

TERCICA INC  
Form S-3  
November 09, 2005  
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As filed with the Securities and Exchange Commission on November 9, 2005

Registration No. 333-

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

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**FORM S-3**  
**REGISTRATION STATEMENT**

*UNDER*  
*THE SECURITIES ACT OF 1933*

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**TERCICA, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or Other Jurisdiction of Incorporation or Organization)

**26-0042539**  
(I.R.S. Employer Identification No.)

**2000 Sierra Point Parkway, Suite 400**

**Brisbane, CA 94005**

**(650) 624-4900**

(Address, including zip code, and telephone number,  
including area code, of Registrant's principal executive offices)

**JOHN A. SCARLETT, M.D.**

**President and Chief Executive Officer**

**Tercica, Inc.**

**2000 Sierra Point Parkway, Suite 400**

**Brisbane, CA 94005**

**(650) 624-4900**

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

**including area code, of agent for service)**

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*Copies to:*

**SUZANNE SAWOCHKA HOOPER, ESQ.**

**Cooley Godward LLP**

**Five Palo Alto Square**

**3000 El Camino Real**

**Palo Alto, CA 94306-2155**

**(650) 843-5000**

*Approximate date of commencement of proposed sale to the public:*

*From time to time after the effective date of this registration statement*

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

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

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

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

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

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### CALCULATION OF REGISTRATION FEE

<u>Title of Each Class of Securities To Be Registered</u>	<u>Amount to be Registered(1)(2)</u>	<u>Proposed Maximum Offering Price Per Share(3)</u>	<u>Proposed Maximum Aggregate Offering Price(3)</u>	<u>Amount of Registration Fee</u>
Common Stock, \$0.001 par value per share	6,296,912	\$ 10.41	\$ 65,550,853.92	\$ 7,715.34

- (1) Includes 260,000 shares of common stock that may be issued upon the exercise of a warrant.
- (2) Pursuant to Rule 416 under the Securities Act, the shares being registered hereunder include such indeterminate number of shares of common stock as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends or similar transactions.
- (3) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457 under the Securities Act. The price per share and aggregate offering price are based on the average of the high and low prices of the registrant's common stock on November 7, 2005, as reported on the Nasdaq National Market.

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

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**Subject to Completion, Dated November 9, 2005**

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

**PROSPECTUS**

**6,296,912 Shares**

**Common Stock**

This prospectus relates to the resale of up to 6,296,912 shares of our common stock that we may issue to the selling stockholder listed in the section beginning on page 19 of this prospectus. The shares of common stock offered under this prospectus by the selling stockholder are issuable to Kingsbridge Capital Limited, or Kingsbridge, pursuant to a common stock purchase agreement between us and Kingsbridge, dated October 14, 2005, and a warrant we issued to Kingsbridge on that date. We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of shares by the selling stockholder.

The selling stockholder may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. We provide more information about how the selling stockholder may sell its shares of common stock in the section entitled Plan of Distribution on page 20. We will not be paying any underwriting discounts or commissions in this offering.

Our common stock is traded on the Nasdaq National Market under the symbol TRCA. On November 8, 2005, the last reported sale price of our common stock was \$10.19 per share.

*Investing in our common stock involves risk. See Risk Factors beginning on page 4 of this prospectus.*

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

The date of this prospectus is \_\_\_\_\_, 200\_\_

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**ABOUT THIS PROSPECTUS**

You should rely only on the information contained or incorporated by reference in this prospectus. We have not, and the selling stockholder has not, authorized anyone to provide you with information different from that contained in this prospectus. The selling stockholder is offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where it is lawful to do so. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock.

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**PROSPECTUS SUMMARY**

*This summary highlights information contained elsewhere or incorporated by reference into this prospectus. Because it is a summary, it does not contain all of the information that you should consider before investing in our securities. You should read this entire prospectus carefully, including the section entitled Risk Factors and the documents that we incorporate by reference into this prospectus, before making an investment decision.*

**TERCICA, INC.**

We are a biopharmaceutical company focused on the development and commercialization of new therapeutics for the treatment of short stature and other related metabolic disorders. Our current product is Increlex<sup>®</sup>, recombinant human insulin-like growth factor-1, or rhIGF-1. We licensed the rights of Genentech, Inc. to develop, manufacture and commercialize rhIGF-1 products for a broad range of indications, including short stature, worldwide. Our initial focus is on developing Increlex as a replacement therapy for primary IGF-1 deficiency, or Primary IGFD. We define the indication Primary IGFD to mean a child who has a height standard deviation score, or Height SDS, and an IGF-1 standard deviation score, or IGF-1 SDS, of less than minus two, and the indication severe Primary IGFD to mean a child who has a Height SDS and IGF-1 SDS of minus three or less, in each case in the presence of normal or elevated levels of growth hormone. We submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, in February 2005 seeking approval of long-term rhIGF-1 replacement therapy for severe Primary IGFD, based on Phase III clinical trial data. The FDA approved our NDA in August 2005 and granted Increlex seven years of orphan drug marketing exclusivity for the long-term treatment of growth failure in children with severe Primary IGFD. We are conducting two late-stage clinical trials for the use of rhIGF-1 in Primary IGFD.

We are in the development stage, have a limited operating history and may not be able to generate revenue or attain profitability. Since our inception, we have not generated any revenue from operations and have a history of significant losses. Given that we expect to incur substantial net losses to commercialize Increlex, it is unclear when, if ever, we will become profitable.

Tercica, Inc. was formed in December 2001 as a Delaware corporation. Our principal executive offices are located at 2000 Sierra Point Parkway, Suite 400, Brisbane, CA 94005. Our telephone number is (650) 624-4900, and our website is located at [www.tercica.com](http://www.tercica.com). The information on our website is not part of this prospectus.

References in this prospectus to we, us and our refer to Tercica, Inc. and its subsidiary. We have applied for registration of the trademarks Increlex, Tercica and the Tercica logo in the United States.

**EQUITY FINANCING FACILITY WITH KINGSBRIDGE**

On October 14, 2005, we entered into a committed equity financing facility, or CEFF, with Kingsbridge, pursuant to which Kingsbridge committed to purchase, subject to certain conditions, up to \$75.0 million of our common stock. In connection with the CEFF, we entered into a common stock purchase agreement and registration rights agreement with Kingsbridge, both dated October 14, 2005, and on that date we also issued a warrant to Kingsbridge to purchase 260,000 shares of our common stock at an exercise price of \$13.12 per share. This warrant is exercisable beginning on April 14, 2006 and for a period of five years thereafter.

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The common stock purchase agreement entitles us to sell and obligates Kingsbridge to purchase, from time to time over a period of three years, shares of our common stock for cash consideration up to an aggregate of \$75.0 million, subject to certain conditions and restrictions. The shares of common stock that may be issued to Kingsbridge under the common stock purchase agreement and the warrant will be issued pursuant to an exemption from registration under the Securities Act of 1933, as amended, or the Securities Act. Pursuant to the registration rights agreement, we have filed a registration statement of which this prospectus is a part, covering the possible resale by Kingsbridge of any shares that we may issue to Kingsbridge under the common stock purchase agreement or upon exercise of the warrant. Through this prospectus, the selling stockholder may offer to the public for resale shares of our common stock that we may issue to Kingsbridge pursuant to the common stock purchase agreement, or that Kingsbridge may acquire upon exercise of the warrant.

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For a period of 36 months from the first trading day following the effectiveness of the registration statement of which this prospectus is a part, we may, from time to time, at our discretion, and subject to certain conditions that we must satisfy, draw down funds under the CEFF by selling shares of our common stock to Kingsbridge. The purchase price of these shares will be at a discount of up to ten percent from the volume weighted average price of our common stock for each of the eight trading days following our election to sell shares, or draw down under the CEFF. The discount on each of these eight trading days will be determined as follows:

<u>VWAP*</u>	<u>PERCENT OF VWAP</u>	<u>(APPLICABLE DISCOUNT)</u>
Greater than or equal to \$14.00 per share	94%	(6)%
Greater than or equal to \$7.50 per share but less than \$14.00 per share	92%	(8)%
Greater than or equal to \$3.00 per share but less than \$7.50 per share	90%	(10)%

\* As set forth in the common stock purchase agreement, VWAP means the volume weighted average price (the aggregate sales price of all trades of our common stock during each trading day divided by the total number of shares of common stock traded during that trading day) of our common stock during any trading day as reported by Bloomberg, L.P. using the AQR function. The VWAP and corresponding discount will be determined for each of the eight trading days during a draw down pricing period.

During the eight trading day pricing period for a draw down, if the VWAP for any one trading day is less than the greater of (i) \$3.00 or (ii) 90 percent of the closing price of our common stock on the trading day immediately preceding the beginning of the draw down period, the VWAP for that trading day will not be used in calculating the number of shares to be issued in connection with that draw down, and the draw down amount for that pricing period will be reduced by one-eighth of the draw down amount initially specified. In addition, if trading in our common stock is suspended for any reason for more than three consecutive or non-consecutive hours during any trading day during a draw down pricing period, that trading day will not be used in calculating the number of shares to be issued in connection with that draw down, and the draw down amount for that pricing period will be reduced by one-eighth of the draw down amount initially specified.

The maximum number of shares of common stock that we can issue pursuant to the CEFF is 6,036,912 shares. An additional 260,000 shares of common stock are issuable if Kingsbridge exercises the warrant that we issued to it in connection with Kingsbridge's entry into the CEFF. We intend to exercise our right to draw down amounts under the CEFF, if and to the extent available, at such times as we have a need for additional capital and when we believe that sales of stock under the CEFF provide an appropriate means of raising capital.

Our ability to require Kingsbridge to purchase our common stock is subject to various limitations. We can make draw downs to a maximum of two percent of our market capitalization at the time of the draw down, or \$7.0 million, whichever is less. Unless we and Kingsbridge agree otherwise, a minimum of three trading days must elapse between the expiration of any draw down pricing period and the beginning of the next succeeding draw down pricing period.

During the term of the CEFF, without the prior written consent of Kingsbridge, we may not issue securities that are, or may become, convertible or exchangeable into shares of common stock where the purchase, conversion or exchange price for that common stock is determined using any floating discount or other post-issuance adjustable discount to the market price of the common stock, including pursuant to an equity line or other financing that is substantially similar to the arrangement provided for in the CEFF.

The issuance of our common stock under the CEFF or upon exercise of the Kingsbridge warrant will have no effect on the rights or privileges of existing holders of common stock except that the economic and voting interests of each stockholder will be diluted as a result of the issuance. Although the number of shares of common stock that stockholders presently own will not decrease, these shares will represent a smaller percentage of our total shares that will be outstanding after any issuances of shares of common stock to Kingsbridge. If we draw down amounts



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under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Such issuances will have a dilutive effect and may further decrease our stock price.

Kingsbridge agreed in the common stock purchase agreement that during the term of the CEFF, neither Kingsbridge nor any of its affiliates, nor any entity managed or controlled by it, will enter into any short sale of any shares of our common stock or engage, through related parties or otherwise, in any derivative transaction directly related to shares of our common stock. In addition, Kingsbridge agreed that neither Kingsbridge nor any of its affiliates, nor any entity managed or controlled by it, will sell during any draw down pricing period, shares of our common stock, other than shares of our common stock purchased (or to be purchased) during that draw down pricing period.

Before Kingsbridge is obligated to buy any shares of our common stock pursuant to a draw down, the following conditions, none of which is in the control of Kingsbridge, must be met as of the draw down exercise date and the date upon which each settlement of the purchase and sale of our common stock occurs:

Each of our representations and warranties in the common stock purchase agreement must be true and correct in all material respects as of the date when made as though made at that time, except for representations and warranties that are expressly made as of a particular date.

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We must have performed, satisfied and complied in all material respects with all covenants, agreements and conditions required by the common stock purchase agreement, the registration rights agreement and the warrant to be performed, satisfied or complied with by us.

We must have complied in all material respects with all applicable federal, state and local governmental laws, rules, regulations and ordinances in connection with the execution, delivery and performance of the common stock purchase agreement and the consummation of the transactions contemplated by it.

The registration statement, which includes this prospectus, shall have previously become effective and shall remain effective.

We shall not have knowledge of any event that could reasonably be expected to have the effect of causing the registration statement applicable to the resale of shares of our common stock by Kingsbridge to be suspended or otherwise ineffective.

Trading in our common stock shall not have been suspended by the Securities and Exchange Commission, or the SEC, the Nasdaq Stock Market or the National Association of Securities Dealers and trading in securities generally on the Nasdaq Stock Market shall not have been suspended or limited.

No statute, rule, regulation, executive order, decree, ruling or injunction shall have been enacted, entered, promulgated or endorsed by any court or governmental authority which prohibits the consummation of any of the transactions contemplated by the common stock purchase agreement.

No action, suit or proceeding before any arbitrator or any governmental authority shall have been commenced, and no investigation by any governmental authority shall have been threatened, against us or any of our officers, directors or affiliates seeking to enjoin, prevent or change the transactions contemplated by the common stock purchase agreement.

We shall have sufficient shares of common stock, calculated using the closing trade price of the common stock as of the trading day immediately preceding a draw down, registered under the registration statement to issue and sell such shares in accordance with such draw down.

The warrant to purchase 260,000 shares of our common stock shall have been duly executed, delivered and issued to Kingsbridge, and we shall not be in default in any material aspect under the warrant.

There is no guarantee that we will be able to meet the foregoing conditions or any other conditions under the common stock purchase agreement or that we will be able to draw down any portion of the amounts available under the CEFF.

We also entered into a registration rights agreement with Kingsbridge. Pursuant to the registration rights agreement, we have filed a registration statement, which includes this prospectus, with the SEC relating to the resale by Kingsbridge of any shares of common stock purchased by Kingsbridge under the common stock purchase agreement or issued to Kingsbridge as a result of the exercise of the Kingsbridge warrant. The effectiveness of this registration statement is a condition precedent to our ability to sell common stock to Kingsbridge under the common stock purchase agreement. We are entitled in certain circumstances, including the existence of certain kinds of nonpublic information, to deliver a blackout notice to Kingsbridge to suspend the use of this prospectus and prohibit Kingsbridge from selling shares under this prospectus. If we deliver a blackout notice in the 15 trading days following a settlement of a draw down, or if the registration statement of which this prospectus is a part is not effective in circumstances not permitted by the registration rights agreement, then we must pay certain amounts to Kingsbridge (or issue Kingsbridge additional shares in lieu of payment) as liquidated damages.

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The foregoing summary of the CEFF does not purport to be complete and is qualified by reference to the common stock purchase agreement, the registration rights agreement and the warrant, copies of which have been filed as exhibits to the registration statement of which this prospectus is a part.

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**RISK FACTORS**

*Investing in our common stock involves a high degree of risk. You should consider carefully the risk factors described below, and all other information contained in or incorporated by reference in this prospectus, before deciding to invest in our common stock. If any of the following risks actually occur, the market price of our common stock could decline, and you could lose all or part of your investment. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations and could result in a complete loss of your 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 September 30, 2005, we have accumulated a deficit of \$152.5 million. We have not generated and may not be able to generate any revenues from operations and may not be able to attain profitability. We incurred a net loss of \$33.0 million during the nine months ended September 30, 2005. 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 or maintain governmental regulatory approvals to market Increlex in the United States or rest of the world 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 another company overcomes our U.S. orphan drug marketing exclusivity or obtains marketing exclusivity in Europe, it will be able to compete with us, and our revenues will be diminished.*

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. Increlex has received from the FDA orphan drug marketing exclusivity for the long-term treatment of patients with severe Primary IGFD. This marketing exclusivity relates to approximately the same number of pediatric patients, and accurately describes the same pediatric patient population for which we submitted our NDA and received marketing approval. However, more than one product may be approved by the FDA for the same orphan indication or disease. As a result, even though our product has been approved and has received marketing exclusivity for severe Primary IGFD, the FDA can still approve other drugs for use in treating the same indication or disease covered by our product, which would create a more competitive market for us.

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We are aware of a drug being developed by Inmed Incorporated, which we believe is a combination product containing rhIGF-1 that is in development for the treatment of severe Primary IGFD. Inmed has announced that: it has submitted an NDA for its combination product and that the FDA has determined that their drug is approvable on December 12, 2005 for the treatment of severe Primary IGFD if Inmed has met certain FDA requests. Inmed's product has received an orphan drug designation from the FDA that covers the treatment of severe Primary IGFD.

In May 2005, the FDA notified us that it considered Inmed's product to be the same drug as Increlex with respect to orphan drug marketing exclusivity. However, we may not be able to benefit from our orphan drug marketing exclusivity in the United States if the FDA determines that, with respect to orphan drug exclusivity, the two drugs are not the same. Furthermore, drugs considered to be the same as Increlex that are clinically superior or provide a major contribution to patient care may be approved for marketing by the FDA despite our initial orphan drug marketing exclusivity. If another company overcomes our U.S. orphan drug exclusivity, they will be able to compete with us, and our revenues will be diminished.

We believe that Inmed's drug has also received an orphan drug designation in Europe from the European Medicines Agency, or EMEA, that covers the treatment of severe Primary IGFD. We have not submitted a marketing authorization in Europe for severe

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Primary IGFD or any other indication. If Inmed's product is ultimately granted orphan drug marketing exclusivity for severe Primary IGFD in Europe, we may not be able to market or sell Increlex for severe Primary IGFD in Europe, and our revenues will be diminished.

*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 and extrapolation of data 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 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;

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. Since the FDA approved 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. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize Increlex.

We believe that the annual wholesale acquisition cost of Increlex therapy for the treatment of severe Primary IGFD for a 24 kilogram child would be approximately \$23,000 per year. The actual cost per year per patient for Increlex will depend on the weight of the child, the treatment dose prescribed and compliance. 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.

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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 do not receive additional regulatory marketing approvals of Increlex, our business will be harmed.***

We are currently developing Increlex in clinical trials for the treatment of Primary IGFD, which has substantially more patients than severe Primary IGFD. The FDA has substantial discretion in the approval process and may decide that our data is insufficient to allow approval of Increlex for Primary IGFD. If we do not receive regulatory marketing approval in the United States for Primary IGFD, our business will be harmed. We will also need to file applications with regulatory authorities in foreign countries to market Increlex for Primary IGFD in foreign countries. We have not submitted a marketing authorization application in Europe for severe Primary IGFD or any other indication. If we fail to obtain European approval for Increlex, the geographic market for Increlex would be limited. If such approvals are delayed, it would postpone our ability to generate revenues in Europe.

***If our contract manufacturers facilities and operations do not maintain satisfactory cGMP compliance, we may be unable to commercialize Increlex.***

The facilities used by and operations of our contract manufacturers to manufacture and test Increlex must undergo continuing inspections by the FDA for compliance with cGMP regulations in order to maintain our Increlex approval. As an example, Cambrex Baltimore is our sole provider of bulk rhIGF-1. We have no alternative manufacturing facilities or plans for additional facilities at this time. We do not know if the Cambrex Baltimore facilities or their operations required for the commercial manufacture of Increlex will continue to receive satisfactory cGMP inspections. In the event these facilities or operations do not continue to receive satisfactory cGMP inspections for the manufacture of our product, or for the operation of their facilities in general, we may need to invest in significant compliance improvement programs, fund additional modifications to our manufacturing processes, conduct additional validation studies, or find alternative manufacturing facilities, any of which would result in significant cost to us as well as result in a delay or prevention of commercialization, and may result in our failure to maintain approval. 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 cGMP regulations and similar foreign standards. We do not have direct control over our contract manufacturers compliance with these regulations and standards. Any of these factors could delay or suspend clinical trials, regulatory submissions or regulatory approvals, entail higher costs and result in our being unable to effectively commercialize Increlex or maintain Increlex in the marketplace, which would adversely affect our ability to generate revenues.

***We rely solely on single-source third parties in the manufacture, testing, storage and distribution of our products.***



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We source all of our fill-finish manufacturing and testing and final product storage and distribution operations, as well as our all of our bulk manufacturing, testing, and shipping operations, through single-source third-party suppliers and contractors. Single-source suppliers are the only approved suppliers currently available to us, and could only be replaced by qualification of new sites for the same operations.

If our contract facilities, contractors or suppliers become unavailable to us for any reason, including failure to comply with cGMP regulations, manufacturing problems or other operational failures, such as equipment failures or unplanned facility shutdowns required to comply with cGMP, damage from any event, including fire, flood, earthquake, or terrorism or if they fail to perform under our agreements with them, such as failing to deliver commercial quantities of bulk drug substance or finished product on a timely basis and at commercially reasonable prices, we may be delayed in manufacturing Increlex or may be unable to maintain validation of Increlex. This could delay or prevent the supply of commercial and clinical product, 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

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refuse to perform under our licenses and/or 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 pre-approval and/or 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.

*We rely in certain cases on single-source and sole-source materials suppliers to manufacture Increlex.*

Certain specific components and raw materials used to manufacture Increlex at our third-party manufacturers are obtained and made available through either single-source or sole-source suppliers. Single-source suppliers are the only approved suppliers currently available to us, and could only be supplemented by qualification of new sources for the material required. Sole-source suppliers are the only source of supply available to us, and could only be replaced through qualification of an alternate material after demonstrating suitability. Supply interruption of these materials could result in a significant delay to our manufacturing schedules and ability to supply product, and would likely be required to undergo lengthy regulatory approval procedures prior to product distribution. Limits or termination of supply of these materials could significantly impact our ability to manufacture Increlex, cause significant supply delays while we qualified, at significant expense, new suppliers or new materials, and would consequently cause harm to our business.

*Difficulties or delays in product manufacturing due to advance scheduling requirements and/or capacity constraints at our third-party manufacturers could harm our operating results and financial performance.*

The manufacture of Increlex requires successful coordination between us and all of our suppliers, contractors, service-providers, and manufacturers. Coordination failures with these different elements of our supply chain could require us to delay shipments and/or impair our ability to supply product. Furthermore, uncertainties in estimating future demand for new products such as Increlex may result in manufacture of surplus inventory requiring us to record charges for any expired, unused product, or may result in inadequate manufacturing of product inventory, causing delays to shipments or no shipments at all. Additionally, our reliance on third-party manufacturing requires long lead times from order to delivery of product, and may be hampered by available capacity at those manufacturers, making our ability to supply product supplies in excess of our forecast extremely difficult. As a consequence, we may have inadequate capacity to meet unexpected demand, which could negatively affect our operating results.

*Claims and concerns may arise regarding the safety and efficacy of Increlex, which could require us to perform additional clinical trials, could slow introduction into the marketplace, or cause reduced sales or product withdrawal after introduction.*

Increlex was approved in the United States for the treatment of severe Primary IGF1 based on long-term and extensive studies and clinical trials conducted to demonstrate product safety and efficacy. Discovery of previously unknown problems with the raw materials, product or manufacturing processes, such as loss of sterility, contamination, new data suggesting an unacceptable safety risk or previously unidentified side effects for the product, could result in a voluntary or mandated withdrawal of the product from the marketplace, either temporarily or permanently. Studies may result in data or evidence suggesting another product is safer, better tolerated, or more efficacious than Increlex, which could lead to reduced sales. Additionally, discovery of unknown problems with our product or manufacturing processes for our product could negatively impact the established safety and efficacy profile and result in possible reduced sales or product withdrawal. Such outcomes could negatively and materially affect our product sales, operating results, and financial condition.

*We will not be able to sell our products if we are not able to maintain our regulatory approval due to changes to existing regulatory requirements.*

Although we have obtained regulatory approval for Increlex in the United States for the treatment of severe Primary IGFD, this product and our manufacturing processes are subject to continued review and ongoing regulation by the FDA post approval, including, for example, changes to manufacturing process standards or good manufacturing practices, changes to product labeling, revisions to existing requirements or new requirements for manufacturing practices, or changing interpretations regarding regulatory guidance. Such changes in the regulatory environment and requirements could occur at any time during the commercialization of Increlex. This could adversely affect our ability to maintain our approval or require us to expend significant resources to maintain our approval, which could result in the possible withdrawal of Increlex from the marketplace, which would harm our business and negatively impact our financial performance.

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*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.

We cannot predict the relative competitive position of Increlex. However, we expect that the following factors, among others, will determine our ability to compete effectively:

safety and efficacy;

product price;

manufacturing costs;

reimbursement adoption;

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.

Growth hormone will likely compete with Increlex for the treatment of patients with severe Primary IGFD and those with Primary IGFD if Increlex is approved for that indication. The major suppliers of commercially available growth hormone in the United States are Genentech, Eli Lilly and Company, Teva Pharmaceutical Industries Ltd., Novo Nordisk A/S, Pfizer Inc. and Serono S.A. Investigators from a Novo Nordisk clinical trial recently presented data that demonstrated growth hormone was effective in a population that included children with Primary IGFD. In addition, children with Primary IGFD may be diagnosed as having idiopathic short stature, or ISS, which will also cause growth hormone to be competitive with Increlex. Eli Lilly and Company and Genentech have received FDA approval for their respective growth hormone products for the treatment of children with ISS.

Insmed's combination product will compete for the treatment of patients with severe Primary IGFD if it is approved by the FDA. 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.

In addition, we believe that Bristol-Meyers Squibb Company, Genentech, Merck & Co., Inc., Novo Nordisk and Pfizer Inc. have conducted research and development of orally available small molecules that cause the release of growth hormone, known as growth hormone secretagogues. 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. Inmed 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 products containing 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 product containing rhIGF-1 to treat the indications for which Increlex has received and may receive approval. This is commonly referred to as off-label use. While under FDA regulations a competitor is not allowed to promote off-label use of its

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product, the FDA does not regulate the practice of medicine and as a result cannot direct physicians as to what product containing rhIGF-1 to prescribe to their patients. As a result, we would have limited ability to prevent off-label use of a competitor's product containing rhIGF-1 to treat any diseases for which we have received FDA approval even if it violates our method of use patents and/or we have orphan drug exclusivity for the use of rhIGF-1 to treat such diseases.

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

If 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 Insmmed Incorporated in the United Kingdom and against Insmmed 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 initiate litigation 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

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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.*



## Edgar Filing: TERCICA INC - Form S-3

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, which we have accomplished, and for either a diabetes indication or a substitute indication by December 31, 2008. 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.

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*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 (e.g., in one of our current Phase III clinical trials of rhIGF-1 in Primary IGF1, patients have not enrolled at the rate we expected);

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, or available drug may become unusable;

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. 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.

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*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 may be unable to obtain or maintain required approvals and may be unable to commercialize Increlex on a timely basis, if at all.

*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.

In addition, we may need additional intellectual property from other third parties to commercialize Increlex for indications other than severe Primary IGF1D or Primary IGF1D. We cannot be certain 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 our cash, cash equivalents and short-term investments as of September 30, 2005 of \$71.0 million and the proceeds available under our senior credit facility and the CEFF will be sufficient to meet our projected operating and capital expenditure 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:

our ability to market and sell sufficient quantities of rhIGF-1;

the costs, timing and scope of additional domestic and international regulatory approvals for rhIGF-1;

the status of competing products;

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; and

the pace of expansion of administrative expenses.

We expect that we will require and attempt to raise additional funds through equity or debt financings, collaborative arrangements with corporate partners or from other sources, including our senior credit facility and the CEFF. However, there can be no assurance that 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.

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*The committed equity financing facility that we entered into with Kingsbridge may not be available to us if we elect to make a draw down, and may require us to pay certain liquidated damages.*

The CEFF entitles us to sell and obligates Kingsbridge to purchase, from time to time over a period of three years, newly issued shares of our common stock for cash consideration of up to an aggregate of \$75.0 million, subject to certain conditions and restrictions. Kingsbridge will not be obligated to purchase shares under the CEFF unless certain conditions are met, which include:

a minimum price for our common stock;

the accuracy of representations and warranties made to Kingsbridge;

compliance with laws;

effectiveness of the registration statement of which this prospectus is a part; and

the continued listing of our stock on the Nasdaq Stock Market.

In addition, Kingsbridge is permitted to terminate the CEFF if it determines that a material and adverse event has occurred affecting our business, operations, properties or financial condition. If we are unable to access funds through the CEFF, or if the CEFF is terminated by Kingsbridge, we may be unable to access capital on favorable terms or at all.

The terms of the CEFF require us to pay certain liquidated damages in the event that the registration statement of which this prospectus is a part is not available for the resale of securities purchased by Kingsbridge under the CEFF or upon exercise of the warrant we issued to Kingsbridge. Except for certain periods of ineffectiveness permitted under the CEFF, we are obligated to pay to Kingsbridge an amount equal to the number of shares purchased under the CEFF and held by Kingsbridge at the date the registration statement of which this prospectus is a part becomes unavailable, multiplied by any positive difference in price between the volume weighted average price on the trading day prior to such period of unavailability and the volume weighted average price on the first trading day after the period of unavailability. In addition, we are entitled in certain circumstances to deliver a "blackout" notice to Kingsbridge to suspend the use of the registration statement of which this prospectus is a part and prohibit Kingsbridge from selling shares under this prospectus. If we deliver a blackout notice in the 15 trading days following a settlement of a draw down, then we must make a blackout payment to Kingsbridge as liquidated damages, or issue Kingsbridge additional shares in lieu of this payment, calculated by means of a varying percentage of an amount based on the number of shares purchased and held by Kingsbridge and the change in the market price of our common stock during the period in which the use of the registration statement is suspended. If the trading price of our common stock declines during a suspension of the registration statement, the blackout payment could be significant and could adversely affect our liquidity and our ability to raise capital.

*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 September 30, 2005, we had 74 full-time employees, and we may need to hire 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.

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 may need to hire a significant number of additional employees. To manage the anticipated growth of our operations, we will need to increase management resources 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 study results from the treatment of 76 children with severe Primary IGFD with rhIGF-1 replacement therapy for an average of 4.4 years, with some patients being treated for over 12 years. None of the 76 children withdrew from treatment due to adverse events. However, some patients experienced hypoglycemia, or low blood glucose levels. Other side effects noted in some patients include hearing deficits, enlargement of the tonsils and intracranial hypertension.

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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 upgraded our finance and accounting systems, procedures and controls and will need to continue to implement additional procedures and controls as we grow our business and organization and to satisfy new reporting requirements. Compliance with Section 404 will apply to us as of December 31, 2005, and Section 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 and Dr. Ross G. Clark, our Chief Technical Officer, whose knowledge of our industry and technical expertise would be extremely difficult to replace. We have at will employment contracts with all of our executive officers. They may terminate their employment without cause or good reason and without notice to us.



**Risks Related to Our Common Stock**

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

While research analysts and others have published forecasts as to the amount and timing of our future revenues and earnings, we have stated that we will not be providing any forecasts of the amount and timing of our future revenues and earnings until after two quarters of our sales and marketing efforts. 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.

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*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 September 30, 2005, our directors, executive officers and principal stockholders and their affiliates beneficially owned approximately 65.4% of our common stock. Our greater than five percent beneficial owners include entities affiliated with MPM Capital, which beneficially owned 21.7%; entities affiliated with Prospect Management Co. II, LLC, which beneficially owned 12.1%; MedImmune, Inc., which beneficially owned 9.5%; and entities affiliated with Rho Ventures, which beneficially owned 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.

*The committed equity financing facility that we entered into with Kingsbridge may result in dilution to our stockholders.*

Pursuant to the CEFF, Kingsbridge committed to purchase, subject to certain conditions, up to \$75.0 million of our common stock. Should we sell shares to Kingsbridge under the CEFF, or issue shares in lieu of any blackout payment, it will have a dilutive effect on the holdings of our current stockholders, and may result in downward pressure on the price of our common stock. If we draw down amounts under the CEFF, we

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will issue shares to Kingsbridge at a discount of up to ten percent from the volume weighted average price of our common stock. If we draw down amounts under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Issuances in the face of a declining share price will have an even greater dilutive effect than if our share price were stable or increasing, and may further decrease our share price.

*Our stock price may be volatile, and an 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:

if Insmed's combination product receives FDA marketing approval;

estimates of our business potential and earnings prospects;

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

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deviations from analysts' projections regarding business potential, costs and/or 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;

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.

***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 or issued pursuant to the CEFF, the market price of our common stock may decline. In addition, the perceived risk of dilution from sales of our common stock to or by Kingsbridge in connection with the CEFF may cause holders of our common stock to sell their shares, or it may encourage short selling by market participants, which could contribute to a decline in our stock price. 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 September 30, 2005, we had 31,653,870 outstanding shares of common stock. Of these shares, the 13,225,000 shares sold in our public offerings that were outstanding as of September 30, 2005 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 18,428,870 shares outstanding as of September 30, 2005 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. In September 2005, we filed a shelf registration statement pursuant to which we may, from time-to-time after the SEC declares the shelf registration statement effective, sell shares of our common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, in one or more offerings, with a total value of up to \$75.0 million. We also filed a registration statement of which this prospectus is a part for the resale of the shares of common stock issuable in connection with the CEFF and the shares of common stock underlying the warrant we issued to Kingsbridge in connection with our entering into the CEFF. In addition, certain holders of shares of our common stock that are parties to our amended and restated investors' rights agreement are entitled to registration rights.

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**FORWARD-LOOKING STATEMENTS**

This prospectus, including the information that we incorporate by reference, contains various forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as anticipates, believes, continue estimates, expects, intends, may, plan, predicts, should, will, or the negative of these terms or other comparable terminology. These forward-looking statements may also use different phrases. Discussions containing these forward-looking statements may be found, among other places, in Business and Management's Discussion and Analysis of Financial Condition and Results of Operations incorporated by reference from our most recent annual report on Form 10-K and in our most recent quarterly report on Form 10-Q subsequent to the filing of our most recent annual report on Form 10-K with the SEC, as well as any amendments thereto reflected in subsequent filings with the SEC. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. Forward-looking statements include, but are not limited to, statements about:

adequate commercial supply of Increlex;

third-party payor reimbursement for Increlex;

our estimates regarding anticipated capital requirements and our need for additional financing;

short stature patient market size and market adoption of Increlex by physicians and patients; and

development and approval of the use of Increlex for additional indications.

Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to differ materially from any future results, performance or achievements expressed or implied by such forward-looking statements. These risks include those risks discussed under the heading Risk Factors and elsewhere in this prospectus. Because the factors referred to above could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statements. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and, except as required by law, we undertake no obligation to publicly revise our forward-looking statements to reflect events or circumstances that arise after the date of this prospectus or the date of documents incorporated by reference in this prospectus that include forward-looking statements.

**USE OF PROCEEDS**

We will not receive any of the proceeds from the sale of shares of our common stock by the selling stockholder pursuant to this prospectus. Any sale of shares by us to Kingsbridge under the common stock purchase agreement or in connection with the exercise of the Kingsbridge warrant

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will be made pursuant to an exemption from the registration requirements of the Securities Act. We will use the proceeds from these sales for general corporate purposes, including clinical trials, production and supply activities, sales and marketing activities, research and development activities, regulatory affairs expenses and general and administrative expenses. The amounts and timing of our actual expenditures will depend on numerous factors, such as the progress of our product development and commercialization efforts and the amount of cash used by our operations. We may also use a portion of the net proceeds to acquire or invest in businesses, products and technologies that are complementary to our own, although we currently are not planning or negotiating any such transactions. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to us from the sale of shares to Kingsbridge. Accordingly, we will retain broad discretion over the use of these proceeds, if any.

**Table of Contents****SELLING STOCKHOLDER**

This prospectus relates to the possible resale by the selling stockholder, Kingsbridge Capital Limited, of shares of common stock that we may issue pursuant to the common stock purchase agreement we entered into with Kingsbridge on October 14, 2005, or upon exercise of the warrant that we issued to Kingsbridge on October 14, 2005. We are filing the registration statement of which this prospectus is a part pursuant to the provisions of the registration rights agreement we entered into with Kingsbridge.

The selling stockholder may from time to time offer and sell pursuant to this prospectus any or all of the shares that it acquires under the common stock purchase agreement or upon exercise of the warrant.

The following table presents information regarding Kingsbridge, as the selling stockholder, and the shares that it may offer and sell from time to time under this prospectus. This table is prepared based on information supplied to us by the selling stockholder, and reflects holdings as of September 30, 2005. As used in this prospectus, the term selling stockholder includes Kingsbridge and any donees, pledges, transferees or other successors in interest selling shares received after the date of this prospectus from a selling stockholder as a gift, pledge, or other non-sale related transfer. The number of shares in the column Number of Shares Being Offered represents all of the shares that a selling stockholder may offer under this prospectus. The selling stockholder may sell some, all or none of its shares. We do not know how long the selling stockholder will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholder regarding the sale of any of the shares.

Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Securities Exchange Act of 1934, as amended. The percentage of shares beneficially owned prior to the offering is based both on 31,653,870 shares of our common stock actually outstanding as of September 30, 2005 and on the assumption that all shares of common stock issuable under the common stock purchase agreement we entered into with Kingsbridge on October 14, 2005 and all shares of common stock issuable upon exercise of the warrant held by Kingsbridge are outstanding as of that date.

<u>Security Holder</u>	<u>Shares of Common Stock</u>		<u>Number of Shares</u>	<u>Shares of Common Stock</u>	
	<u>Beneficially Owned</u>			<u>Shares Beneficially</u>	
	<u>Prior to Offering</u>		<u>Being Offered</u>	<u>Owned After Offering</u>	
	<u>Number</u>	<u>Percent</u>		<u>Number</u>	<u>Percent</u>
<u>Kingsbridge Capital Limited(1)</u>	6,296,912(2)	16.6%	6,296,912(2)		%

- (1) The address of Kingsbridge is Kingsbridge Capital Limited, c/o Kingsbridge Corporate Services Limited, Main Street, Kilcullen, County Kildare, Republic of Ireland.
- (2) Consists of 6,036,912 shares of common stock, the maximum number of shares of common stock issuable under the common stock purchase agreement we entered into with Kingsbridge on October 14, 2005, and 260,000 shares of common stock issuable upon exercise of the warrant we issued to Kingsbridge on October 14, 2005, which warrant is not exercisable before April 14, 2006. For the purposes hereof, we assume the issuance of all 6,296,912 shares. Maria O Donoghue and Adam Gurney have shared voting and investment control of the securities held by Kingsbridge. Kingsbridge does not accept third party investments.



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**PLAN OF DISTRIBUTION**

We are registering 6,296,912 shares of common stock under this prospectus on behalf of Kingsbridge. Except as described below, to our knowledge, the selling stockholder has not entered into any agreement, arrangement or understanding with any particular broker or market maker with respect to the shares of common stock offered hereby, nor, except as described below, do we know the identity of the brokers or market makers that will participate in the sale of the shares.

The selling stockholder may decide not to sell any shares. The selling stockholder may from time to time offer some or all of the shares of common stock through brokers, dealers or agents who may receive compensation in the form of discounts, concessions or commissions from the selling stockholder and/or the purchasers of the shares of common stock for whom they may act as agent. In effecting sales, broker-dealers that are engaged by the selling stockholder may arrange for other broker-dealers to participate. Kingsbridge is an underwriter within the meaning of the Securities Act. Any brokers, dealers or agents who participate in the distribution of the shares of common stock may also be deemed to be underwriters, and any profits on the sale of the shares of common stock by them and any discounts, commissions or concessions received by any such brokers, dealers or agents may be deemed to be underwriting discounts and commissions under the Securities Act. Kingsbridge has advised us that it may effect resales of our common stock through any one or more registered broker-dealers. To the extent the selling stockholder may be deemed to be an underwriter, the selling stockholder will be subject to the prospectus delivery requirements of the Securities Act and may be subject to certain statutory liabilities of, including but not limited to, Sections 11, 12 and 17 of the Securities Act and Rule 10b-5 under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

The selling stockholder will act independently of us in making decisions with respect to the timing, manner and size of each sale. Such sales may be made over the Nasdaq Stock Market, on the over-the-counter market, otherwise, or in a combination of such methods of sale, at then prevailing market prices, at prices related to prevailing market prices or at negotiated prices. The shares of common stock may be sold according to one or more of the following methods:

a block trade in which the broker or dealer so engaged will attempt to sell the shares of common stock as agent but may position and resell a portion of the block as principal to facilitate the transaction;

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

an over-the-counter distribution in accordance with the rules of the Nasdaq;

ordinary brokerage transactions and transactions in which the broker solicits purchasers;

privately negotiated transactions;

a combination of such methods of sale; and

any other method permitted pursuant to applicable law.

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Any shares covered by this prospectus which qualify for sale pursuant to Rule 144 of the Securities Act may be sold under Rule 144 rather than pursuant to this prospectus. In addition, the selling stockholder may transfer the shares by other means not described in this prospectus.

Any broker-dealer participating in such transactions as agent may receive commissions from Kingsbridge (and, if they act as agent for the purchaser of such shares, from such purchaser). Broker-dealers may agree with Kingsbridge to sell a specified number of shares at a stipulated price per share, and, to the extent such a broker-dealer is unable to do so acting as agent for Kingsbridge, to purchase as principal any unsold shares at the price required to fulfill the broker-dealer commitment to Kingsbridge. Broker-dealers who acquire shares as principal may thereafter resell such shares from time to time in transactions (which may involve crosses and block transactions and which may involve sales to and through other broker-dealers, including transactions of the nature described above) on the Nasdaq Stock Market, on the over-the-counter market, in privately-negotiated transactions or otherwise at market prices prevailing at the time of sale or at negotiated prices, and in connection with such resales may pay to or receive from the purchasers of such shares commissions computed as described above. To the extent required under the Securities Act, an amendment to this prospectus, or a supplemental prospectus will be filed, disclosing:

the name of any such broker-dealers;

the number of shares involved;

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the price at which such shares are to be sold;

the commission paid or discounts or concessions allowed to such broker-dealers, where applicable;

that such broker-dealers did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, as supplemented; and

other facts material to the transaction.

Underwriters and purchasers that are deemed underwriters under the Securities Act may engage in transactions that stabilize, maintain or otherwise affect the price of the securities, including the entry of stabilizing bids or syndicate covering transactions or the imposition of penalty bids. Kingsbridge and any other persons participating in the sale or distribution of the shares will be subject to the applicable provisions of the Exchange Act and the rules and regulations thereunder including, without limitation, Regulation M. These provisions may restrict certain activities of, and limit the timing of, purchases by the selling stockholder or other persons or entities. Furthermore, under Regulation M, persons engaged in a distribution of securities are prohibited from simultaneously engaging in market making and certain other activities with respect to such securities for a specified period of time prior to the commencement of such distributions, subject to special exceptions or exemptions. Regulation M may restrict the ability of any person engaged in the distribution of the securities to engage in market-making and certain other activities with respect to those securities. In addition, the anti-manipulation rules under the Exchange Act may apply to sales of the securities in the market. All of these limitations may affect the marketability of the shares and the ability of any person to engage in market-making activities with respect to the securities.

We have agreed to pay the expenses of registering the shares of common stock under the Securities Act, including registration and filing fees, printing expenses, administrative expenses and certain legal and accounting fees, as well as certain fees of counsel for the selling stockholder incurred in the preparation of the CEFF agreements and the registration statement of which this prospectus forms a part. The selling stockholder will bear all discounts, commissions or other amounts payable to underwriters, dealers or agents, as well as transfer taxes and certain other expenses associated with the sale of securities.

Under the terms of the Kingsbridge common stock purchase agreement and the registration rights agreement, we have agreed to indemnify the selling stockholder and certain other persons against certain liabilities in connection with the offering of the shares of common stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute toward amounts required to be paid in respect of such liabilities.

At any time a particular offer of the shares of common stock is made, a revised prospectus or prospectus supplement, if required, will be distributed. Such prospectus supplement or post-effective amendment will be filed with the SEC, to reflect the disclosure of required additional information with respect to the distribution of the shares of common stock. We may suspend the sale of shares by the selling stockholder pursuant to this prospectus for certain periods of time for certain reasons, including if the prospectus is required to be supplemented or amended to include additional material information.

**LEGAL MATTERS**

The validity of the securities being offered hereby will be passed upon by Cooley Godward LLP, Palo Alto, California.

### **EXPERTS**

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2004, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

### **WHERE YOU CAN FIND MORE INFORMATION**

We file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any document we file at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference room. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including Tercica. The SEC's Internet site can be found at <http://www.sec.gov>.

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We incorporate by reference into this prospectus the documents listed below and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, including any filings after the date of this prospectus but before the end of any offering made under this prospectus. The SEC file number for the documents incorporated by reference in this prospectus is 0-50461. We incorporate by reference the following information that has been filed with the SEC:

our current report on Form 8-K filed with the SEC on January 11, 2005;

our current report on Form 8-K filed with the SEC on January 24, 2005;

our current report on Form 8-K filed with the SEC on February 8, 2005;

our current reports on Form 8-K filed with the SEC on February 17, 2005 (except for the information furnished under Item 2.02 or any related exhibit);

our current report on Form 8-K filed with the SEC on February 28, 2005;

our current report on Form 8-K filed with the SEC on March 11, 2005;

our current report on Form 8-K filed with the SEC on March 18, 2005;

our annual report on Form 10-K for the year ended December 31, 2004 filed with the SEC on March 24, 2005 (the 2004 10-K );

our current report on Form 8-K filed with the SEC on April 19, 2005;

the information specifically incorporated by reference into our 2004 Form 10-K from our definitive proxy statement on Schedule 14A filed with the SEC on April 29, 2005;

our current report on Form 8-K filed with the SEC on May 3, 2005;

our quarterly report on Form 10-Q for the quarterly period ended March 31, 2005 filed with the SEC on May 16, 2005;

our current report on Form 8-K filed with the SEC on May 19, 2005;

our current report on Form 8-K filed with the SEC on May 26, 2005;

our current report on Form 8-K filed with the SEC on June 3, 2005;

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our current report on Form 8-K filed with the SEC on June 17, 2005;

our quarterly report on Form 10-Q for the quarterly period ended June 30, 2005 filed with the SEC on August 4, 2005;

our current report on Form 8-K filed with the SEC on August 15, 2005;

our current report on Form 8-K filed with the SEC on August 17, 2005;

our current report on Form 8-K filed with the SEC on August 22, 2005;

our current report on Form 8-K filed with the SEC on August 31, 2005;

our current report on Form 8-K filed with the SEC on October 18, 2005;

our quarterly report on Form 10-Q for the quarterly period ended September 30, 2005 filed with the SEC on November 4, 2005; and

the description of our common stock, which is registered under Section 12 of the Exchange Act in our registration statement on Form 8-A, filed with the SEC on March 3, 2004, including any amendments or reports filed for the purpose of updating such description.

Any information in any of the foregoing documents will automatically be deemed to be modified or superseded to the extent that information in this prospectus or in a later filed document that is incorporated or deemed to be incorporated herein by reference modifies or replaces such information.

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We also incorporate by reference any future filings (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items) made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, until we file a post-effective amendment which indicates the termination of the offering of the securities made by this prospectus. Information in such future filings updates and supplements the information provided in this prospectus. Any statements in any such future filings will automatically be deemed to modify and supersede any information in any document we previously filed with the SEC that is incorporated or deemed to be incorporated herein by reference to the extent that statements in the later filed document modify or replace such earlier statements.

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, without charge upon written or oral request, a copy of any or all of the documents that are incorporated by reference into this prospectus but not delivered with the prospectus, including exhibits which are specifically incorporated by reference into such documents. Requests should be directed to: Investor Relations, Tercica, Inc., 2000 Sierra Point Parkway, Suite 400, Brisbane, CA 94005, telephone: (650) 624-4900.

**Table of Contents****PART II****INFORMATION NOT REQUIRED IN THE PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution.**

The following table sets forth the estimated costs and expenses payable by the registrant in connection with the common stock being registered. The selling stockholder will not bear any portion of such expenses. All the amounts shown are estimates, except for the SEC registration fee.

SEC Registration Fee	\$ 7,715.34
Nasdaq National Market Listing Fee	45,000.00
Accounting Fees and Expenses	15,000.00
Legal Fees and Expenses	35,000.00
Transfer Agent Fees and Expenses	5,000.00
Printing and miscellaneous expenses	2,284.66
	<hr/>
<b>Total</b>	<b>\$ 110,000.00</b>
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**Item 15. Indemnification of Directors and Officers.**

As permitted by Section 145 of the Delaware General Corporation Law, the registrant's restated certificate of incorporation includes a provision that eliminates the personal liability of its directors for monetary damages for breach of their fiduciary duty as directors. In addition, as permitted by Section 145 of the Delaware General Corporation Law, the bylaws of the registrant provide that: (1) the registrant is required to indemnify its directors and officers for serving the registrant in those capacities or for serving other business enterprises at the registrant's request, to the fullest extent permitted by Delaware law, including in those circumstances in which indemnification would otherwise be discretionary; (2) the registrant may, in its discretion, indemnify employees and agents in those circumstances where indemnification is not required by law; (3) the registrant is required to advance expenses, as incurred, to its directors and officers in connection with defending a proceeding, except that such director or officer shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification; (4) the registrant will not be obligated pursuant to the bylaws to indemnify a person with respect to proceedings initiated by that person, except with respect to proceedings authorized by the registrant's board of directors or brought to enforce a right to indemnification; (5) the rights conferred in the bylaws are not exclusive, and the registrant is authorized to enter into indemnification agreements with its directors, officers, employees and agents and to obtain insurance to indemnify such persons; and (6) the registrant may not retroactively amend the bylaw provisions to reduce its indemnification obligations to directors, officers, employees and agents in these matters arising prior to such time.

The registrant's policy is to enter into indemnification agreements with each of its directors and executive officers that provide the maximum indemnity allowed to directors and executive officers by Section 145 of the Delaware General Corporation Law and the bylaws, as well as certain additional procedural protections. The registrant has also obtained directors and officers insurance to insure such persons against certain liabilities.

The amended and restated investors' rights agreement between the registrant and certain investors provides for cross-indemnification in connection with registration of the registrant's common stock on behalf of such investors. In addition, the common stock purchase agreement and



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the registration rights agreement between the registrant and Kingsbridge Capital Limited provides for cross-indemnification in connection with the registration of the registrant's common stock on behalf of Kingsbridge Capital Limited and the entering into of the transactions contemplated by the common stock purchase agreement and the registration rights agreement.

The indemnification provisions noted above may be sufficiently broad to permit indemnification of the registrant's officers and directors for liabilities arising under the Securities Act of 1933, as amended.

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**Item 16. Exhibits.**

Exhibit Number	Description of the Document
3.1	Certificate of Incorporation (1)
3.2	Bylaws (2)
4.1	Form of Specimen Stock Certificate (2)
4.2	Reference is made to Exhibits 3.1 and 3.2
4.3	Warrant issued to Kingsbridge Capital Limited, dated October 14, 2005 (3)
5.1	Opinion of Cooley Godward LLP
10.13A	Common Stock Purchase Agreement, by and between Kingsbridge Capital Limited and the Registrant, dated October 14, 2005 (3)
10.13B	Registration Rights Agreement, by and between Kingsbridge Capital Limited and the Registrant, dated October 14, 2005 (3)
23.1	Consent of Independent Registered Public Accounting Firm
23.2	Consent of Cooley Godward LLP (included in Exhibit 5.1)
24.1	Power of Attorney (included on signature page)

- (1) Incorporated by reference to the Registrant's quarterly report on Form 10-Q (File No. 000-50461) filed on May 13, 2004.
- (2) Incorporated by reference to the Registrant's registration statement on Form S-1 (File No. 333-108729) and amendments thereto, declared effective on March 16, 2004.
- (3) Incorporated by reference to the Registrant's quarterly report on Form 10-Q (File No. 000-50461) filed on November 4, 2005.

**Item 17. Undertakings.**

The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
- (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
- (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price

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represent no more than 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement;

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

*Provided, however,* that paragraphs (1)(i) and (1)(ii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

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(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

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

(4) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

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

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**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Brisbane, State of California, on November 8, 2005.

**TERCICA, INC.**

By: /s/ John A. Scarlett

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John A. Scarlett, M.D.  
President and Chief Executive Officer

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**Table of Contents****POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints John A. Scarlett, M.D. and Stephen N. Rosenfield, and each of them, as true and lawful attorneys-in-fact and agents, with full powers of substitution and resubstitution, for them and in their name, place and stead, in any and all capacities, to sign any and all amendments (including pre-effective and post-effective amendments) to this registration statement and any additional registration statements filed pursuant to Rule 462, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission (the SEC), and generally to do all such things in their names and behalf in their capacities as officers and directors to enable the registrant to comply with the provisions of the Securities Act and all requirements of the SEC, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed below by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ John A. Scarlett</u>	President, Chief Executive Officer and Director	November 8, 2005
John A. Scarlett, M.D.	<i>(Principal Executive Officer)</i>	
<u>/s/ Susan Wong</u>	Acting Chief Financial Officer, Vice President,	November 8, 2005
Susan Wong	Finance and Controller <i>(Principal Accounting and Financial Officer)</i>	
<u>/s/ Michael J. Astrue</u>	Director	November 8, 2005
Michael J. Astrue		
<u>/s/ Alexander Barkas</u>	Director	November 8, 2005
Alexander Barkas, Ph.D.		
<u>/s/ Ross G. Clark</u>	Director	November 8, 2005
Ross G. Clark, Ph.D.		
<u>/s/ Karin Eastham</u>	Director	November 8, 2005
Karin Eastham		
<u>/s/ Dennis Henner</u>	Director	November 8, 2005
Dennis Henner, Ph.D.		

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/s/ Mark Leschly

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Director

November 8, 2005

Mark Leschly

/s/ David L. Mahoney

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Director

November 8, 2005

David L. Mahoney

/s/ Thomas G. Wiggans

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Director

November 8, 2005

Thomas G. Wiggans

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**EXHIBITS INDEX**

<b>Exhibit Number</b>	<b>Description of the Document</b>
3.1	Certificate of Incorporation (1)
3.2	Bylaws (2)
4.1	Form of Specimen Stock Certificate (2)
4.2	Reference is made to Exhibits 3.1 and 3.2
4.3	Warrant issued to Kingsbridge Capital Limited, dated October 14, 2005 (3)
5.1	Opinion of Cooley Godward LLP
10.13A	Common Stock Purchase Agreement, by and between Kingsbridge Capital Limited and the Registrant, dated October 14, 2005 (3)
10.13B	Registration Rights Agreement, by and between Kingsbridge Capital Limited and the Registrant, dated October 14, 2005 (3)
23.1	Consent of Independent Registered Public Accounting Firm
23.2	Consent of Cooley Godward LLP (included in Exhibit 5.1)
24.1	Power of Attorney (included on signature page)

- (1) Incorporated by reference to the Registrant's quarterly report on Form 10-Q (File No. 000-50461) filed on May 13, 2004.
- (2) Incorporated by reference to the Registrant's registration statement on Form S-1 (File No. 333-108729) and amendments thereto, declared effective on March 16, 2004.
- (3) Incorporated by reference to the Registrant's quarterly report on Form 10-Q (File No. 000-50461) filed on November 4, 2005.