. For the nine months ended September 30, 2005 our consolidated net loss was $28 million.

We have one drug that was recently approved for commercial sale, IPLEX (mecasermin rinfabate (rDNA origin) injection)) for the treatment of growth failure in children with severe primary IGF-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH, and we are in the earlier stages of researching and developing two other lead drug candidates, rhIGFBP-3 and INSM-18. IPLEX is also in development for other metabolic and endocrine indications. rhIGFBP-3 and INSM-18 are currently in pre-clinical and clinical development for a variety of cancers including breast, lung, colon and prostate.

All of our products are currently in, or have just completed, the research and development stage. 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, or have just completed, the research and development stage. Our long-term viability and growth depend on the successful development and 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).

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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.

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 lawsuit 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.

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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 IPLEX in patients with severe Primary IGFD and plan to include the data from the trial in a Marketing Authorization Application (MAA) to the European Medicines Agency (EMEA). We must receive approval of these applications before we can market IPLEX in certain countries outside of the United States. We are also planning and conctucting clinical trials with rhIGFBP-3 and INSM-18.

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 IPLEX in broader chronic indications might increase the risk of diabetic retinopathy. This may materially adversely affect our business, financial condition and results of operations.

In previously published clinical trials of rhIGF-1, concerns were raised that long-term use of rhIGF-1 might lead to an increased incidence and/or severity of retinopathy, a disease of new blood vessel growth in the eye which results in loss of vision. Because our product contains rhIGF-1, the United States Food and Drug Administration (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 or prevent our commercialization of IPLEX for these broader chronic indications. Adverse results in these trials could prevent our commercialization of IPLEX for broad chronic indications or could jeopardize existing development and approvals in other indications.

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We cannot be certain that we will obtain additional 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 IPLEX in patients with severe Primary IGFD and plan to include the data in a MAA submission to the EMEA. We must receive approval of these applications before we can market IPLEX in certain countries outside of the United States. We also must submit results of this study, particularly regarding immunogenicity, to the FDA as agreed for the approval of IPLEX.

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 and for commercialization is essentially the same as the new drug product produced. We have had several discussions with the FDA and intend to have discussions with foreign regulatory agencies regarding our Phase III clinical study and this comparability analysis. We believe we understand what is required to satisfy the EMEA. We plan to submit this data to the appropriate regulatory authorities as part of the regulatory process. If we do not properly understand what is required to satisfy regulatory authorities or 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 IPLEX. If the EMEA does 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 the 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 the 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

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reasons cannot satisfy ongoing regulatory requirements, we may not receive FDA and/or EMEA 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 the 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 product candidates. 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 a product we are developing in a particular indication, we may be precluded or delayed from commercializing the product 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 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, even if our product is approved and receives orphan drug status, like our drug IPLEX, the FDA can still approve different drugs for use in treating the same indication or disease covered by our product, which could create a more competitive market for us.

The grant of orphan drug market exclusivity or pediatric drug market exclusivity to a competitor for a drug that we are currently developing in the same indication will adversely affect our business, financial condition and results of operations.

Manufacturing capacity necessary to supply IPLEX 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 or successfully develop our own manufacturing capabilities, 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.

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

Our ITP facility and the facilities used by our contract manufacturers, including Avecia Limited, to manufacture IPLEX must undergo inspections by the FDA and/or the EMEA for compliance with cGMP regulations, both before and after IPLEX approval. 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 additional approvals for IPLEX. In addition, ITP, our contract manufacturers, and any alternative contract manufacturer we may utilize, will be subject to ongoing periodic inspection by the FDA and the 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 our ITP manufacturing facility and then sent to an additional third party contract manufacture for sterile filtration and filling into vials. Should our ITP 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 IPLEX or validation of the manufacturing process for IPLEX. This could delay our clinical trials and the approval of our 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 IPLEX 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 IPLEX 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 IPLEX , or higher costs of production and result in our failure to effectively commercialize IPLEX.

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 IPLEX. and we would lose potential revenues.

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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.

Now that the FDA has permitted us to commence commercial sales of IPLEX, we 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 there are fewer children with severe Primary IGFD deficiency than we estimate, we may not generate sufficient revenues to continue development of other products or to continue operations, or we may not be able to complete our clinical trials.

If there are fewer children with severe Primary IGFD deficiency than we estimate, we may not generate sufficient revenues to continue development of other indications or products and may cease operations. We estimate that the number of children in the United States with Primary IGFD is approximately 6,000. Our estimate of the size of the patient population is based on our interpretation of published studies. If our interpretation and extrapolation of data from these published studies do not accurately reflect the number of children with Primary IGFD, our assessment of the market may be incorrect, making it difficult or impossible for us to meet our revenue goals.

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 approved product and product candidates, if approved for marketing, will achieve market acceptance. If our products do not receive market acceptance for any reason, it will adversely affect our business, financial condition and results of operations. The degree of market acceptance of any products we develop will depend on a number of factors, including:

- the establishment and demonstration in the medical community of the clinical efficacy and safety of our products;
- their potential advantage over existing and future treatment methods;
- their price; and
- reimbursement policies of government and third-party payers, including hospitals and insurance companies.

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

products which are more effective or less costly, or that seem more cost-effective than our products.

In addition, legislation and regulations affecting the pricing of pharmaceuticals may change in ways adverse to us 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.

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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.

Changes and reforms in the health care system or reimbursement policies may adversely affect the sale of our future products or our ability to obtain an adequate level of reimbursement or acceptable prices for our future products.

Our ability to earn sufficient returns on our products, if and when such products are approved and ready for marketing, will depend in part on the extent to which reimbursement for our products and related treatments will be available from government health administration authorities, private health coverage insurers, managed care organizations and other third-party payers. If we fail to obtain appropriate reimbursement, it could prevent us from successfully commercializing our future products.

There have been and continue to be efforts by governmental and third-party payers to contain or reduce the costs of health care through various means, including limiting coverage and the level of reimbursement. We expect that there will continue to be a number of legislative proposals to implement government controls and other reforms to limit coverage and reimbursement. The announcement of these proposals or reforms could impair our ability to raise capital. The adoption of these proposals or reforms could impair our operations and financial condition.

Additionally, third-party payers, including Medicare, are increasingly challenging the price of medical products and services and are limiting the reimbursement levels offered to consumers for these medical products and services. If purchasers or users of our future products are not able to obtain adequate reimbursement from third-party payers for the cost of using these products, they may forego or reduce their use. Significant uncertainty exists as to the reimbursement status of newly approved health care products, including gene therapy treatments, and whether adequate third-party coverage will be available.

We cannot provide any assurance that third-party payers will provide adequate reimbursement, if any, for IPLEX™.

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.

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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 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 do not believe that existing cash reserves, including amounts raised in our 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. For example, in August 2005, our Chief Financial Officer resigned to work for a medical company. We cannot assure that we will attract and retain appropriate 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;

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

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

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

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

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

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

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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-1 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 IPLEX™ or rhIGFBP-3. We can give no assurances that such patents can be avoided, invalidated or licensed. If any third party were to assert a claim for infringement, we can give no assurances that we would be successful in the litigation or that such litigation would not have a material adverse effect on our business, financial condition and results of operation. Furthermore, we may not be able to afford the expense of defending against such a claim.

Third parties, including Genentech Inc., Tercica, Novartis, Ciba-Geigy, Cephalon, Pharmacia(Pfizer), Fujisawa, Amgen, and Chiron Corporation hold United States and/or foreign patents possibly directed to the composition, production and/or use of rhIGF-1, rhIGFBP-3, IPLEX™ and/or recombinant proteins in general. After examining these patents, we do not believe they present an obstacle to our plans to commercialize IPLEX™ and rhIGFBP-3 or INSM-18. 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-1. Genentech, Inc. owns U.S. and foreign patents directed to using IGF-1 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 IPLEX™ for certain indications, and may expose us to liability for induced infringement for off-label use of IPLEX™.

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.

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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.

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 417 patent has claims directed to particular uses of a combination of IGFBP-3 and IGF-1. 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. A trial date in this litigation has not been set.

In addition, on December 23, 2004, Genentech Inc. and Tercica Inc. sued Insmed for infringement of two U.S. Patents 5,187,151 and 6,331,414. These patents are directed to certain methods of using IGF-1/IGFBP-3 and methods of producing human IGF-1, respectively. On February 16, 2005, Tercica filed an amended complaint, adding an infringement allegation against Insmed with respect to U.S. Patent No. 5,528,287. 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. We moved to dismiss the amended complaint for lack of jurisdiction and on other grounds. At a hearing on the motion on April 15, 2005, the court granted our motion and dismissed the case with leave for plaintiffs to refile the complaint. A Second Amended Complaint was filed on April 22, 2005 by Genentech Inc. and Tercica Inc. against Insmed. We moved to dismiss the portion of the Second Amended Complaint that relates to U.S. Patent No. 5,528,287. On June 29, 2005, the Court denied our motion to dismiss. On July 14, 2005, Insmed filed its Answer and Counterclaims. In the Answer and Counterclaims, we denied infringement and seeks a declaratory judgment that the asserted patents are not infringed, are invalid, and/or are unenforceable. Plaintiffs Reply to the Counterclaims was filed on August 5, 2005. On October 17, 2005, Tercica and Genentech filed a Third Amended Complaint adding Insmed Therapeutic Proteins as a Defendant. The Answer and Counterclaims in response to the Third Amended Complaint were filed by us on October 27, 2005. Discovery is ongoing and a trial date is scheduled for November 2006.

On May 27, 2005, plaintiffs filed a motion for preliminary injunction seeking an order barring Insmed, until trial, from making, using or selling the drug called SomatoKine, (now known as IPLEX™) with respect to its allegations of infringement of U.S. Patent Nos. 6,331,414 and 5,187,151, and requesting that Insmed be required to share any orphan drug exclusivity it obtains with Tercica. We filed our opposition to the motion for a Preliminary Injunction on June 10, 2005. On June 16, 2005, plaintiffs withdrew their motion for a preliminary injunction. The case is now in discovery.

Insmed cannot predict with certainty the outcome of proceedings involving Tercica, Inc. or Genetech, Inc. An adverse ruling on any of the claims alleged could seriously impact our ability to make, use or sell our products and may have a material adverse effect on our business, financial condition and results of operations.

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We are currently a defendant in a pending civil action. An unfavorable settlement or judgment in this action could harm our business and financial condition.

On December 6, 2005, with an Amendment on December 15, 2005, Tercica Inc. filed a lawsuit in U.S. District Court for the Northern District of California against Insmed alleging deceptive promotional statements and unfair business practices related to Tercica, Inc. s product, Increlex™. The complaint alleges that Insmed has publicly disseminated unlawful information in violation of the California Business and Professions Code and the Federal Lanham Act. Tercica is requesting injunctive and monetary relief.

Although Insmed denies any liability and believes that Tercica, Inc. s true motive in filing the action is to inappropriately damage Insmed, no assurances can be given as to the outcome of this action. An unfavorable settlement or decision in this action could negatively affect our operations and financial condition. Any liability resulting from this action may exceed our financial resources. Discovery has not initiated in this action and no trial date has been set.

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 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 our leading product was only recently approved for commercial sale and our other products are under development, we cannot predict the relative competitive position of our products. 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, we are aware of at least one other company, Tercica, Inc., that has received approval from the FDA for a product for this indication or a similar indication. Tercica, Inc. s product was approved for the long term treatment of growth failure in children with severe primary IGF-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH. We believe this indication would include patients with GHIS. We also believe Tercica may also be planning to develop rhIGF-1 for some of the same indications that we plan to pursue with IPLEX™.

Growth hormone may also be a competitive product for the treatment of some indications that we may pursue with IPLEX™ such as HIV associated adipose redistribution syndrome. 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-1 deficiency. We are also aware that Serono is seeking regulatory approval for their growth hormone, Serostim, for the treatment of HIV associated adipose redistribution syndrome. We are also aware that Theratechnologies is conducting Phase III trials for a growth hormone releasing agonist for the treatment of HIV associated adipose redistribution syndrome.

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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 IPLEX™.

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, inhalable insulin, GLP-1 analogues and oral hypoglycemic drugs.

Further, 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 three products, Symlin, Byetta, and a long-acting release (LAR) formulation of Byetta, for the treatment of type 2 diabetes. Symlin and Byetta were recently approved for use by the FDA. Tercica, Inc. has indicated that it plans to pursue the development of rhIGF-1 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 IGF-1 pathway as rhIGFBP-3. These companies include Imclone, Amgen, OSI Pharmaceuticals, Bristol-Meyer Squibb and Genentech.

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

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

Competitors could develop and gain FDA approval of products containing rhIGF-1, which could adversely affect our competitive position in all indications where we are currently developing IPLEX

rhIGF-1 manufactured by other parties may be approved for use in other indications in the United States in the future, including severe insulin resistance, myotonic muscular dystrophy and HIV associated adipose redistribution syndrome. In the event there are other rhIGF-1 products approved by the FDA to treat indications other than those covered by IPLEX , physicians may elect to prescribe a competitor s product containing rhIGF-1 to treat the indications for which IPLEX has received and may receive approval. This is commonly referred to as off-label use. While under FDA regulations a competitor is not allowed to promote off-label use of its product, the FDA does not regulate the practice of medicine and as a result cannot direct physicians as to what product containing rhIGF-1 to prescribe to their patients. As a result, we would have limited ability to prevent off-label use of a competitor s product containing rhIGF-1 to treat any diseases for which we have received FDA approval even if it violates our patents and/or we have orphan drug exclusivity for the use of rhIGF-1 to treat such diseases.

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It is illegal for Insmed to promote IPLEX for uses other than those approved by the regulatory authorities. Such off-label promotion, as it is known, may result in regulatory actions against Insmed even if such activities by Insmed are inadvertent.

Physicians may prescribe drugs for uses that are not described in the product s labeling and that differ from those approved by the FDA. Such off-label uses are common across medical specialties. Although the FDA does not regulate the practice of medicine, the FDA does restrict manufacturers communications with respect to off-label use. Companies cannot promote FDA-approved drugs for off-label uses; a company may engage in truthful, non-misleading, and non-promotional speech concerning its products. For example, while we may inform physicians that we are conducting a clinical trial to evaluate the safety and effectiveness of IPLEX in unapproved uses and encourage those physicians to refer eligible patients to enroll in the clinical trial, we cannot promote that the product is effective for unapproved uses. We may also educate physicians about a particular disease state and how that disease is properly diagnosed so that patients who qualify for the clinical trial might be identified, and survey physicians who are lawfully prescribing our products or competitors products for off-label uses to monitor patients experiences. We may also, pursuant to FDA policies, respond to unsolicited requests from health care professionals and engage in appropriate scientific exchange of information about unapproved uses. As we have no sales and marketing experience, we have not engaged in these lawful activities in the past. Our sales and marketing employees may not understand the regulations against off-label promotion. We do not yet have policies and procedures in place to regulate the lawful promotion of our marketed products within their labeled indications. However, employees will be trained to follow specific policies and procedures designed to instruct the lawful promotion of our products and must certify that they will abide by them. We cannot guarantee that our employees will follow these policies and procedures. The FDA actively enforces regulations prohibiting promotion of off-label uses and the promotion of products for unapproved uses. The FDA s regulations and policies are subject to varying interpretations, which are evolving. We cannot guarantee that we will change our policies as the FDA s regulations and policies change. Failure to comply with these regulations and policies in the past or with respect to future activities can result in regulatory enforcement action by the FDA and other governmental bodies, which would have an adverse effect on our revenues, business and financial prospects.

Competitors could develop and gain FDA approval of products containing rhIGF-1, which could adversely affect our competitive position.

We are aware of one other company currently marketing rhIGF-1 in the United States for a human therapeutic indication rhIGF-1 manufactured by other parties may be approved for use in the United States in the future. In the event there are other rhIGF-1 products approved by the FDA to treat indications other than those covered by Increlex, physicians may elect to prescribe a competitor s product containing rhIGF-1 to treat the indications for which Increlex has received and may receive approval. This is commonly referred to as off-label use. While under FDA regulations a competitor is not allowed to promote off-label use of its product, the FDA does not regulate the practice of medicine and as a result cannot direct physicians as to what product containing rhIGF-1 to prescribe to their patients. As a result, we would have limited ability to prevent off-label use of a competitor s product containing rhIGF-1 to treat any diseases for which we have received FDA approval even if it violates our method of use patents and/or we have orphan drug exclusivity for the use of rhIGF-1 to treat such diseases.

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.

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

As of January 31, 2006, the convertible notes issued by us on March 15, 2005 and the warrants issued by us in March 2005, November 2004 and July 2003 were convertible into and exercisable for up to approximately 11.2 million shares of our common stock, representing approximately 15% of the our then outstanding common stock.

As of January 31, 2006, our outstanding options to our employees, officers, directors and consultants were exercisable for up to 6.1 million shares of our common stock, representing approximately an additional 8% of our then outstanding common stock.

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

The market price of our stock has been and may continue to be highly volatile, and 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;

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,

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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, 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 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 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.

Our common stock may be thinly traded from time to time, which means large transactions in our common stock may be difficult to conduct in a short time frame.

On occasion we have a low volume of daily trades in our common stock on The Nasdaq National Market. Any large transactions in our common stock may be difficult to conduct and may cause significant fluctuations in the price of our common stock.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not necessarily improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates.

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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 and the documents incorporated by reference herein contain 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 sections captioned Management s Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the fiscal year ended December 31, 2004, as amended, and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2005, June 30, 2005 and September 30, 2005, which report is incorporated herein by reference, and such section of any subsequently filed Exchange Act reports.

These forward-looking statements may include, but are not limited to:

- the failure to meet expectations with respect to our future performance;
- our dependence on collaborative relationships;
- pricing pressures and other competitive factors;
- our reliance on financial markets for future capital requirements;
- demand for and market acceptance of our products and services;
- the availability and extent of utilization of manufacturing capacity and raw materials;
- the uncertainties of litigation;
- successful development of products and services and the timing of product and service introductions;
- our ability to license certain technologies or maintain our license agreements;
- failure to comply with U.S. Food and Drug Administration requirements;
- our ability to develop and implement new technologies;
- our ability to protect our intellectual property;

changes in healthcare policy;

our ability to attract and retain qualified personnel;

the impact of new accounting policies; and

other risks and uncertainties, including those set forth or incorporated in this prospectus or any prospectus supplement, and those detailed from time to time in our filings with the SEC.

In some cases, you can identify forward-looking statements by terms such as may, will, should, could, would, expects, plans, anticipa believes, estimates, forecasts, projects, predicts, potential, and similar expressions 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.

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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. Also these forward-looking statements represent our estimates and assumptions only as of the date of this prospectus.

USE OF PROCEEDS

Unless otherwise indicated in a prospectus supplement, we expect to use the net proceeds from the sale of these securities for research and development, product marketing, other general corporate purposes, which may also include acquisitions, investments, capital expenditures, repurchases of our capital stock, and for any other purposes that we may specify in any prospectus supplement. We may also invest the net proceeds temporarily in short-term securities until we use them for their stated purpose.

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DESCRIPTION OF COMMON STOCK AND PREFERRED STOCK

This summary of the our capital stock is qualified in all respects by reference to our articles of incorporation and bylaws, that are incorporated by reference into the registration statement which includes this prospectus and, with respect to preferred stock, the certificate of designation which will be filed with the SEC for each series of preferred stock we may designate, if any.

We will describe in a prospectus supplement the specific terms of any common stock or preferred stock that we may offer pursuant to this prospectus. If indicated in a prospectus supplement, the terms of such common stock or preferred stock may differ from the terms described below.

Authorized Capital Stock

Presently our authorized capital stock consists of 500,000,000 shares of common stock and 200,000,000 shares of preferred stock. The authorized shares of common stock and preferred stock are available for issuance without further action by our shareholders, unless such action is required by applicable law or the rules of any stock exchange or automated quotation system on which our securities may be listed or traded. If the approval of our shareholders is not so required, our board of directors may determine not to seek shareholder approval.

Common Stock

As of January 31, 2006, we had 76,756,342 shares of common stock outstanding. Holders of our common stock are entitled to one vote in the election of directors and on all other matters submitted to a vote of shareholders. They are only entitled to receive dividends when, as and if declared by our board of directors out of funds legally available for distribution, subject to the prior rights of any holders of preferred stock then outstanding. Holders of our common stock have no conversion or redemption rights or sinking fund provisions and no preemptive or other rights to subscribe for other Insmed securities. In the event of our liquidation, dissolution or winding up, the holders of our common stock are entitled to receive pro rata the assets of Insmed which are legally available for distribution, after payments of all debts and other liabilities and subject to the prior rights of any holders of preferred stock then outstanding. Our common stockholders do not have cumulative voting rights in the election of directors. All of the outstanding shares of our common stock are fully paid and nonassessable.

Our common stock is listed on The Nasdaq National Market under the trading symbol INSM. Wachovia Bank, N.A. is the transfer agent and registrar for our common stock. Its address is 1525 West W.T. Harris Blvd., 3C3, Charlotte, NC 28262-8522.

Preferred Stock

As of January 31, 2006, we had no shares of preferred stock outstanding. The 200,000,000 shares of preferred stock authorized by our articles of incorporation may be issued in one or more series and with rights and preferences that may be fixed or designated by our board of directors without any further action by our shareholders. To date, of the 200,000,000 authorized shares of preferred stock, our board of directors has designated 500,000 shares as Series A Junior Participating Preferred Stock. The designation, powers, preferences, rights and qualifications,

limitations and restrictions of the preferred stock of each additional series will be fixed by the certificate of designation relating to such series, which will specify the terms of the preferred stock, including:

the designation of the series, which may be by distinguishing number, letter or title;

the number of shares of the series, which number the board of directors may thereafter (except where otherwise provided in the preferred stock designation) increase or decrease (but not below the number of shares thereof then outstanding);

whether dividends, if any, shall be cumulative or noncumulative and the dividend rate of the series;

the dates on which dividends, if any, shall be payable;

the redemption rights and price or prices, if any, for shares of the series;

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the terms and amount of any sinking fund provided for the purchase or redemption of shares of the series;

the amounts payable on shares of the series in the event of any voluntary or involuntary liquidation, dissolution or winding up of the affairs of Insmed;

the preemptive rights, if any, for shares of the series;

whether the shares of the series shall be convertible into shares of any other class or series, or any other security, of Insmed or any other corporation, and, if so, the specification of such other class or series or such other security, the conversion price or prices or rate or rates, any adjustments thereof, the date or dates as of which such shares shall be convertible and all other terms and conditions upon which such conversion may be made;

restrictions on the issuance of shares of the same series or of any other class or series; and

the voting rights, if any, of the holders of shares of the series, provided that no share of preferred stock of any series will be entitled to more than one vote per share of preferred stock.

If we issue a series of preferred stock in the future that has voting rights or preferences over our common stock with respect to the payment of dividends and upon our liquidation, dissolution or winding up, the rights of the holders of our common stock offered hereby may be adversely affected.

Certain Anti-Takeover Provisions in our Certificate of Incorporation and Bylaws

The following is a summary of certain provisions of Virginia law and our articles of incorporation and bylaws. This summary does not purport to be complete and is qualified in its entirety by reference to the corporate law of Virginia and our articles of incorporation and bylaws.

Articles of Incorporation and Bylaws

Our articles of incorporation and bylaws contain various provisions intended to promote the stability of our shareholder base and render more difficult certain unsolicited or hostile attempts to take us over that could disrupt Insmed, divert the attention of our directors, officers and employees and adversely affect the independence and integrity of our business.

Pursuant to our articles of incorporation, our directors are divided into three classes, with each class serving a three-year term and consisting as nearly as possible of one-third of the directors.

Our bylaws provide that a special meeting of shareholders may be called only by the chairman of the board, a majority of the entire board of directors or the president. Shareholders are not permitted to call, or to require that the board of directors call, a special meeting of shareholders.

Our bylaws establish an advance notice procedure for shareholders to nominate candidates for election as directors or to bring other business before meetings of our shareholders.

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 percent of the outstanding votes entitled to be cast voting together as a single class. Our bylaws may be amended by the affirmative vote of a majority of the entire board of directors, unless otherwise required by the articles of incorporation or Virginia law. If shareholder voting is required for an amendment to the bylaws, 75 percent of the then outstanding stock voting together as a single voting group must vote in the affirmative to approve the amendment.

We are also subject to Virginia law regulating business combinations, defined to include a broad range of transactions, between Virginia corporations and interested shareholders, defined as persons who have acquired at least 10% of a corporation s stock without the prior approval of our board of directors. Under one statutory provision, subject to limited exceptions, a corporation may not engage in any business combination with any

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interested shareholder for a period of three years after the date such person became an interested shareholder unless a majority of our 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. Under a second statutory provision, Virginia law requires an interested shareholder 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 our outstanding voting stock. 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 our outstanding disinterested shares vote to restore the voting rights to the purchased stock. The Virginia statutes contain provisions enabling a corporation to avoid their restrictions. We have not sought to elect out of the statutes. Therefore, the restrictions imposed by these statutes will apply to us and any applicable shareholders.

Rights Plan

Our board of directors has adopted a rights plan. As a result, we issued one purchase right for each outstanding share of common stock. One purchase right will also be issued for each additional share of common stock that we issue. The rights become exercisable if, without the prior approval of our board of directors, a person or group acquires 15% or more of our outstanding common stock or commences or announces a tender or exchange offer which would result in such ownership. Each right that becomes exercisable entitles the registered holder to purchase one one-thousandth of a share of our junior participating preferred stock at a purchase price of $35 per one-thousandth of a share, subject to adjustment.

If, after the rights become exercisable, we were to be acquired through a merger or other business combination transaction or 50% or more of our assets or earning power were sold, each right would permit the holder to purchase, for the purchase price, common stock of the surviving company having a market value of twice the purchase price.

The rights expire on May 16, 2011, unless earlier redeemed or exchanged by us. The purchase price payable and the shares of preferred stock issuable upon exercise of the rights are subject to adjustment as described in the rights plan. In addition, our board of directors retains the authority to redeem, at $0.01 per right, the rights at any time prior to the acquisition by a person or group of 15% or more of our outstanding common stock.

DESCRIPTION OF WARRANTS

We may issue securities warrants for the purchase of preferred stock and/or common stock. Securities warrants may be issued independently or together with preferred stock and/or common stock and may be attached to or separate from any offered securities. Each series of securities warrants will be issued under a separate warrant agreement to be entered into between us and a warrant agent. The securities warrant agent will act solely as our agent in connection with the securities warrants and will not assume any obligation or relationship of agency or trust for or with any registered holders of securities warrants or beneficial owners of securities warrants. This summary of some provisions of the securities warrants is not complete. You should refer to the securities warrant agreement, including the forms of securities warrant certificate representing the securities warrants, relating to the specific securities warrants being offered for the complete terms of the securities warrant agreement and the securities warrants. That securities warrant agreement, together with the terms of securities warrant certificate and securities warrants, will be filed with the SEC in connection with the offering of the specific securities warrants.

The particular terms of any issue of securities warrants will be described in the prospectus supplement relating to the issue. Those terms may include:

the title of such warrants;

the aggregate number of such warrants;

the price or prices at which such warrants will be issued;

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- the currency or currencies (including composite currencies) in which the price of such warrants may be payable;
- the amount and terms of the securities purchasable upon exercise of such warrants and the procedures and conditions relating to the exercise of such warrants;
- the price at which the securities purchasable upon exercise of such warrants may be purchased;
- the date on which the right to exercise such warrants will commence and the date on which such right shall expire;
- any provisions for adjustment of the number or amount of securities receivable upon exercise of the warrants or the exercise price of the warrants;
- if applicable, the minimum or maximum amount of such warrants that may be exercised at any one time;
- if applicable, the designation and terms of the securities with which such warrants are issued and the number of such warrants issued with each such security;
- if applicable, the date on and after which such warrants and the related securities will be separately transferable;
- information with respect to book-entry procedures, if any; and
- any other terms of such warrants, including terms, procedures and limitations relating to the exchange or exercise of such warrants.

The prospectus supplement relating to any warrants to purchase equity securities may also include, if applicable, a discussion of certain U.S. federal income tax and ERISA considerations.

Securities warrants for the purchase of preferred stock and common stock will be offered and exercisable for U.S. dollars only. Securities warrants will be issued in registered form only.

Each securities warrant will entitle its holder to purchase the number of shares of preferred stock or common stock at the exercise price set forth in, or calculable as set forth in, the applicable prospectus supplement.

After the close of business on the expiration date, unexercised securities warrants will become void. We will specify the place or places where, and the manner in which, securities warrants may be exercised in the applicable prospectus supplement.

Upon receipt of payment and the warrant certificate properly completed and duly executed at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement, we will, as soon as practicable, forward the purchased securities. If less than all of the warrants represented by the warrant certificate are exercised, a new warrant certificate will be issued for the remaining warrants.

Prior to the exercise of any securities warrants to purchase preferred stock or common stock, holders of the securities warrants will not have any of the rights of holders of the preferred stock or common stock purchasable upon exercise, including the purchase of preferred stock or common stock, the right to vote or to receive any payments of dividends on the preferred stock or common stock purchasable upon exercise.

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PLAN OF DISTRIBUTION

We may offer and sell the securities covered by this prospectus in one or more of the following ways, or any other way set forth in an applicable prospectus supplement, from time to time:

- to or through underwriters or dealers;
- directly to one or more purchasers;
- through agents; or
- through a combination of any such methods above described.

The prospectus supplement will set forth the terms of the offering of the securities covered by this prospectus, including:

- the name or names of any underwriters, dealers or agents and the amounts of securities underwritten or purchased by each of them;
- any over-allotment options under which underwriters may purchase additional securities from us;
- any underwriting discounts or commissions or agency fees and other items constituting underwriters or agents compensation;
- the initial public offering price of the securities and the proceeds to us and any discounts, commissions or concessions allowed or reallowed or paid to dealers; and
- any securities exchanges or markets on which the securities may be listed.

Any initial public offering price and any discounts or concessions allowed or reallowed or paid to dealers may be changed from time to time.

If underwriters are used in an offering, we will execute an underwriting agreement with such underwriters and will specify the name of each underwriter and the terms of the transaction (including any underwriting discounts and other terms constituting compensation of the underwriters and any dealers) in a prospectus supplement. The securities may be offered to the public either through underwriting syndicates represented by managing underwriters or directly by one or more investment banking firms or others, as designated. If an underwriting syndicate is used, the managing underwriters will be specified on the cover of the prospectus supplement. If underwriters are used in the sale, the offered securities will be acquired by the underwriters for their own accounts and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. Any public offering price and any discounts or concessions allowed or reallowed or paid to dealers may be changed from time to time. Unless otherwise set forth in the prospectus supplement, the obligations of the underwriters to purchase the offered securities will be subject to conditions precedent and the underwriters

will be obligated to purchase all of the offered securities if any are purchased.

We may authorize underwriters or other persons acting as our agents to solicit offers by institutions to purchase the securities subject to the underwriting agreement from us, at the public offering price stated in the applicable prospectus supplement, under delayed delivery contracts providing for payment and delivery on a specified date in the future. If we sell securities under these delayed delivery contracts, the applicable prospectus supplement would state that this is the case and would describe the conditions to which these delayed delivery contracts will be subject and the commissions payable for that solicitation.

We may grant to the underwriters options to purchase additional securities to cover over-allotments, if any, at the public offering price, with additional underwriting commissions or discounts, as may be set forth in a related prospectus supplement. The terms of any over-allotment option will be set forth in the prospectus supplement for those securities.

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If any underwriters are involved in the offer and sale, they may engage in transactions that maintain or otherwise affect the price of the securities. These transactions may include over-allotment transactions, purchases to cover short positions created by the underwriter in connection with the offering and the imposition of penalty bids in accordance with Regulation M under the Exchange Act. If an underwriter creates a short position in the securities in connection with the offering, i.e., if it sells more securities than set forth on the cover page of the applicable prospectus supplement, the underwriter may reduce that short position by purchasing the securities in the open market. In general, purchases of a security to reduce a short position could cause the price of the security to be higher than it might be in the absence of such purchases. As noted above, underwriters may also choose to impose penalty bids on other underwriters and/or selling group members. This means that if underwriters purchase securities on the open market to reduce their short position or to stabilize the price of the securities, they may reclaim the amount of the selling concession from those underwriters and/or selling group members who sold such securities as part of the offering.

Neither we nor any underwriter make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of such securities. In addition, neither we nor any underwriter make any representation that such underwriter will engage in such transactions or that such transactions, once commenced, will be discontinued without notice.

If dealers are used in an offering, we will sell the securities to the dealers as principals. The dealers then may resell the securities to the public at varying prices which they determine at the time of resale. We may solicit offers to purchase the securities directly and we may sell the securities directly to institutional or other investors, who may be deemed to be an underwriter within the meaning of the Securities Act with respect to any resales of those securities. The terms of these sales, including the terms of any bidding or auction process, if utilized, will be described in the applicable prospectus supplement. The names of the dealers and the terms of the transaction will be specified in a prospectus supplement.

The securities may be sold directly by us through agents we designate from time to time at a fixed price or prices, which may be changed, or at varying prices determined at the time of sale. If agents are used in an offering, the names of the agents and the terms of the agency will be specified in a prospectus supplement. Unless otherwise indicated in a prospectus supplement, the agents will act on a best-efforts basis for the period of their appointment.

Dealers and agents named in a prospectus supplement may be deemed to be underwriters (within the meaning of the Securities Act) of the securities described therein. In addition, we may sell the securities directly to institutional investors or others who may be deemed to be underwriters within the meaning of the Securities Act with respect to any resales thereof.

Underwriters, dealers and agents may be entitled to indemnification by us against specific civil liabilities, including liabilities under the Securities Act, or to contribution with respect to payments which the underwriters or agents may be required to make in respect thereof, under underwriting or other agreements. The terms of any indemnification provisions will be set forth in a prospectus supplement. Certain underwriters, dealers or agents and their associates may engage in transactions with and perform services for us in the ordinary course of business.

If so indicated in a prospectus supplement, we may authorize underwriters or other persons acting as our agents to solicit offers by institutional investors to purchase securities pursuant to contracts providing for payment and delivery on a future date. We may enter contracts with commercial and savings banks, insurance companies, pension funds, investment companies, educational and charitable institutions and other institutional investors. The obligations of any institutional investor will be subject to the condition that its purchase of the offered securities will not be illegal at the time of delivery. The underwriters and other agents will not be responsible for the validity or performance of such contracts.

Each series of securities will be a new issue of securities and will have no established trading market (other than our common stock). Any common stock sold pursuant to a prospectus supplement will be eligible for quotation and trading on The Nasdaq National Market, subject to official notice of issuance. Any underwriters to whom securities are sold by us for public offering and sale may make a market in the securities, but such underwriters will not be obligated to do so and may discontinue any market making at any time without notice. The securities, other than the common stock, may or may not be listed on a national securities exchange or eligible for quotation and trading on The Nasdaq National Market.

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In order to comply with the securities laws of some states, if applicable, the securities offered hereby will be sold in those jurisdictions only through registered or licensed brokers or dealers. In addition, in some states securities may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and complied with.

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LEGAL MATTERS

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

EXPERTS

The consolidated financial statements of Insmed appearing in Insmed s Annual Report (Form 10-K) for the year ended December 31, 2004, and Insmed management s assessment of the effectiveness of internal control over financial reporting as of December 31, 2004, included therein, have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their reports thereon, included therein, and incorporated herein by reference. Such consolidated financial statements and management s assessment are incorporated herein by reference in reliance upon such reports given on the authority of such firm 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 SEC. You may read and copy any documents we file at the SEC s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-00330 for further information on the Public Reference Room. Our SEC filings are also available to the public on our web site at http://www.insmed.com or at the SEC s web site at http://www.sec.gov.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference the information we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and later information that we file with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below, and any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended (other than Current Reports on Form 8-K containing only Regulation FD or Regulation G disclosure furnished under Item 9 or 12 of Form 8-K, unless otherwise indicated therein), until all the shares registered by this prospectus are sold. The documents we incorporate by reference are:

1. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2004 (as amended on June 10, 2005);

2. Our Quarterly Reports on Form 10-Q for the three months ended March 31, 2005 (as amended June 10, 2005), June 30, 2005 and September 30, 2005;

3. Our Current Reports on Form 8-K, filed with the SEC on January 24, and January 13, 2006, and December 19, December 14, December 9, October 5, September 29, September 28, September 15, August 16, August 9, June 10, May 26, May 17, May 11, April 19, April 14, March 16, March 11, February 22 and January 3, 2005 (other than Current Reports on Form 8-K containing only Regulation FD or Regulation G disclosure furnished under Item 9 or 12 of Form 8-K, unless otherwise indicated therein).

4. The description of our common stock contained in our Registration Statement on Form 8-A, as filed with the SEC on June 1, 2000, including any amendment or report filed for the purpose of updating that description; and

5. The description of our Preferred Stock Purchase Rights contained in our Registration Statement on Form 8-A, as filed with the SEC on May 17, 2001, as amended by our Registration Statement on Form 8-A/A, as filed with the SEC on March 17, 2005, and including any amendment or report filed for the purpose of updating that description.

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We will provide to each person, including any beneficial owners, to whom a prospectus is delivered, upon written or oral request, a copy of any or all of the documents that have been incorporated by reference in this prospectus but not delivered with the prospectus. Request for such documents can be made by contacting us at that following address and telephone number:

Insmed Incorporated

Attention: Mr. Michael Duncan

4851 Lake Brook Drive

Glen Allen, Virginia 23060

Telephone: (804) 565-3000

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PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. 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 Incorporated (the Registrant). All amounts shown are estimates except the SEC registration fee.

SEC Registration Fee	$ 8,025
NASD filing fee	8,000
The Nasdaq National Market Additional Listing Fee	50,000
Transfer agent s fees and expenses	5,000
Printing Expenses	75,000
Accounting Fees and Expenses	35,000
Legal Fees and Expenses	100,000
Miscellaneous	50,000
Total	$ 331,025

Item 15. Indemnification of Directors and Officers.

The Virginia Stock Corporation Act (the VSCA) permits, and our articles of incorporation require, indemnification of our directors and officers in a variety of circumstances, which may include indemnification for liabilities under 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. Our 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, we carry insurance on behalf of directors, officers, employees or agents that may cover liabilities under the Securities Act. Our 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 us or our shareholders 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.

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Item 16. Exhibits.

Exhibit Number	Description
1.1	Form of Underwriting Agreement.*
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 SEC 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	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, filed as Exhibit 4.5 to the Registrant s Current Report on Form 8 K filed March 16, 2005 with the Securities and Exchange Commission.
4.7	Form of Common Stock Warrant Agreement (together with form of Common Stock Warrant Certificate).*
4.8	Form of Preferred Stock Warrant Agreement (together with form of Preferred Stock Warrant Certificate).*
4.9	Form of Certificate of Designation for the Preferred Stock (together with Preferred Stock Certificate).*
5.1	Opinion of Woods Rogers PLC.
23.1	Consent of Ernst & Young LLP.
23.2	Consent of Woods Rogers PLC (included in Exhibit 5.1).
24.1	Power of Attorney (included on the signature page of this Registration Statement).

* To be subsequently filed by an amendment to the Registration Statement or by a Current Report on Form 8-K.

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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), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the Registration Statement is on Form S-3 or Form F-3, and the information required to be included in a post-effective amendment by those paragraphs is contained in 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, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of 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 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.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As

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provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date;

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(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-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized in Reston, Virginia, on February 3, 2006.

INSMED INCORPORATED

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

Geoffrey Allan, Ph.D.
President and Chief Executive Officer (Principal Executive officer)

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS that each person whose signature appears below constitutes and appoints Geoffrey Allan and Michael Duncan, and each of them, with the power to act without the other, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution for him or her or in his or her name, place and stead, in any and all capacities to sign any and all amendments or post-effective amendments to this registration statement, and to file the same, with all exhibits thereto, and other documents in connection therewith, and in connection with any registration of additional securities pursuant to Rule 462(b) under the Securities Act of 1933, as amended, to sign any abbreviated registration statements and any and all amendments thereto, and to file the same, with all exhibits thereto and other documents in connection therewith, in each case, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue hereof.

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)	February 3, 2006
/s/ Michael Duncan Michael Duncan	Principal Financial and Accounting Officer	February 3, 2006
/s/ Kenneth G. Condon Kenneth G. Condon	Director	February 3, 2006
/s/ Graham K. Crooke, MB.BS	Director	February 3, 2006

Graham K. Crooke, MB.BS		
/s/ Steinar J. Engelsen, M.D.	Director	February 3, 2006
Steinar J. Engelsen, M.D.		

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Signature	Title	Date
/s/ Melvin Sharoky, M.D. Melvin Sharoky, M.D.	Director	February 3, 2006
/s/ Randall W. Whitcomb, M.D. Randall W. Whitcomb, M.D.	Director	February 3, 2006

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