INSMED INC
Form 10-K
March 12, 2008
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2007

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number 0-30739

INSMED INCORPORATED

(Exact name of registrant as specified in its charter)

Virginia	54-1972729
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer identification no.)
8720 Stony Point Parkway Richmond, Virginia 23235	
(Address of principal executive offices) (zip code)	(804) 565-3000 (Registrant s telephone number including area code)

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

Title of each class	Name of each exchange on which registered
Common Stock, par value $0.01/share	Nasdaq Capital Market

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

(Title of class)

Common Stock

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a small reporting company (See the definitions of large accelerated filer, accelerated filer, and small reporting company in Rule 12b-2 of the Exchange Act).

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨ Small Reporting Company ¨

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant on June 30, 2007 was $**98,583,736** (based on the closing price for shares of the registrant s Common Stock as reported on the Nasdaq Global Market on that date). In determining this figure, the registrant has assumed that all of its directors, officers and persons owning 10% or more of the outstanding Common

Stock are affiliates. This assumption shall not be deemed conclusive for any other purpose.

On February 28, 2008, there were **121,904,312** shares of the registrant s common stock, $.01 par value, outstanding.

Portions of the registrant s definitive Proxy Statement to be filed with the Securities and Exchange Commission no later than 120 days, or April 29, 2008, after the registrant s fiscal year ended December 31, 2007, and to be delivered to shareholders in connection with the 2008 Annual Meeting of Shareholders, are herein incorporated by reference in Part III and a small section of Part II.

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INSMED INCORPORATED

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In this Form 10-K, we use the words the Company, Insmed, Insmed Incorporated, we, us and our to refer to Insmed Incorporated, a Virgi corporation. This Form 10-K also contains trademarks of third parties. Each trademark of another company appearing in this Form 10-K is the property of its owner.

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PART I

We may from time to time make written or oral forward-looking statements , including statements contained in our filings with the Securities and Exchange Commission (including this Annual Report on Form 10-K and the Exhibits hereto and thereto), in our reports to stockholders and in other communications. Such statements give our current expectations or forecasts of future events; they do not relate strictly to historical or current facts. One can identify these forward-looking statements by use of words such as may, could, should, would, believe, anticipate, estimate, expect, intend, plan, projects, outlook or similar expressions. In particular, these include statements relating to our beliefs, plans, objectives, goals, future actions, prospective products or product approvals, future performance or results of current and anticipated products, the outcome of contingencies, such as legal proceedings and financial results. These statements are based upon the current beliefs and expectations of management and are subject to significant risks and uncertainties. Our actual results may differ materially from those set forth in the forward-looking statements. Forward-looking statements involve certain risks and uncertainties that are subject to change based on various factors (many of which are beyond our control). Factors that could cause or contribute to differences in our actual results include those discussed in Item 1A under the section entitled Risk Factors, as well as those discussed in Item 7 under the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere throughout this Annual Report on Form 10-K and in any other documents incorporated by reference. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosures we make on related subjects in our 10-Q and 8-K reports to the Securities and Exchange Commission.

ITEM 1. BUSINESS

BUSINESS OVERVIEW

We are a development stage company with expertise in recombinant protein drug development. We have a state-of-the art FDA-approved commercial biologics manufacturing facility located in Boulder, Colorado, and our corporate office is located in Richmond, Virginia.

We are pursuing a dual path strategy involving entry into the follow-on biologics follow-on biologics) arena (also known as biosimilars, biogenerics and biologics) and advancing our proprietary protein platform into niche markets with unmet needs. In the follow-on biologics field, we are developing a robust pipeline of products targeted for markets in anemia, neutropenia and autoimmune diseases. On the proprietary protein front, our product, the FDA-approved IPLEX , is in various stages of development for a number of serious medical conditions. Based on a comprehensive market analysis, our current resource allocation strategy for IPLEX is focused primarily on Myotonic Muscular Dystrophy (MMD) followed by Amyotrophic Lateral Sclerosis (ALS) in Italy, also known as Lou Gehrig s disease. Other areas where IPLEX has also shown potential such as HIV-associated Adipose Redistribution Syndrome (HARS), , and Retinopathy of Prematurity (ROP) will be considered in the future when our primary indications have been fully pursued.

PRODUCT PLATFORMS

FOLLOW-ON BIOLOGICS

Follow-on biologics, also known as biogenerics or biosimilars, are versions of drugs produced through biological processes. The biologics on which they are based differ from traditional small molecule drugs such as Aspirin® and Lipitor®, and all other medicines typically taken in pill form in several important ways. First, biologics are made up of complex molecules, such as proteins, that must be administered via direct injection because if they were administered orally, they would be broken down in the digestive tract and never reach their intended targets. Second, these drugs are produced not by merely combining chemicals but by the natural

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processes of living cells. In the manufacture of biologics, the DNA of cells is engineered such that the cells themselves produce the desired proteins. Third, the production of biologics is much more exacting than that of small-molecule drugs. Growing one type of genetically-engineered cell while excluding all other organisms from the mix is inherently more difficult than simply achieving sterile conditions (no living organisms at all) under which traditional drugs are manufactured.

The process of testing, developing, and manufacturing medicines often takes several years. We believe our FDA- approved facility, coupled with our protein development expertise represents a significant asset and offers a combination of specialized manufacturing skills and drug approval capability which is currently scarce elsewhere in the industry. To design, build and gain FDA approval for a similar facility would require a sizeable capital investment and take several years to complete. As we have the asset available now along with the skill set in house to develop and manufacture a portfolio of follow-on biologics and take them through the FDA approval process we believe we are uniquely positioned to take advantage of this emerging market with the goal of being ready to enter the market when the innovator product comes off patent. Our strategy is to manufacture high quality medicines and bring them to market following the patent expiration of the innovator product, thus providing savings for patients and payors, and expanding access to critically needed medicines.

Biologics comprise one of the fastest growing and most expensive categories of drugs. By 2009, sales are estimated to reach $90 billion and according to published reports, an estimated $10 billion worth of biologic drugs are expected to come off patent by 2010.*

In the follow-on biologics field, we are developing a robust pipeline of products targeted as treatments for anemia, neutropenia and autoimmune diseases. In November 2007 we announced completion of development of two key follow on biologics at our facilities in Boulder, Colorado, INS-19 (Granulocyte Colony Stimulating Factor or G-CSF) and INS-20 (Peg G-CSF). By achieving these critical development milestones, Insmed is positioned to initiate clinical studies for INS-19 and INS-20 in 2008

**Engel & Novitt, LLP, Potential Savings That Might Be Realized by the Medicare Program From Enactment of Legislation Such as The Access to Life-Savings Medicine Act (H.R. 6257/S. 4016) That Establishes A New cBLA Pathway For follow-on biologics. Table 4a., January2, 2007.*

INS-19 Granulocyte Colony Stimulating Factor

Colony-stimulating factors are glycoproteins that act on bone marrow and certain cells in the blood to stimulate the development and growth of white blood cells. Granulocyte-Colony Stimulating Factor (G-CSF) is one of these glycoproteins that binds to specific cell surface receptors and stimulates the production of disease fighting cells called neutrophils. Recombinant human G-CSF (Recombinant G-CSF) is a synthetic version of G-CSF which is produced in bacteria. Recombinant human G-CSF mimics the biological effects of naturally occurring G-CSF and is used to treat certain medical conditions were a person s neutrophils are too low (neutropenia), such as in cancer patients who are receiving certain chemotherapeutic regimens, patients receiving bone marrow transplants, or in patients who have chronically low neutrophils for other reasons.

We have developed a high yield manufacturing process. Extensive physicochemical characterization demonstrates that the molecule is highly similar to the innovator product, Neupogen®. With direct comparison of INS-19 to Neupogen®, bioassay data demonstrates comparable bioactivity, and pharmacodynamic preclinical studies demonstrate comparable effects on neutrophil count at equivalent doses. We have initiated preclinical toxicology studies with INS-19 and are planning to initiate clinical studies in 2008.

INS-20 Pegylated Granulocyte Colony Stimulating Factor

Pegylated G-CSF is a chemically modified version of G-CSF in which a water soluble polymer called polyethylene glycol is attached to the protein. The pegylated protein has a prolonged biological activity after it is injected into the patient. This allows less frequent dosing for the patient as compared to G-CSF.

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With INS-20 (Peg G-CSF) we have achieved a similar level of purity when compared with the innovator product, Neulasta®. Preclinical pharmacodynamic and toxicology studies are currently underway with INS-20 and clinical studies are planned later in 2008.

Other potential FOB candidates are also targeted which are in the preliminary stages of development. These include Interferon beta-1b, Interferon beta-1a and Erythropoietin.

PROPRIETARY PROTEIN PLATFORM

IPLEX

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

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

Following an external review of the markets for the various indications which could be served by IPLEX we have prioritized our targets and have selected MMD as our initial primary indication for IPLEX . We are also evaluating IPLEX as a treatment for ALS in Italy as part of our EAP. Other areas where IPLEX has also shown potential such as HIV-associated Adipose Redistribution Syndrome (HARS), , and Retinopathy of Prematurity (ROP) will be considered in the future when our primary indications have been fully pursued.

Development of IPLEX in Myotonic Muscular Dystrophy

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

Based on information published by the Muscular Dystrophy Association (the MDA), we believe that there are approximately 40,000 patients that suffer from MMD in the United States. At present, there is no approved treatment for this disease.

Ongoing Clinical Study

A Phase III enabling clinical trial investigating IPLEX as a treatment for MMD has been initiated, with the help of a $2.1 million grant from the MDA. This expanded Phase II program is a 24 week, 60 patient, placebo controlled trial using a dose of 1.0 mg/kg/day of IPLEX. This study is ongoing and is evaluating the effects of IPLEX on endurance, cognitive function, GI function, muscle function, lean body mass and insulin sensitivity. A final report is expected in 2009.

Expanded Access Program for Patients in Italy with ALS

ALS is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord. Motor neurons reach from the brain to the spinal cord and from the spinal cord to the muscles throughout the body. The progressive degeneration of the motor neurons in ALS eventually leads to their death. When the motor neurons die, the ability of the brain to initiate and control muscle movement is lost. With voluntary muscle action

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progressively affected, patients in the later stages of the disease may become totally paralyzed. Yet, through it all, for the vast majority of people, their minds remain unaffected.

At the request of the Italian Ministry of Health, we established an Expanded Access Program in Italy to provide IPLEX to physicians for use in their patients with ALS. The request came as a result of several Italian Court rulings ordering the Italian National Health System to provide IPLEX to specific ALS patients who have petitioned the Court. Through an agreement with Cephalon, which holds patent rights in the European Union to IGF-1 as it relates to the treatment of ALS, we are able to provide IPLEX to physicians in Italy and receive payment for the drug, on a cost recovery basis, from the Italian Health Authorities. We plan to evaluate the patient outcomes to determine if a clinical trial is warranted. There are an estimated 1,000 new cases of ALS per year in Italy.

IPLEX and Short-Stature Market

In the past, we were focused on development and commercialization of IPLEX for the treatment of growth failure in children with severe primary IGF-1 deficiency. IPLEX was approved by the FDA for treatment of severe primary IGF-1 deficiency in December 2005 and was commercially launched in the second quarter of 2006. As a result of our recent settlement agreement with Tercica, Inc. and Genentech, Inc., discussed below, we have withdrawn IPLEX from this market.

In December 2004, Tercica and Genentech filed patent infringement suits against us in the U.S. District Court for the Northern District of California and in the United Kingdom at the High Court of Justice, Chancery Division, Patents Court. In these cases, Tercica and Genentech alleged that production and use of IPLEX infringed claims in certain U.S. and European patents, owned by Genentech and licensed to Tercica, directed to methods of using rhIGF-1/rhIGFBP-3 and methods of producing rhIGF-1 and IGFBP-3. In June 2006, Tercica also filed an unfair competition suit against us in the U.S. District Court of the Eastern District of Virginia, claiming that we disseminated misleading statements to the market in connection with our marketing of IPLEX.

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

On March 5, 2007, we reached a settlement agreement ending all litigation with Tercica and Genentech. Pursuant to the agreement, we agreed to cease sales and marketing of IPLEX in the United States and agreed to withdraw our European Marketing Authorization Application for IPLEX. We will continue to provide IPLEX to named patients with ALS in Italy under our Expanded Access Program. The agreement also gives us the right, through a worldwide development partnership with Tercica and Genentech, to market IPLEX for conditions not related to short-stature. These indications include severe insulin resistance, MMD and HARS, among others. The development partnership includes provisions that give us a 50% share of profits and reimbursement for 50% of development costs if either Tercica or Genentech exercises opt-in rights for marketing of IPLEX in any of these new indications that we develop. In addition, as part of the settlement agreement, Tercica and Genentech waived the damages awarded by the jury in the patent infringement suit from the U.S. District Court for the Northern District of California.

Oncology Programs INSM-18 and rhIGFBP-3

INSM-18 and rhIGFBP-3 are in early clinical development and are primarily being investigated for the treatment of cancer. We believe both INSM-18 and rhIGFBP-3 are promising potential novel treatments for a variety of cancer types. Preclinical models demonstrate that both treatments interact with the IGF system to reduce tumor growth.

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INSM-18

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

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

Completed Clinical Study

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

rhIGFBP-3

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

RESEARCH AND DEVELOPMENT

Since we began operations in late 1999, we have devoted substantially all of our resources to the research and development of a number of product candidates for metabolic and endocrine diseases. Our research and development efforts are now principally focused on pursuing a dual path strategy involving entry into the follow-on biologics arena (also known as biosimilars, biogenerics and biologics) and advancing our proprietary protein platform into niche markets with unmet needs. In the follow-on biologics field, we are developing a robust pipeline of products targeted for markets in anemia, neutropenia and autoimmune diseases. In addition, on the proprietary protein front our lead product, the FDA-approved IPLEX, is being studied as a treatment for several serious medical conditions with our primary focus being on MMD and ALS in Italy. We conduct very little of our own preclinical laboratory research. We have outsourced several Phase II clinical studies with IPLEX and our other anti-cancer product candidates, INSM-18 and rhIGFBP-3, and plan on conducting additional clinical studies in the future.

Research and development expenses primarily include expenses incurred in preparing and obtaining necessary approvals from regulatory bodies, certain expenses involving the development of manufacturing

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processes and clinical studies. Our research and development expenses were approximately $21.1 million as of the fiscal year ended December 31, 2006 (fiscal 2006) and $18.9 million for the year ended December 31, 2007 (fiscal 2007).

MANUFACTURING

We currently manufacture our own supply of IPLEX and rhIGFBP-3 at our Boulder, Colorado, FDA-approved manufacturing facility. We are also developing a line of follow-on biologics targeted for markets in anemia, neutropenia and autoimmune diseases when the innovator products come off patent. The manufacturing process requires compliance with current good manufacturing practices, or cGMP, and other similar regulations. IPLEX, a complex of two proteins, rhIGF-1 and its binding protein rhIGFBP-3, and our FOB candidates, are manufactured using recombinant DNA technology. This manufacturing process is complicated and involves expression of the proteins by bacterial fermentation followed by purification and combination. We currently outsource to third-party contract manufacturers some of the analytical testing and the final fill, finish and labeling of IPLEX and our follow-on biologics product candidates.

As part of ongoing regulatory compliance, it is likely that the FDA will inspect our manufacturing facilities and our contract manufacturers facilities from time to time to ensure compliance with cGMP. If these facilities are not in compliance with cGMP, the FDA will likely require us to halt manufacturing until we bring the facilities into compliance. This could take a substantial period of time and could adversely affect the development and timing of our clinical studies FOB candidates and our Expanded Access Program. If for any other reason we are unable to manufacture sufficient quantities of our product candidates and their components to meet our planned time and cost parameters, the development of our FOB candidates and the timing of our clinical studies for additional indications may be adversely affected.

We may expend significant resources for the expansion and modification of our manufacturing facility over the next three years in an effort to increase our production capacity and the efficiency of our operations. During 2007 we notified our landlord of our intention to renew our lease through February 2013. At the present time we believe this facility meets our needs through 2009 for our MMD clinical study and Expanded Access Program needs for IPLEX and the production of our selected FOB candidates.

PATENTS AND PROPRIETARY RIGHTS

Patent Portfolio

Proprietary protection is important to our business, and our policy is to protect our technology by filing patent applications for technology that we consider important. We directly hold several U.S. patents relating to the composition, production, antibodies and methods of use for IPLEX and rhIGFBP-3. In addition, foreign counterparts to the above-referenced U.S. patents have issued or are pending issue in the major pharmaceutical markets, such as the European Union, Canada and Japan. The various issued patents relate to IPLEX and rhIGFBP-3 compositions, methods of production and methods of treatment, and expire at various times during the years 2010 through 2019.

As part of the ongoing development of IPLEX, INSM-18 and rhIGFBP-3 we have filed or intend to file patent applications related to new production methods, improved formulations, new medical uses and new dosing regimens in the United States and in many of the major international pharmaceutical markets. As with any pending patent application, there can be no assurance that any of these applications will issue in the United States, European Union. Canada, Japan or in any other country where we decide to file for protection. There also can be no assurance that a subsequent U.S. or foreign patent will later be held valid and enforceable.

As part of our business strategy, we plan to license intellectual property that we feel may be important to the development and commercialization of our products. The agreements that we have entered into are subject to termination upon material breach by us. Our ability to maintain licensure under these agreements is dependent on

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our ability to meet the obligations defined in these agreements and although we take steps to ensure compliance with the provisions of these agreements, we cannot assure that the licensors will not take dispute with our actions and will seek to terminate the agreements. We currently have the following licensing arrangements in place:

In March 2007, we were granted a license or sublicense as applicable to patents held by Tercica and Genentech to develop IPLEX in certain medical indications in the United States and foreign territories, as discussed earlier in this section;

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

In January 2004, we were granted a non-exclusive license to patent rights pertaining to the use of IGF-1 therapy for the treatment of extreme or severe insulin resistant diabetes from Fujisawa Pharmaceutical Co., Ltd.; and

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

Reflecting our commitment to safeguarding proprietary information, we require our employees and consultants to sign confidentiality agreements. Furthermore, we enter into research agreements in which we exchange proprietary materials and information with collaborators including material transfer agreements, research agreements, development agreements and clinical trial agreements. These agreements prohibit unauthorized disclosure of our proprietary information. Despite our efforts to protect our proprietary information, unauthorized parties may attempt to obtain and use our proprietary information. Policing unauthorized use of our proprietary information is difficult and the steps we have taken might not prevent misappropriation, particularly in foreign countries where the laws may not protect our proprietary rights as fully as do the laws of the United States.

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

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

Third Party Patents

Third parties hold U.S. and foreign patents possibly directed to the composition, production and use of rhIGF-1, rhIGFBP-3, IPLEX and recombinant proteins generally. We are not aware of any patents that would prevent us from pursuing our plans to commercialize IPLEX and rhIGFBP-3. We can provide no assurance, however, that a third party will not assert a contrary position in the future, for instance in the context of an infringement action. Likewise, we cannot predict with certainty the outcome of such a proceeding. In the event of a successful claim against us for infringement or misappropriation of a third party s proprietary rights, we may be required to:

pay damages, including up to treble damages and the other party s attorneys fees, which may be substantial;

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

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expend significant resources to redesign our product so that it does not infringe the proprietary rights of others;

develop or acquire non-infringing proprietary rights, which may not be possible and would require additional clinical trials and regulatory approvals;

redesign our product to avoid infringing on third party proprietary rights, which may result in significant regulatory delays associated with conducting additional clinical trials or other steps to obtain regulatory approval; and

obtain one or more licenses from third parties for the infringed proprietary rights, which may not be available to us on acceptable terms or at all.

Furthermore, litigation with any third party, even if the allegations are without merit, would likely be expensive and time-consuming and divert management s attention.

Any conclusions regarding non-infringement and invalidity are based in part on a review of publicly available databases and other information. There may be information not available to us or otherwise not reviewed by us that might change our conclusions. Moreover, the scope and validity of patent claims are determined based on many facts and circumstances, and in a litigation, a court may reach a different conclusion on any given patent claim than the conclusions that we have reached.

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

COMPETITION

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

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

In the follow-on biologics field we are developing several candidates which we plan to have ready for the marketplace when the innovator products patents expire. We believe Sandoz, Teva, and Barr have follow-on biologics capabilities. Mylan, Watson, Par, and Apotex have not disclosed follow-on biologics strategies. Companies with injectable generic/branded strategies, Hospira and Abraxis, have been acquiring Follow-on biologics assets through licensing. Four companies developing follow-on biologics in emerging markets (Shantha, Wockhardt, Dr Reddy s in India, and Dragon in China) have focused primarily on their home markets. They have not announced deals to license their products to developed markets. Two companies developing follow-on biologics in emerging markets (Biocon and Intas, both in India) have announced licensing agreements with companies in developed markets.

In the proprietary protein area, we are aware of several pharmaceutical companies that are developing drugs in various forms of muscular dystrophy including PTC Therapeutics, Asklepios Biopharmaceutical Inc., Wyeth and Schering-Plough/Key Pharmaceutical, AVI Biopharma, Cephalon and Transgene, however, we believe that

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IPLEX is the only drug that is in development for the treatment of MMD. We are also aware that rhIGF-1 has been shown in a small clinical study to have positive effects in patients with MMD and that Nifendipine, Coenzyme Q10, DHEA-S and low dose Metformin have all been investigated for the treatment of MMD, however we are unaware of any formal development programs to pursue this indication for these drugs.

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

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

GOVERNMENT REGULATION

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

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

PROPRIETARY PROTEIN PLATFORM

FDA Approval Process

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

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

Clinical studies to support NDA approval are typically conducted in three sequential phases, but the phases may overlap. In Phase I clinical studies, the product is tested in a small number of patients or healthy volunteers, primarily for safety at one or more doses and to assess pharmacokinetics. In Phase II clinical studies, in addition

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to safety, the sponsor evaluates the efficacy of the product on targeted indications, identifies possible adverse effects and safety risks in a patient population, and assesses dose tolerance and optimal dose range. If a compound is found to be potentially effective and to have an acceptable safety profile in Phase II studies, Phase III studies, also referred to as pivotal studies, are undertaken. Phase III clinical studies typically involve testing for safety and clinical efficacy in an expanded patient population at geographically-dispersed study sites.

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

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

If the FDA s evaluations of the NDA and the clinical and manufacturing procedures and facilities are favorable, the FDA may issue either an approval letter or an approvable letter, which contains the conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA s satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug for certain approved indications. In addition, an approval letter may contain various post-marketing commitments or agreements, which are often referred to as Phase IV studies. If the FDA s evaluation of the NDA submission and the clinical and manufacturing procedures and facilities is not favorable, the FDA may refuse to approve the NDA and issue a not approvable letter.

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

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

The Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Act, amended the Federal Food, Drug, and Cosmetic Act (the FDCA). Under the Hatch-Waxman Act, newly-approved drugs and indications may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, meaning that the FDA has not previously approved any other new drug containing the same active moiety. However, in the case of a combination drug containing a new chemical entity and a non-new chemical entity,

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five year exclusivity does not attach to the new chemical entity. The Hatch-Waxman Act prohibits the submission of an Abbreviated NDA, or ANDA, for a generic drug, or a Section 505(b)(2) NDA for another version of such drug during the five year exclusive period. However, the submission of an ANDA or Section 505(b)(2) NDA containing a paragraph IV certification claiming that a patent listed in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, or Orange Book, for the drug is invalid or will not be infringed by the manufacture, use or sale of the new product is permitted after four years. The submission of a paragraph IV certification may trigger a 30-month stay of approval of the ANDA or Section 505(b)(2) NDA. Protection under Hatch-Waxman will not prevent the submission or approval of another full NDA; however, the applicant would be required to conduct its own preclinical and adequate and well-controlled clinical studies to demonstrate safety and effectiveness. The Hatch-Waxman Act also provides three years of marketing exclusivity for the approval of new and supplemental NDAs, for, among other things, new indications, dosage forms, or strengths of an existing drug, if new clinical investigations that were conducted or sponsored by the applicant are essential to the approval of the application.

IPLEX is currently protected by a three year exclusivity period for the treatment of severe primary IGF-1 deficiency, which expires on December 12, 2008. This exclusivity runs concurrently with a seven year period of orphan drug exclusivity, which prevents the FDA from approving another marketing application for the same drug for the same indication, except in the limited circumstances described below. In addition, the FDA s Orange Book publication lists two patents covering IPLEX to which a generic applicant must certify.

Orphan Drug Designation and Exclusivity

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

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

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

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more effective or otherwise clinically superior. This period may be reduced to six years if the conditions that originally justified orphan drug designation change or the sponsor makes excessive profits. We have obtained orphan medicine designation in the European Union for IPLEX for the treatment of extreme insulin resistance.

Other Regulatory Requirements

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

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

FOLLOW-ON BIOLOGICS

For historical reasons, some biologic pharmaceuticals, such as human insulin and human growth hormones, are approved under FDCA, while most other biologic pharmaceuticals are approved under the Public Health Services Act (the PHS) through the submission of biologic license applications (BLAs). The Hatch-Waxman Act, amended the FDCA and established an abbreviated approval pathway for generic versions of referenced drug products approved under FDCA. Although the FDA has recognized an abbreviated approval pathway for generic versions of biologic pharmaceuticals approved under the FDCA, the FDA has not yet recognized an abbreviated regulatory pathway that would enable the timely and cost-efficient approval of follow-on biologics. We and other companies are working with Congress and the FDA to overcome this barrier. We are committed to working toward a streamlined regulatory approval process that will ensure that we can bring follow-on biologics to market that have been approved under the PHS since 1997.

During fiscal 2006, there were several significant developments in the follow-on biologics area. While Congress and the FDA continue to review options for a regulatory pathway for follow-on biologics in the United States, the European Medicines Agency has already moved forward, publishing guidelines in November 2005 to streamline the process for approving follow-on biologics in the European Union. Following publication of these guidelines, the European Commission granted marketing authorization in the European Union for two follow-on biologics, Sandoz s Omnitrope® in April 2006 and Biopartner s Valtropin® in May 2006, both of which are recombinant human growth hormone products.

EMPLOYEES

At December 31, 2007, we had 94 employees, including 17 in research and development, 31 in regulatory, clinical and quality assurance, 29 in manufacturing, and 17 in finance and administration.

Our continued success will depend in large measure on our ability to attract and retain highly skilled employees who are in great demand. None of our employees are represented by a labor union and we believe that our relations with our employees are generally good.

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Available Information

We file electronically with the U.S. Securities and Exchange Commission, or SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. We make available on our website at http://www.insmed.com, free of charge, copies of these reports as soon as reasonably practicable after filing these reports with, or furnishing them to, the SEC.

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ITEM 1A. RISK FACTORS

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

In Item 1A (Risk Factors) of our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2007, which was filed with the Securities and Exchange Commission on November 8, 2007, we describe risk factors related to the Company. Our updated risk factors are included below in this Item 1A.

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

We 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 implement our revised business plan with a renewed focus on research and development activities. As of December 31, 2007, we had $16.5 million of cash and investments on hand, which we believe is sufficient to fund our activities into the fourth quarter of 2008. However, our future capital requirements will depend on many factors, including factors associated with:

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

We may also need to spend more money than currently expected because we may further change our alter drug development plans, acquire additional drugs or drug candidates or we may misjudge our costs. We have no committed sources of capital and do not know whether additional financing will be available when needed, or, if available, that the terms will be favorable. There can be no assurance that our cash reserves together with any subsequent funding will satisfy our capital requirements. The failure to satisfy our capital requirements will adversely affect

our business, financial condition and results of operations. Our independent registered public accounting firm has expressed their view that there are material uncertainties which cast significant doubt upon our ability to continue as a going concern. The addition of this going concern disclosure may discourage investors from purchasing our stock.

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

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

We are entering into a new market area, the contours of which are unclear, the result of which could have a material adverse affect on our business.

Our future success depends to a significant extent upon our ability to develop and market and license emerging and new products, including follow-on biologics. The market for follow-on biologics is very uncertain at this time, as it is based on technologies that have not been formally reviewed or accepted by the FDA or other regulatory authorities. It is possible that the FDA s review and acceptance of our new products may take time and resources, require independent third-party analysis or not be accepted by the FDA or other regulatory authorities. Moreover, consumer demand for new product categories such as follow-on biologics is inherently uncertain. There can be no assurance that we will successfully develop and market follow-on biologics, or that we will ever achieve significant revenues or operating income from follow-on biologics, or if significant revenues are achieved, that they can be sustained. The failure of our follow-on biologics to be accepted by consumers and achieve revenues could have a material adverse effect on our business prospects, financial condition and results of operations.

If the FDA does not establish specific guidelines or arrive at a consensus regarding the scientific analyses required for characterizing follow-on biologics, and if the U.S. Congress does not take action to create an abbreviated regulatory pathway for follow-on biologics, our business would be adversely affected.

The regulatory climate for follow-on biologics remains unclear. Although there has been some legislative activity in the past, there is currently no established statutory or regulatory pathway for approval of follow-on biologics. The FDA has approved the majority of protein products under the Public Health Service Act, or PHS, through the use of biologic license applications, of BLAs. Unlike drugs approved through the submission of NDAs under section 505 of the Food, Drug and Cosmetic Act, or the FDCA, there is no provision in the PHS for an abbreviated BLA approval pathway, and the FDA has stated that it does not believe it has the authority to rely on prior BLA approvals or their underlying data to approve a follow-on biologic. Moreover, even for proteins initially approved as NDAs there is uncertainty as to what data the FDA may deem necessary to demonstrate the sameness required for approval of an ANDA under section 505(j) of the FDCA. In addition, there has been opposition to the FDA s use of section 505(b)(2), which allows an applicant to rely on information from published scientific literature and/or a prior approval of a similar drug, to approve a follow-on biologic approved under section 505 of the FDCA.

Although the FDA has previously stated its intention to draft guidance that is broadly applicable to follow-on biologics, the agency has not yet issued such guidance to date and may never do so. Protracted timelines and failure of the FDA to establish standards for approval of follow-on biologics or of the U.S. Congress to enact legislation establishing an abbreviated pathway for approval for follow-on biologics could materially adversely affect our business, results of operations and financial position.

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

At present the Italian Health Authority approves all drug payments for IPLEX used by Italian patients with ALS in Italy as part of our Expanded Access Program. Should the Italian Health Authority decide to stop approving IPLEX for ALS it would significantly affect our cash position and could require us to raise funds sooner than anticipated, which may only be available to us on less than favorable terms.

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

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

- identify potential drug product candidates;
- design and conduct appropriate laboratory, preclinical and other research;
- submit for and receive regulatory approval to perform clinical studies;
- design and conduct appropriate preclinical and clinical studies according to good laboratory and good clinical practices;
- select and recruit clinical investigators;
- select and recruit subjects for our studies;
- collect, analyze and correctly interpret the data from our studies;
- submit for and receive regulatory approvals for marketing; and
- manufacture the drug product candidates according to cGMP.

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

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

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

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

the regulatory approvals of our products are delayed or we are required to conduct further research and development of our products prior to receiving regulatory approval;

we are unable to build a sales and marketing group to successfully launch and sell our products;

we are unable to raise the additional funds needed to successfully develop and commercialize our products or acquire additional products for growth;

we are required to allocate available funds to litigation matters;

we are unable to manufacture the quantity of product needed in accordance with current good manufacturing practices to meet market demand, or at all;

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

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- competition from other products or technologies prevents or reduces market acceptance of our products;
- we do not have and cannot obtain the intellectual property rights needed to manufacture or market our products without infringing on another company s patents;
- we are unsuccessful in defending against patent infringement claims being brought against us our products or technologies; or
- we are unable to obtain reimbursement for our product or such reimbursement may be less than is necessary to produce a reasonable profit.

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

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

We are a development stage company with expertise in protein recombinant drug development. We have incurred losses each year of operation and we expect to continue incurring operating losses for the foreseeable future. The process of developing and commercializing our products requires significant pre-clinical testing and clinical trials as well as regulatory approvals for comme