TERCICA INC
Form 8-K
February 17, 2005

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the

Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 16, 2005

TERCICA, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

000-50461	**26-0042539**
(Commission File Number)	**(IRS Employer Identification No.)**

651 Gateway Boulevard, Suite 950

South San Francisco, CA 94080-7111

(Address of principal executive offices, including Zip Code)

Registrant s telephone number, including area code: (650) 624-4900

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

ITEM 8.01. Other Events.

Tercica, Inc. (Tercica) hereby updates its description of certain risks and uncertainties that may have a material adverse effect on its business, financial condition or results of operations from those described in the Risk Factors section of Tercica s Quarterly Report on Form 10-Q for the quarter ended September 30, 2004, filed with the SEC on November 12, 2004, as follows:

RISK FACTORS

Investors should carefully consider the risks described below as well as the other information in our filings under the Securities and Exchange Act of 1934, as amended, before making an investment decision. The risks described below update those risks described in the Risk Factors section of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2004, filed with the SEC on November 12, 2004. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and investors may lose all or part of their investment.

Risks Related to Our Business

We are a development stage company with a limited operating history and may not be able to commercialize any products, generate revenue or attain profitability.

We are a development stage company focused on the development and commercialization of Increlex for the treatment of short stature and other endocrine disorders. From our inception in October 2000 through December 31, 2004, we have accumulated a deficit of $119.5 million. We have not generated and may not be able to generate any revenue from operations and may not be able to attain profitability. We incurred a net loss of $41.0 million during the year ended December 31, 2004. We expect to incur substantial net losses, in the aggregate and on a per share basis, for the foreseeable future as we attempt to develop and commercialize Increlex for Severe Primary IGFD and Primary IGFD. We are unable to predict the extent of these future net losses, or when we may attain profitability, if at all. These net losses, among other things, have had and will continue to have an adverse effect on our stockholders equity and net current assets.

We anticipate that for the foreseeable future our ability to generate revenues and achieve profitability will be solely dependent on the successful commercialization of Increlex for the treatment of Severe Primary IGFD and Primary IGFD. There is no assurance we will be able to obtain governmental regulatory approval to market Increlex in the United States or Western Europe for these indications or any other indication. If we are unable to generate significant revenue from Increlex or attain profitability, we will not be able to sustain our operations.

If we do not receive a regulatory marketing approval of Increlex for Severe Primary IGFD, our business will be harmed.

We need FDA approval to market Increlex for therapeutic uses in the United States. We are currently developing Increlex for the treatment of Severe Primary IGFD and Primary IGFD. We expect to submit an NDA in the United States for marketing Increlex for the treatment of Severe Primary IGFD in March 2005. Delays may occur with our planned submission due to unexpected issues.

The FDA has substantial discretion in the approval process and may:

refuse to accept our NDA for filing;

decide after review of our NDA that our data is insufficient to allow approval of Increlex for Severe Primary IGFD; and/or

limit our approval and/or restrict our marketing labeling to a small subset of patients with Severe Primary IGFD.

We cannot predict the size of the subset of patients with Severe Primary IGFD to which the FDA may limit any marketing approval and labeling for Increlex. If we fail to obtain the FDA s approval for the marketing of Increlex for this indication, we will not be able to commercialize Increlex in the near term, and our business will be harmed.

In the protocol for the Phase III clinical trial that we are using to support our NDA filing for Severe Primary IGFD, the disease being treated was identified as growth hormone insensitivity syndrome, or GHIS. Everywhere in this document where we discuss existing Phase III clinical trial results for rhIGF-1, such results were from children identified at the time as having GHIS. However, there are varying academic and clinical terminologies that describe children with GHIS and IGF-1 deficiency. We believe that the disease described by the term Severe Primary IGFD is substantially equivalent to the disease described by the term GHIS, relates to approximately the same number of pediatric patients and accurately describes the pediatric patient population for which we will be filing our NDA and seeking regulatory marketing approval.

If the FDA disagrees with us and determines that Severe Primary IGFD is not substantially equivalent to GHIS and/or that the number of children with GHIS are less than those with Severe Primary IGFD, the FDA may:

- determine that our data do not support an NDA filing for Severe Primary IGFD;
- may not accept or approve our NDA for the treatment of Severe Primary IGFD; and/or
- may limit our approval and/or restrict our marketing labeling to a small subset of patients with Severe Primary IGFD.

Even if the FDA agrees with us that Severe Primary IGFD is substantially equivalent to GHIS, the FDA may:

- still determine that our data do not support an NDA filing for Severe Primary IGFD or GHIS;
- not accept or approve our NDA for the treatment of Severe Primary IGFD or GHIS; and/or
- limit our approval and/or restrict our marketing labeling to a small subset of patients with Severe Primary IGFD.

Since our NDA filing and marketing approval for Severe Primary IGFD are key to our business plan and development of Increlex, any of the FDA s determinations, requirements or labeling restrictions discussed above would substantially harm our business.

The means by which the FDA could restrict our marketing labeling could include, for example, requiring us to include in our Increlex labeling additional specific diagnostic tests to establish the diagnosis of Severe Primary IGFD and/or requiring that children must fail to respond to treatment with growth hormone prior to being treated with Increlex. Such requirements would add additional cost and complexity in making the diagnosis of Severe Primary IGFD and substantially limit the number of patients for whom Increlex is prescribed, which would substantially harm our business.

The regulatory review and marketing approval process in the United States, which includes evaluation of preclinical studies and clinical trials of our rhIGF-1 for Severe Primary IGFD, as well as the evaluation of our manufacturing process and our contract manufacturers facilities, is

lengthy, expensive and uncertain. Securing FDA approval for Increlex for Severe Primary IGFD will require the submission of extensive preclinical and clinical data and supporting information to the FDA to establish Increlex s safety and effectiveness for this indication, as well as for any additional indications for which we seek marketing approval. We have limited experience in filing and pursuing applications necessary to gain FDA approvals.

We have completed the manufacturing of the conformance lots in our process validation campaign. If the FDA is not satisfied with our validation data, we may need to expend additional resources to conduct further studies to obtain manufacturing data that the FDA believes is sufficient. Depending on the extent of these additional studies, approval of our NDA or other applications may be delayed by several years, or may require us to expend more resources than we have planned or are available. It is also possible that additional studies may not suffice to make our NDA or other applications approvable. If any of these outcomes occur, we may be forced to abandon our NDA or other applications for approval, which might cause us to cease operations.

We will need to file similar applications with regulatory authorities in foreign countries to market Increlex for any indications in those countries. We have not yet initiated the regulatory process in Europe. If we fail to obtain European approval, the geographic market for Increlex would be limited. If such approval is delayed, it would postpone our ability to generate revenues in Europe.

If there are fewer children with Severe Primary IGFD or Primary IGFD 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 or Primary IGFD 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 short stature is approximately one million, of which approximately 380,000 are referred to pediatric endocrinologists for evaluation. We believe that approximately 30,000 of these children have Primary IGFD, of which approximately 6,000 have Severe Primary IGFD. Our estimate of the size of the patient population is based on published studies as well as internal data, including our interpretation of a study conducted as part of Genentech s National Cooperative Growth Study program. This study reported results of the evaluation of the hormonal basis of short stature in approximately 6,450 children referred to pediatric endocrinologists over a four-year period. We believe that the aggregate numbers of children in Western Europe with Primary IGFD and Severe Primary IGFD are substantially equivalent to the numbers in the United States. If the results of Genentech s study or our interpretation of and extrapolation from the study do not accurately reflect the number of children with Primary IGFD or Severe Primary IGFD, our assessment of the market may be incorrect, making it difficult or impossible for us to meet our revenue goals or to enroll a sufficient number of patients in our clinical trials on a timely basis, or at all.

Increlex may fail to achieve market acceptance, which could harm our business.

rhIGF-1 has never been commercialized in the United States or Western Europe for any indication. Even if approved for sale by the appropriate regulatory authorities, physicians may not prescribe Increlex, in which event we may be unable to generate significant revenue or become profitable.

Acceptance of Increlex will depend on a number of factors including:

- acceptance of Increlex by physicians and patients as a safe and effective treatment;
- adequate reimbursement by third parties;
- relative convenience and ease of administration of Increlex;
- prevalence and severity of side effects; and
- competitive product approvals.

Reimbursement may not be available for Increlex, which could diminish our sales and impact our ability to achieve profitability.

Market acceptance, our sales of Increlex and our profitability will depend on reimbursement policies and health care reform measures. The levels at which government authorities and third-party payors, such as private health insurers and health maintenance organizations, reimburse the price patients pay for our product will affect the commercialization of Increlex. We believe that Increlex will be reimbursed to a similar extent that growth hormone therapy is reimbursed. If our assumption regarding reimbursement for Increlex is incorrect, our expected revenues may be substantially reduced. We cannot be sure that reimbursement in the United States or elsewhere will be available for Increlex. If the FDA approves Increlex for Severe Primary IGFD, only prescriptions for that indication may be reimbursable. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, Increlex. We have not commenced efforts to have Increlex reimbursed by governments or third-party payors. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize Increlex.

We believe that the price per patient of Increlex therapy for the treatment of Primary IGFD will not be less than approximately $20,000 per year. However, we have not yet determined what the actual price per patient will be. In addition, it is possible that the children receiving Increlex therapy during the first few years of our launch are younger and/or smaller than those children receiving the drug in ensuing years, and the price per patient could be

less than in subsequent years. If our assumptions regarding the price per patient of Increlex therapy for the treatment of Primary IGFD are incorrect, the market opportunity for Increlex therapy for the treatment of Primary IGFD may be substantially reduced.

In recent years, officials have made numerous proposals to change the health care system in the United States. These proposals include measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. If our product becomes subject to government legislation that limits or prohibits payment for Increlex, or that subjects the price of our product to governmental control, we may not be able to generate revenues, attain profitability or commercialize our product. Because these initiatives are subject to substantial political debate, which we cannot predict, the trading price of biotechnology stocks, including ours, may become more volatile as this debate proceeds.

As a result of legislative proposals and the trend towards managed health care in the United States, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly approved drugs, which, in turn, will put pressure on the pricing of drugs.

If we are unable to establish with the FDA that our rhIGF-1 is comparable to that produced by Genentech, our ability to commercialize rhIGF-1 may be delayed or prevented.

Until January 2004, all of our clinical trials were conducted using rhIGF-1 manufactured by Genentech. In order to obtain FDA approval of Increlex, we intend to submit a comprehensive assessment program to demonstrate structural and functional comparability between the Genentech-manufactured rhIGF-1 and Increlex as part of our NDA. If the FDA determines that this approach is insufficient to assess whether the manufacturing changes have affected the final product safety, identity, purity or potency of Increlex compared to the rhIGF-1 used in the existing clinical studies, then the FDA could require us to conduct additional clinical trials in order to demonstrate comparability as part of the Increlex approval process. Any additional clinical trial would require us to incur significant expenses and significantly delay or prevent the commercialization of Increlex.

The differences between the production of the Genentech-manufactured rhIGF-1 and Increlex include:

- relocation of the manufacturing facility for bulk rhIGF-1 product from Genentech to Cambrex Bio Science Baltimore, Inc.;
- use of a new master cell bank derived from the Genentech master cell bank;
- change of some of the raw material suppliers;
- change of the final vial size, configuration and site of manufacture;
- process changes;

analytical methods changes;

equipment used; and

a solvent used in the purification process.

Our comparability assessment required the evaluation of a number of technical parameters, such as the impurity profile and stability. Any of these factors could affect the comparability of the Genentech-manufactured rhIGF-1 and Increlex and, as a result, delay or prevent our ability to commercialize Increlex.

If our contract manufacturers facilities and operations do not achieve a satisfactory cGMP inspection or if our contract manufacturers facilities become unavailable, we may be unable to sell Increlex.

The facilities used by and operations of our contract manufacturers to manufacture Increlex must undergo an inspection by the FDA for compliance with cGMP regulations before Increlex can be approved. Currently, Cambrex Baltimore is our sole provider of bulk rhIGF-1. We have no alternative manufacturing facilities or plans for additional facilities at this time. Cambrex Baltimore has never commercially manufactured rhIGF-1 for any party,

including us. We do not know if the Cambrex Baltimore facilities or their operations required for the commercial manufacture of Increlex will receive a satisfactory cGMP inspection. In the event these facilities or operations 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 delay of up to several years in or prevent us from obtaining an approval for Increlex. In addition, Cambrex Baltimore, and any alternative contract manufacturer we may utilize, will be subject to ongoing periodic inspection by the FDA and corresponding state and foreign agencies for compliance with GMP regulations and similar foreign standards. We do not have direct control over our contract manufacturers compliance with these regulations and standards.

If Cambrex Baltimore s facilities become unavailable to us for any reason, including failure to comply with cGMP regulations, damage from any event, including fire, flood, earthquake, or terrorism or if they fail to perform under our agreement with them, we may be delayed or unable to complete validation of Increlex or manufacture Increlex. This could delay or prevent the approval of our NDA and our clinical trials, or delay or otherwise adversely affect revenues. If the damage to any of these facilities is extensive, or, for any reason, they do not operate in compliance with cGMP or are unable or refuse to perform under our agreements, we will need to find alternative facilities. The number of contract manufacturers with the expertise and facilities to manufacture rhIGF-1 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 expense to arrange for alternative manufacturers. If we need to change to other commercial manufacturers, these manufacturers facilities and processes, prior to our use, would likely have to undergo cGMP compliance inspections. In addition, we would need to transfer and validate the processes and analytical methods necessary for the production and testing of rhIGF-1 to these new manufacturers.

Any of these factors could delay or suspend clinical trials, regulatory submissions, regulatory approvals or commercialization of Increlex, entail higher costs and result in our being unable to effectively commercialize Increlex. Furthermore, if Cambrex Baltimore fails to deliver commercial 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 Increlex, and we would lose potential revenues.

Delays in performing testing and characterization work on Increlex may delay or prevent our NDA approval.

We have contracted with AAI Development Services, a division of aaiPharma Inc., or AAI, to perform some of the testing and characterization work on Increlex. AAI has publicly disclosed that it has financial difficulties, a substantially new management team and that it is pursuing asset sales. If there are business interruptions at AAI resulting from its financial condition, or for any other reason, we may need to reassign all or a portion of AAI s work to an alternative contractor, and our NDA approval may be delayed or prevented.

If another party obtains orphan drug and/or pediatric exclusivity for rhIGF-1 for children with IGFD, we may be precluded from commercializing Increlex in that indication.

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 FDA approval 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. If a competitor obtains approval before us of the same drug as defined by the FDA, or if our drug is determined to be contained within that drug, for the same indication, we would be blocked from obtaining approval for our product for seven years, unless our product can be shown to be clinically superior. In addition, more than one product may be approved by the FDA for the same orphan indication or disease as long as the products are different drugs. As a result, if our product is approved and receives orphan drug status, the FDA can still approve other drugs for use in treating the same indication or disease covered by our product, which could create a more competitive market for us.

In some cases, pediatric exclusivity can provide an additional six months of market exclusivity. Under Section 505a of the Federal Food, Drug, and Cosmetic Act, six months of market exclusivity may be granted in exchange for the voluntary completion of pediatric studies in accordance with an FDA-issued Written Request. The FDA may issue a Written Request for studies on unapproved or approved indications, where it determines that information relating to the use of a drug in a pediatric population, or part of the pediatric population, may produce health benefits in that population. We have not requested or received a Written Request for such pediatric studies, although we may ask the FDA to issue a Written Request for such studies in the future. To receive the six-month pediatric market

exclusivity, we would have to receive a Written Request from the FDA, conduct the requested studies, and submit reports of the studies in accordance with a written agreement with the FDA or, if there is no written agreement, in accordance with commonly accepted scientific principles. There is no guarantee that FDA will issue a Written Request for such studies or accept the reports of the studies. Although we intend to file for pediatric exclusivity where appropriate, we have not yet sought pediatric exclusivity for any indication.

Increlex has received from the FDA orphan drug designation for the treatment of GHIS. We believe that the disease described by the term Severe Primary IGFD is substantially equivalent to the disease described by the term GHIS, relates to approximately the same number of pediatric patients, and accurately describes the pediatric patient population for which we will be filing our NDA and seeking regulatory marketing approval. However, with respect to orphan drug designation, the FDA may determine that Severe Primary IGFD is not substantially equivalent to GHIS and/or that the number of children who have GHIS are less than those with Severe Primary IGFD. Accordingly, even if we were to receive an FDA marketing approval for Severe Primary IGFD, our orphan drug marketing designation and exclusivity may be limited to a small subset of children with Severe Primary IGFD. We cannot predict the size of the subset of children with Severe Primary IGFD to which our orphan drug marketing exclusivity may be limited. If we do not obtain orphan drug marketing exclusivity for Severe Primary IGFD, we could face competition for these patients and our business would be harmed.

We are aware of a drug being developed by Insmed Incorporated, which we believe is a combination product containing rhIGF-1 that is in development for the treatment of GHIS. In January 2005, Insmed announced that it had filed an NDA for its combination product for the GHIS indication. This product has received an orphan drug designation from the FDA, and in Europe, the European Medicines Agency, or EMEA, for the treatment of GHIS. The FDA and EMEA could determine that this other product is the same drug as our product or that our product is contained within this other product and is used for the same indication. If the FDA and EMEA makes this determination and the other product is approved first, the approval of Increlex for either Severe Primary IGFD or Primary IGFD could be blocked for up to seven and one-half years in the United States, and ten years in Europe, which could force us to curtail or cease our operations. Even if our product is approved first, we may not be able to benefit from the orphan drug marketing exclusivity if this other product is determined by the FDA and EMEA to be clinically superior because products that are clinically superior may be approved for marketing by the FDA and EMEA notwithstanding our initial approval and our initial orphan drug marketing exclusivity.

We face significant competition from large pharmaceutical, biotechnology and other companies that could harm our business.

The biotechnology industry is intensely competitive and characterized by rapid technological progress. In each of our potential product areas, we face significant competition from large pharmaceutical, biotechnology and other companies. Most of these companies have substantially greater capital resources, research and development staffs, facilities and experience at conducting clinical trials and obtaining regulatory approvals. In addition, many of these companies have greater experience and expertise in developing and commercializing products.

Since Increlex is under development, we cannot predict the relative competitive position of Increlex if it is approved for use. However, we expect that the following factors will determine our ability to compete effectively: safety and efficacy; product price; ease of administration; and marketing and sales capability.

We believe that many of our competitors spend significantly more on research and development-related activities than we do. Our competitors may discover new treatments, drugs or therapies or develop existing technologies to compete with Increlex. Our commercial opportunities will be reduced or eliminated if these competing products are more effective, have fewer or less severe side effects, are more convenient or are less expensive than Increlex.

There is no drug in the United States or Europe approved as a replacement therapy for the treatment of Severe Primary IGFD, Primary IGFD or Adult IGFD. In January 2005, Insmed announced that it had filed an NDA for its combination product for the treatment of GHIS. In addition, we

are aware that Chiron Corporation has developed a process to manufacture rhIGF-1 using yeast expression and has intellectual property with respect to that process. We use bacterial expression, which differs from yeast expression, to manufacture Increlex.

Growth hormone may also be a competitive product for the treatment of some patients with Primary IGFD or Adult IGFD. Higher doses of growth hormone may be effective in patients with Primary IGFD and Adult Primary IGFD that are resistant to lower doses of growth hormone. The major suppliers of commercially available growth hormone are Genentech., Eli Lilly and Company, Novo Nordisk A/S, Pfizer Inc. and Serono S.A. In 2003, Eli Lilly and Company received FDA approval for its growth hormone, Humatrope, for the treatment of children with

idiopathic short stature, or ISS. Children with Primary IGFD may be diagnosed as having ISS, which may cause growth hormone to be competitive with Increlex. We believe that Novo Nordisk is conducting clinical trials for the use of its growth hormone in IGF-1 deficient patients.

In addition, we believe that Bristol-Meyers Squibb Company, Genentech, Inc., Merck & Co., Inc., Novo Nordisk A/S and Pfizer Inc. 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 has licensed certain rights to Novo Nordisk s growth hormone secretagogues and is actively developing one of these compounds for use in cancer cachexia, a wasting disorder affecting some cancer patients.

Many companies are seeking to develop products and therapies for the treatment of diabetes. These competitors include multinational pharmaceutical companies, specialized biotechnology firms, and universities and other research institutions. Insmed has also conducted clinical trials using a product that contains rhIGF-1 for the treatment of diabetes. It is possible that there are other products currently in development or that exist on the market that may compete directly with Increlex.

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

Although we are not aware of any other company currently marketing rhIGF-1 in the United States for any 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 rhIGF-1 to treat the indications for which Increlex receives 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 rhIGF-1 to prescribe to their patients. As a result, we would have limited ability to prevent off-label use of a competitor s 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.

If we fail to protect our intellectual property rights, competitors may develop competing products, and our business will suffer.

lf we are not able to protect our proprietary technology, trade secrets and know-how, our competitors may use our inventions to develop competing products. We have licensed intellectual property rights, including patent rights, relating to rhIGF-1 technologies from Genentech. However, these patents may not protect us against our competitors. Patent litigation is very expensive, and we therefore may be unable to pursue patent litigation to its conclusion because currently we do not generate revenues.

We do not have patent composition coverage on the rhIGF-1 protein alone. Although we have licensed from Genentech its rights to its methods of use and manufacturing patents, it may be more difficult to establish infringement of such patents as compared to a patent directed to the rhIGF-1 protein composition alone. Our licensed patents may not be sufficient to prevent others from competing with us. We cannot rely solely on our patents to be successful. The standards that the U.S. Patent and Trademark Office and foreign patent offices use to grant patents, and the standards that United States and foreign courts use to interpret patents, are not the same and are not always applied predictably or uniformly and can change, particularly as new technologies develop. As such, the degree of patent protection obtained in the United States may differ substantially from that obtained in various foreign countries. In some instances, patents have issued in the United States while substantially less or no protection has been obtained in Europe or other countries. Our United States Patent No. 6,331,414 B1 licensed from Genentech is directed to methods for bacterial expression of rhIGF-1 and expires in 2018. We have no equivalent European patent. The European Patent Office has determined that the claims of Genentech s corresponding European patent application are not patentable under European patent law in view of public disclosures made before the application was filed.

We are uncertain of the level of protection, if any, that will be provided by our licensed patents if we attempt to enforce them, and they are challenged in court where our competitors may raise defenses such as invalidity, unenforceability or possession of a valid license. For example, we initiated patent infringement proceedings against Avecia Limited and Insmed Incorporated in the United Kingdom and against Insmed Incorporated in the United States to enforce patent rights we licensed from Genentech. The United States action, among other things, alleges infringement of United States Patent No. 6,311,414 B1 identified above. If the court finds any of the patents at issue

in those litigations, including United States Patent No. 6,311,414 B1, to be invalid or unenforceable, we would be prevented from enforcing such patents against third parties in the future, thus preventing us from using the affected patents to exclude others from competing with us. In addition, the type and extent of patent claims that will be issued to us in the future are uncertain. Any patents that are issued may not contain claims that will permit us to stop competitors from using similar technology.

In addition to the patented technology licensed from Genentech, we also rely on unpatented technology, trade secrets and confidential information, such as the proprietary information we use to manufacture Increlex. We may not be able to effectively protect our rights to this technology or information. Other parties may independently develop substantially equivalent information and techniques or otherwise gain access to or disclose this technology. We generally require each of our employees, consultants, collaborators, and certain contractors to execute a confidentiality agreement at the commencement of an employment, consulting or collaborative relationship with us. However, these agreements may not provide effective protection of this technology or information or, in the event of unauthorized use or disclosure, they may not provide adequate remedies.

We may incur substantial costs as a result of patent infringement litigation or other proceedings relating to patent and other intellectual property rights, and we may be unable to protect our intellectual property rights.

In December 2004, we initiated patent infringement proceedings against Avecia Limited and Insmed Incorporated in the United Kingdom and against Insmed in the United States to enforce patent rights we licensed from Genentech. We cannot predict the outcome of such litigation. Either or both of those actions could require a substantial diversion of financial and personnel resources in support of such actions and expose us to liability for costs or other awards of damages. Declaratory judgments of invalidity against our patents asserted in such actions could prevent us from using the affected patents to exclude others from competing with us.

In addition, a third party may claim that we are using its inventions covered by its patents and may go to court to stop us from engaging in our operations and activities. Although no third party has claimed that we are infringing on their patents, patent lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we are infringing the third party s patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party damages for having infringed the other party s patents. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do so. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

We are aware of a U.S. patent of Chiron Corporation related to processes of manufacturing rhIGF-1 in yeast host cells, to fusion proteins, DNA, and yeast host cells useful in such processes of manufacturing rhIGF-1 in yeast host cells, and to rhIGF-1 made as a product of such processes. While we use bacterial expression, not yeast expression, in our process for manufacturing Increlex, we cannot predict whether our activities relating to the development and commercialization of Increlex in the United States will be found to infringe Chiron s patent in the event Chiron brings patent infringement proceedings against us. We may not be able to obtain a license to Chiron s patent under commercially reasonable terms, if at all. If we are unable to obtain a license to Chiron s patent, and if in any patent infringement proceeding Chiron brings against us the court decides that our activities relating to the development and commercialization of Increlex in the United States infringe Chiron s patent, the court may award damages and/or injunctive relief to Chiron. Any such damages, injunctive relief and/or other remedies the court may award could render any further development and commercialization of Increlex commercially infeasible for us or otherwise curtail or cease any further development and commercialization of Increlex.

We cannot be certain that others have not filed patent applications for technology covered by our licensor s issued patents or our pending applications or our licensor s pending applications or that we or our licensors were the first to invent the technology because:

some patent applications in the United States may be maintained in secrecy until the patents are issued,

patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and

publications in the scientific literature often lag behind actual discoveries and the filing of patents relating to those discoveries.

Patent applications may have been filed and may be filed in the future covering technology similar to ours. Any such patent application may have priority over our patent applications and could further require us to obtain rights to issued patents covering such technologies. In the event that another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our United States patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could harm our business.

If we lose our licenses from Genentech, we may be unable to continue our business.

We have licensed intellectual property rights and technology from Genentech, under our U.S. and International License and Collaboration agreements with Genentech. Under each agreement, Genentech has the right to terminate our license if we are in material breach of our obligations under that agreement and fail to cure that breach. Under the terms of the agreements, we are obligated, among other things, to use reasonable business efforts to meet specified milestones, including filing for regulatory approval in the United States for an IGFD indication by December 31, 2005 and for either a diabetes indication or a substitute indication by December 31, 2006. Additionally, we are obligated to file for regulatory approval in either the European Union or Japan for an IGFD indication by December 31, 2007. If we fail to use reasonable business efforts to meet our development milestones for either agreement, Genentech may terminate that agreement. If either agreement were terminated, then we would lose our rights to utilize the technology and intellectual property covered by that agreement to develop, manufacture and commercialize Increlex for any indication. This may prevent us from continuing our business.

We are subject to Genentech s option rights with respect to the commercialization of Increlex for all diabetes and non-orphan indications in the United States.

Under our U.S. License and Collaboration Agreement with Genentech, Genentech has the option to elect to jointly commercialize rhIGF-1 for all diabetes and non-orphan indications in the United States. Orphan indications are designated by the FDA under the Orphan Drug Act, and are generally rare diseases or conditions that affect fewer than 200,000 individuals in the United States. With respect to those non-orphan and diabetes indications in the United States, once Genentech has exercised its option to jointly develop and commercialize, Genentech has the final decision on disputes relating to development and commercialization of such indications. Our ability to sublicense the development and commercialization of such products requires the consent of Genentech.

We do not know whether our planned clinical trials will begin on time, or at all, or will be completed on schedule, or at all.

The commencement or completion of any of our clinical trials may be delayed or halted for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities either do not approve a clinical trial protocol or place a clinical trial on clinical hold;

patients do not enroll in clinical trials at the rate we expect;

patients experience adverse side effects;

patients develop medical problems that are not related to our products or product candidates;

third-party clinical investigators do not perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol and good clinical practices, or other third-party organizations do not perform data collection and analysis in a timely or accurate manner;

contract laboratories fail to follow good laboratory practices;

interim results of the clinical trial are inconclusive or negative;

sufficient quantities of the trial drug may not be available;

our trial design, although approved, is inadequate to demonstrate safety and/or efficacy;

re-evaluation of our corporate strategies and priorities; and

limited financial resources.

In addition, we may choose to cancel, change or delay certain planned clinical trials, or replace one or more planned clinical trials with alternative clinical trials. While we are assessing our potential development strategy for Adult IGFD, we do not currently intend to initiate a clinical trial in this area, and cannot be sure as to when we may initiate clinical trials in this area, if at all. We are currently evaluating multiple, existing trial results from the use of Increlex in diabetes in order to refine our conclusions and potential development plans and timelines for diabetes. Our clinical trials or intended clinical trials may be subject to further change from time to time as we evaluate our research and development priorities and available resources. Our development costs will increase if we need to perform more or larger clinical trials than planned. Significant delays for our current or planned clinical trials may harm the commercial prospects for Increlex and our prospects for profitability.

Clinical development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials.

To gain approval to market a product for treatment of a specific disease, we must provide the FDA and foreign regulatory authorities with clinical data that demonstrate the safety and statistically significant efficacy of that product for the treatment of the disease. Clinical development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. If a clinical trial failed to demonstrate safety and statistically significant efficacy, we would likely abandon the development of that product, which could harm our business and may result in a precipitous decline in our stock price.

If third-party clinical research organizations do not perform in an acceptable and timely manner, our clinical trials could be delayed or unsuccessful.

We do not have the ability to conduct all of our clinical trials independently. We rely on clinical investigators, third-party clinical research organizations and consultants to perform a substantial portion of these functions. If we cannot locate acceptable contractors to run our clinical trials or enter into favorable agreements with them, or if these contractors do not successfully carry out their contractual duties, satisfy FDA requirements for the conduct of clinical trials, or meet expected deadlines, we will be unable to obtain required approvals and will be unable to commercialize Increlex on a timely basis, if at all.

If we are unable to establish a direct sales force in the United States, our business may be harmed.

We currently do not have a sales organization. If Increlex is approved by the FDA for Severe Primary IGFD, we intend to market that therapy directly to pediatric endocrinologists in the United States through our own sales force. We will need to incur significant additional expenses and commit significant additional management resources to establish this sales force. We may not be able to establish these capabilities despite these additional expenditures. If we elect to rely on third parties to sell Increlex in the United States, we may receive less revenue and incur greater costs than if we sold it directly. In addition, we may have little or no control over the sales efforts of those third parties. In the event we are unable to sell Increlex, either directly or through third parties, our business would be harmed.

We may need others to market and commercialize Increlex in Europe.

We may need others to market and commercialize Increlex in Europe. If we decide to sell Increlex in Europe through a third party, we will need to enter into marketing arrangements with them. We may not be able to enter into marketing arrangements with third parties on favorable terms, or at all. In addition, these arrangements could result in lower levels of income to us than if we marketed Increlex entirely on our own. In the event that we are unable to enter into a marketing arrangement for Increlex in Europe, we may not be able to develop an effective sales force to successfully commercialize our product in Europe. If we fail to enter into marketing arrangements for our product and are unable to develop an effective international sales force, our revenues could be limited.

If we fail to identify and in-license other patent rights, products or product candidates, we may be unable to grow our revenues.

We do not conduct any preclinical laboratory research. Our strategy is to in-license products or product candidates and further develop them for commercialization. The market for acquiring and in-licensing patent rights, products and product candidates is intensely competitive. If we are not successful in identifying and in-licensing other patent rights, products or product candidates, we may be unable to grow our revenues with sales from new products. If the FDA approves Increlex for Severe Primary IGFD only, only prescriptions for that indication may be reimbursable. In this event, we would need to invest significant resources in discovery research and preclinical development to obtain new product candidates.

In addition, we may need additional intellectual property from other third parties to commercialize Increlex for certain diabetes indications We cannot be sure that we will be able to obtain a license to any third-party technology we may require to conduct our business.

If we fail to obtain the capital necessary to fund our operations, we will be unable to execute our business plan.

We believe that we have existing cash and investment securities sufficient to meet our capital requirements through at least the end of 2006 based on our current business plan. We expect capital outlays and operating expenditures to increase over the next several years as we expand our operations.

Our future capital needs and the adequacy of our available funds will depend on many factors, including:

- the costs, timing, scope of domestic and international regulatory approvals for rhIGF-1;
- our ability to market and sell rhIGF-1;
- the commercial readiness of our rhIGF-1 manufacturing operations at Cambrex Baltimore, including the success of our cGMP production activities;
- the success of drug product manufacturing and results of stability and product comparability studies performed at third-party contractors;
- the rate of progress and cost of our future clinical trials and other research and development activities;
- the pace of expansion of administrative expenses; and
- the status of competing products.

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. If additional funds are not available, we may be forced to curtail or cease operations.

If we are unable to manage our expected growth, we may not be able to implement our business plan.

Our ability to implement our business plan requires an effective planning and management process. As of December 31, 2004, we had 60 employees; however, we will need to hire a significant number of additional employees in the near term. Our offices are located in the San Francisco Bay area where competition for personnel with biopharmaceutical skills is intense. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development and commercialization activities. The lease for our corporate headquarters expires in June 2005, and we must move to another facility. If we are unable to secure a suitable facility on reasonable terms, our business would be harmed.

We expect that our anticipated future growth will place a significant strain on our management, systems and resources. In particular, to fulfill our strategy to commercialize Increlex in the United States, we will need to hire a significant number of additional employees. To manage the anticipated growth of our operations, we will need to increase management resources, secure additional office space and implement new financial and management controls, reporting systems and procedures. If we are unable to manage our growth, we could be unable to execute our business strategy.

If product liability lawsuits are brought against us, we may incur substantial liabilities.

One potential risk of using growth factors like rhIGF-1 is that it may increase the likelihood of developing cancer or, if patients already have cancer, that the cancer may develop more rapidly. Increlex may also increase the risk that diabetic patients may develop or worsen an existing retinopathy, which could lead to the need for additional therapy such as laser treatment of the eyes or result in blindness. We have Phase III results from the treatment of 71 children with Severe Primary IGFD with rhIGF-1 replacement therapy for an average of 3.9 years, with some patients being treated for as long as 11.5 years. None of the 71 children discontinued rhIGF-1 treatment due to safety concerns. However, some patients experienced hypoglycemia, or low blood glucose levels. Hearing deficits and enlargement of the tonsils were also noted in some patients.

There may also be other adverse events associated with the use of Increlex, which may result in product liability suits being brought against us. While we have licensed the rights to develop and commercialize rhIGF-1 in certain indications, we are not indemnified by any third party, including our contract manufacturers, for any liabilities arising out of the development or use of rhIGF-1.

Whether or not we are ultimately successful in defending product liability litigation, such litigation would consume substantial amounts of our financial and managerial resources, and might result in adverse publicity or reduced acceptance of Increlex in the market, all of which would impair our business. We have obtained clinical trial insurance and product liability insurance; however, we may not be able to maintain our clinical trial insurance or product liability insurance at an acceptable cost, if at all, and this insurance may not provide adequate coverage against potential claims or losses.

Budgetary or cash constraints may force us to delay our efforts to develop certain research and development programs in favor of developing others, which may prevent us from meeting our stated timetables and completing these projects through to product commercialization.

Because we are an emerging company with limited resources, and because research and development is an expensive process, we must regularly assess the most efficient allocation of our research and development resources. Accordingly, we may choose to delay or abandon our research and development efforts for the treatment of a particular indication or project to allocate those resources to another indication or project, which could cause us to fall behind our initial timetables for development. As a result, we may not be able to fully realize the value of some of our product candidates in a timely manner, since they will be delayed in reaching the market, or may not reach the market at all.

We must implement additional finance and accounting systems, procedures and controls as we grow our business and organization and to satisfy new reporting requirements.

As a public reporting company, we must comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the Securities and Exchange Commission, including expanded disclosures and accelerated reporting requirements and more complex accounting rules. Compliance with Section 404 of the Sarbanes-Oxley Act of 2002 and other requirements will increase our costs and require additional management resources. We recently have been upgrading our finance and accounting systems, procedures and controls and will need to continue to implement additional finance and accounting systems, procedures and controls as we grow our business and organization and to satisfy new reporting requirements. Compliance with Section 404 will apply in 2005, and 404 reporting will first occur in our Form 10-K for our fiscal year ending December 31, 2005. If we are unable to complete the required assessment as to the adequacy of our internal control reporting or if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal controls over financial reporting as of December 31, 2005, investors could lose confidence in the reliability of our internal controls over financial reporting, which could adversely affect our stock price.

If we are unable to attract and retain additional qualified personnel, our ability to commercialize Increlex and develop other product candidates will be harmed.

Our success depends on our continued ability to attract and retain highly qualified management and scientific personnel and on our ability to develop relationships with leading academic scientists and clinicians. We are highly dependent on our current management and key medical, scientific and technical personnel, including: Dr. John A. Scarlett, our President and Chief Executive Officer; Dr. Ross G. Clark, our Chief Technical Officer; Thomas H. Silberg, our Chief Operating Officer; Timothy P. Lynch, our Chief Financial Officer and Treasurer; and Stephen N. Rosenfield, our General Counsel and Secretary, whose knowledge of our industry and technical expertise would be extremely difficult to replace. In addition, we have not obtained life insurance benefiting us if any of our key employees left or was seriously injured and unable to work.

We have employment contracts with all of our executive officers. Each of these employment relationships is at will. All of our executive officers may terminate their employment without notice and without cause or good reason, except for Mr. Lynch. Mr. Lynch may terminate his employment with two weeks notice to us and without cause or good reason. We may terminate any of our executive officers without cause, in which event they would be entitled to severance payments. In the event of a change in control, we may be obligated to make severance payments and to accelerate the vesting of certain stock options.

Risks Related to Our Common Stock

If our officers, directors and largest stockholders choose to act together, they are able to control our management and operations, acting in their best interests and not necessarily those of other stockholders.

As of February 15, 2005, our directors, executive officers and principal stockholders and their affiliates beneficially own approximately 62.4% of our common stock. Our greater than five percent beneficial owners include entities affiliated with MPM Capital, which beneficially own 22.4%; entities affiliated with Prospect Management Co. II, LLC, which beneficially own 12.1%; entities affiliated with Medimmune Ventures, which beneficially own 9.5%; and entities affiliated with Rho Ventures, which beneficially own 9.5%. Our directors, executive officers and principal stockholders and their affiliates collectively have the ability to determine the election of all of our directors and to determine the outcome of most corporate actions requiring stockholder approval. They may exercise this ability in a manner that advances their best interests and not necessarily those of other stockholders.

Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us, which may be beneficial to our stockholders, more difficult.

Provisions of our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even if doing so would benefit our stockholders. These provisions:

- establish a classified board of directors so that not all members of our board may be elected at one time;
- authorize the issuance of blank check preferred stock that could be issued by our board of directors to increase the number of outstanding shares and hinder a takeover attempt;
- limit who may call a special meeting of stockholders;
- prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; and
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings.

In addition, Section 203 of the Delaware General Corporation Law, which prohibits business combinations between us and one or more significant stockholders unless specified conditions are met, may discourage, delay or prevent a third party from acquiring us.

Our stock price may be volatile, and your investment in our stock could decline in value.

The trading price of our common stock has fluctuated significantly since our initial public offering in March 2004, and is likely to remain volatile in the future. The trading price of our common stock could be subject to wide fluctuations in response to many events or factors, including the following:

- estimates of our business potential and earnings prospects;
- an assessment of our management;
- quarterly variations in our operating results;
- significant developments in the businesses of biotechnology companies;

changes in financial estimates by securities analysts;

changes in market valuations or financial results of biotechnology companies;

announcements by us or our competitors of new trial results, regulatory filings or developments, new products, significant acquisitions, strategic partnerships or joint ventures;

deviations from projections regarding business potential and earnings prospects;

additions or departures of key personnel;

changes in the structure of healthcare payment or reimbursement systems, regulations or policies;

activities of short sellers and risk arbitrageurs;

future sales of our common stock;

general economic, industry and market conditions; and

volume fluctuations, which are particularly common among highly volatile securities of biotechnology companies.

In addition, the stock market has experienced volatility that has particularly affected the market prices of equity securities of many biotechnology companies, which often has been unrelated or disproportionate to the operating performance of these companies. These broad market fluctuations may adversely affect the market price of our common stock. If the market price of our common stock declines in value, you may not realize any return on your investment in us and may lose some or all of your investment.

If our results do not meet analysts forecasts and expectations, our stock price could decline.

Analysts who cover our business and operations provide valuations regarding our stock price and make recommendations whether to buy, hold or sell our stock. Our stock price may be dependent upon such valuations and recommendations. Analysts valuations and recommendations are based primarily on our reported results and their forecasts and expectations concerning our future results regarding, for example, expenses, revenues, clinical trials, regulatory marketing approvals and competition. Our future results are subject to substantial uncertainty, and we may fail to meet or exceed analysts forecasts and expectations as a result of a number of factors, including those discussed under the section Risks Related to Our Business. If our results do not meet analysts forecasts and expectations, our stock price could decline as a result of analysts lowering their valuations and recommendations or otherwise.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies have experienced greater than average stock price volatility in recent years. If we faced such litigation, it could result in substantial costs and a diversion of management s attention and resources, which could harm our business.

Substantial sales of shares may impact the market price of our common stock.

If our stockholders sell substantial amounts of our common stock, including shares issued upon the exercise of outstanding options, the market price of our common stock may decline. These sales also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. As of December 31, 2004, we had 24,595,869 outstanding shares of common stock. Of these shares, the 6,325,000 shares sold in our initial public offering that were outstanding as of December 31, 2004 were freely tradable without restriction or further registration, other than shares purchased by our officers, directors or other affiliates within the meaning of Rule 144 under the Securities Act of 1933. The remaining 18,270,869 shares outstanding as of December 31, 2004 are now freely tradable, subject to volume limitations, certain restrictions on sales by affiliates and vesting in the case of early exercised options.

We have filed a registration statement covering shares of common stock issuable upon exercise of options and other grants pursuant to our stock plans. The holders of 17,285,928 shares of our common stock outstanding as of December 31, 2004 are entitled to registration rights.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

February 16, 2005

TERCICA, INC.

By: /s/ STEPHEN N. ROSENFIELD

Stephen N. Rosenfield

Senior Vice President of Legal Affairs