GREENLIGHT CAPITAL RE, LTD. Form 10-K February 17, 2015

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 10-K

X ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2014

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number 001-33493

Greenlight Capital Re, Ltd. (Exact Name of Registrant as Specified in Its Charter)

Cayman Islands (State or Other Jurisdiction of Incorporation or Organization) N/A (I.R.S. Employer Identification No.)

65 Market Street, Suite 1207, Camana Bay P.O. Box 31110 Grand Cayman, KY1-1205 Cayman Islands (Address of Principal Executive Offices)

Registrant's telephone number, including area code: 345-943-4573

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

Title of Class Class A ordinary shares, \$0.10 par value per share Name of Exchange on Which Registered The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulations S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

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

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

Large accelerated filer x Accelerated filer o Non-accelerated filer o Smaller reporting company o

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

The aggregate market value of voting and non-voting Class A ordinary shares held by non-affiliates of the registrant as of June 30, 2014 was \$976,961,597 based on the closing price of the registrant's Class A ordinary shares reported on the Nasdaq Global Select Market on June 30, 2014, the last business day of the registrant's most recently completed second fiscal quarter. Solely for the purpose of this calculation and for no other purpose, the non-affiliates of the registrant are assumed to be all shareholders of the registrant other than (i) directors of the registrant, (ii) executive officers of the registrant who are identified as "named executives" pursuant to Item 11 of this Form 10-K, (iii) any shareholder that beneficially owns 10% or more of the registrant's common shares and (iv) any shareholder that has one or more of its affiliates on the registrant's board of directors. Such exclusion is not intended, nor shall it be deemed, to be an admission that such persons are affiliates of the registrant.

Class A Ordinary Shares, \$0.10 par value	31,159,035
Class B Ordinary Shares, \$0.10 par value	6,254,895
(Class)	Outstanding as of February 13, 2015

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement for the registrant's 2015 annual meeting of shareholders, to be filed subsequently with the Securities and Exchange Commission, or the SEC, pursuant to Regulation 14A, under the Securities Exchange Act of 1934, as amended, or the Exchange Act, relating to the registrant's annual general meeting of shareholders scheduled to be held on April 29, 2015 are incorporated by reference in Part III of this annual report on Form 10-K.

# GREENLIGHT CAPITAL RE, LTD.

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## PART I

Special Note About Forward-Looking Statements

Certain statements in Management's Discussion and Analysis, other than purely historical information, including estimates, projections, statements relating to our business plans, objectives and expected operating results, and the assumptions upon which those statements are based, are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements generally are identified by the words "believe," "project," "predict," "expect," "anticipate," "estimate," "intend," "plan," "may," "should," "will," "would," "will be," "will continue," "will likely result," and similar expressions. Forward-looking statements are based on current expectations and assumptions that are subject to risks and uncertainties which may cause actual results to differ materially from the forward-looking statements. A detailed discussion of risks and uncertainties that could cause actual results and events to differ materially from such forward-looking statements is included in the section entitled "Risk Factors" (refer to Part I, Item 1A) and include but are not limited to:

Our results will likely fluctuate from period to period and may not be indicative of our long-term prospects;

If our losses and loss adjustment expenses greatly exceed our loss reserves, our financial condition may be significantly and negatively affected;

The property and casualty reinsurance market may be affected by cyclical trends;

The effect of emerging claim and coverage issues on our business is uncertain;

Rating agencies may downgrade or withdraw either of our ratings;

We depend on DME Advisors, LP ("DME Advisors"), to implement our investment strategy;

Loss of key executives could adversely impact our ability to implement our business strategy; and

Currency fluctuations could result in exchange rate losses and negatively impact our business.

We caution that the foregoing list of important factors is not intended to be and is not exhaustive. We undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise and all subsequent written and oral forward-looking statements attributable to us or individuals acting on our behalf are expressly qualified in their entirety by this paragraph. If one or more risks or uncertainties materialize, or if our underlying assumptions prove to be incorrect, actual results may vary materially from what we projected. Any forward-looking statements in this Form 10-K reflect our current view with respect to future events and are subject to these and other risks, uncertainties and assumptions relating to our operations, results of operations, growth, strategy and liquidity. Readers are cautioned not to place undue reliance on the forward-looking statements which speak only to the dates on which they were made.

We intend to communicate certain events that we believe may have a material adverse impact on our operations or financial position, including property and casualty catastrophic events and material losses in our investment portfolio, in a timely manner through a public announcement. Other than as required by the Exchange Act, we do not intend to make public announcements regarding reinsurance or investments events that we do not believe, based on management's estimates and current information, will have a material adverse impact on our operations or financial position.

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## Item 1. BUSINESS

Unless otherwise indicated or unless the context otherwise requires, all references in this annual report on Form 10-K to "the Company," "we," "us," "our" and similar expressions are references to Greenlight Capital Re, Ltd. and its consolid subsidiaries. Unless otherwise indicated or unless the context otherwise requires, all references in this annual report to entity names are as set forth in the following table:

Reference Greenlight Capital Re Greenlight Re GRIL Verdant Entity's legal name Greenlight Capital Re, Ltd. Greenlight Reinsurance, Ltd. Greenlight Reinsurance Ireland, Ltd. Verdant Holding Company, Ltd.

## **Company Overview**

Greenlight Capital Re is a holding company that was incorporated in July 2004 under the laws of the Cayman Islands. In August 2004, we raised gross proceeds of \$212.2 million from private placements of Greenlight Capital Re's Class A ordinary shares and Class B ordinary shares, or, collectively, the ordinary shares. On May 24, 2007, Greenlight Capital Re raised proceeds of \$208.3 million, net of underwriting fees, in an initial public offering of Class A ordinary shares, as well as an additional \$50.0 million from a private placement of Class B ordinary shares.

We are a Cayman Islands headquartered global specialist property and casualty reinsurer with a reinsurance and investment strategy that we believe differentiates us from most of our competitors. We conduct our reinsurance operations through two licensed and regulated reinsurance entities: Greenlight Re, based in the Cayman Islands, and GRIL, based in Dublin, Ireland. Greenlight Re provides multi-line property and casualty reinsurance globally, while GRIL focuses mainly on the European market and serves clients located in Europe. Our goal is to build long-term shareholder value by selectively offering customized reinsurance solutions, in markets where capacity and alternatives are limited, which we believe will yield favorable long-term returns on equity.

We aim to complement our underwriting results with a non-traditional investment approach in order to achieve higher rates of return over the long term than reinsurance companies that employ more traditional, fixed-income investment strategies. We manage our investment portfolio according to a value-oriented philosophy, in which we take long positions in perceived undervalued securities and short positions in perceived overvalued securities.

In addition, from time to time, we may seek to form long-term strategic alliances with insurance companies and general agents to complement our property and casualty reinsurance business and our non-traditional investment approach. To facilitate such strategic alliances, we formed Verdant, which, among other activities, has made and may make strategic investments in a select group of property and casualty insurers and general agents in the United States.

Because we employ an opportunistic underwriting philosophy, period-to-period comparisons of our underwriting results may not be meaningful. In addition, our historical investment results may not necessarily be indicative of future performance. Due to the nature of our reinsurance and investment strategies, our operating results will likely fluctuate from period to period.

## Description of Business

Greenlight Re is licensed and regulated by the Cayman Islands Monetary Authority ("CIMA") to write property and casualty reinsurance business as well as long term business (e.g., life insurance, long term disability, long term care,

etc.); however, to date we have not written any long term business. GRIL is licensed and regulated by the Central Bank of Ireland ("CBI") to write property and casualty reinsurance business. Currently, we manage our business on the basis of one operating segment: property and casualty reinsurance. We currently offer excess of loss and quota share products in the property and casualty market. Our underwriting operations are designed to capitalize on inefficiencies that we perceive exist in the traditional approach to underwriting. We believe that we conduct our business differently from traditional reinsurers in multiple ways, including:

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we focus on offering customized reinsurance solutions to select customers at times and in markets where capacity and alternatives are limited rather than pursuing and participating in broadly available traditional property and casualty opportunities;

we aim to build a reinsurance portfolio of frequency and severity contracts with favorable ultimate economic results measured after all loss payments have been made rather than focusing on interim reported results when losses may be incurred but not yet reported or paid;

we seek to act as the lead underwriter on a majority of the contracts we underwrite in an effort to obtain greater influence in negotiating pricing, terms and conditions rather than focusing on taking a minority participation in contracts that have been negotiated and priced by another party;

we maintain a small staff of experienced generalist underwriters that are capable of underwriting many lines of property and casualty business rather than a large staff of underwriters, each with an individual, specific focus on certain lines of business;

we implement a "cradle to grave" service philosophy where the same deal team underwrites and services each reinsurance contract rather than separating underwriting and servicing duties among many employees; and

we compensate our management with a cash bonus structure largely dependent on our underwriting results over a multi-year period rather than on premium volume or preliminary underwriting results in any given financial accounting period.

Our investment strategy, like our reinsurance strategy, is designed to maximize returns over the long term while minimizing the risk of capital loss. Unlike the investment strategies of many of our competitors, which invest primarily in fixed-income securities either directly or through fixed-fee arrangements with one or more investment managers, our investment strategy is to invest in long and short positions primarily in publicly-traded equity and corporate debt instruments exclusively through a joint venture with DME Advisors LLC ("DME"). Our investment advisor, DME Advisors, is compensated with a fixed annual fee based on assets under management and the joint venture participant, DME, is compensated on the positive performance of our portfolio. DME Advisors, which makes investments on our behalf, is a value-oriented investment advisor that analyzes companies' available financial data, business strategies and prospects in an effort to identify undervalued and overvalued securities. DME Advisors and DME are both controlled by David Einhorn, the Chairman of our Board of Directors and the president of Greenlight Capital, Inc. DME Advisors has the contractual right to manage substantially all of our investable assets until December 31, 2016, and is required to follow our investment guidelines and to act in a manner that is fair and equitable in allocating investment opportunities to us. However, DME Advisors is not otherwise restricted with respect to the nature or timing of making investments for our account.

We measure our success by long-term growth in book value per share, which we believe is the most comprehensive gauge of the performance of our business. Accordingly, our incentive compensation plans are designed to align employee and shareholder interests. Compensation under our cash bonus plan is largely dependent on the ultimate underwriting returns of our business measured over a multi-year period, rather than premium targets or estimated underwriting profitability for the year in which we initially underwrote the business.

We characterize the reinsurance risks we assume as frequency or severity and aim to balance the risks and opportunities of our underwriting activities by creating a diversified portfolio of both types of businesses, although we generally have a preference for frequency business.

Frequency business is characterized as contracts containing a potentially large number of smaller losses emanating from multiple events. Clients generally buy this protection to increase their own underwriting capacity and typically select a reinsurer based upon the reinsurer's financial strength, service and expertise. We expect the results of frequency business to be less volatile than those of severity business from period to period due to its greater predictability. We also expect that over time the profit margins and return on equity of our frequency business will be lower than those of our severity business.

Severity business is typically characterized as contracts with the potential for significant losses emanating from one event or multiple events. Clients generally buy this protection to reduce volatility from their balance sheets, and accordingly, we expect the results of severity business to be volatile from period to period. However, over the long term, we also expect that our severity business will generate higher profit margins and return on equity than our frequency business.

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While we intend to continue to add to, and diversify, our portfolio, our allocation of risk will vary based on our perception of the opportunities available in each line of business. Moreover, our focus on certain lines will fluctuate based upon market conditions and we may only offer or underwrite a limited number of lines in any given period. We intend to continue to:

target markets where capacity and alternatives are underserved or constrained;

seek clients with appropriate expertise in their line of business;

employ strict underwriting discipline;

select reinsurance opportunities with favorable returns on capital over the life of the contract; and

strengthen and expand relationships with existing clients.

The following table sets forth our gross premiums written by line of business:

	Year end	led December 3	31							
	2014				2013			2012		
	(\$ in tho	usands)								
Property										
Aviation	\$ 391		0.1	%	\$168		%	\$—		%
Commercial	11,529		3.6		9,999	1.9		15,110	3.5	
Energy	2,131		0.6		659	0.1				
Motor physical damage	24,008		7.4		57,952	10.8		60,262	14.1	
Personal	64,479		19.9		,>					
John A. Scarlett, M.D.	55	President, Chief Executive Officer and Director								
Ross G. Clark, Ph.D.	55	Chief Technical Officer and Director								
Susan Wong	43	Acting Chief Financial Officer, Vice President, Finance and Chief Accounting Officer								
Stephen N. Rosenfield	56	Executive Vice President of Legal Affairs, General Counsel and Secretary								
Andrew Grethlein, Ph.D.	41	Senior Vice President, Pharmaceutical Operations								
Chris E. Rivera	44	Senior Vice President, Commercial								

		Operations
Thorsten von Stein, M.D., Ph.D.	44	Chief Medical
		Officer and
		Senior Vice
		President of
		Clinical and
		Regulatory
		Affairs

*John A. Scarlett* has served as our President and Chief Executive Officer and as a member of our board of directors since February 2002. From March 1993 to May 2001, Dr. Scarlett served as President and Chief Executive Officer of Sensus Drug Development Corporation, a development stage pharmaceutical company. In 1995, he co-founded Covance Biotechnology Services, Inc., a biotechnology contract manufacturing company, and served as a member of its board of directors from inception to 2000. From 1991 to 1993, Dr. Scarlett headed the North American Clinical Development Center and served as Senior Vice President of Medical and Scientific Affairs at Novo Nordisk Pharmaceuticals, Inc., a wholly owned subsidiary of Novo Nordisk A/S, a pharmaceutical company. From 1985 to 1990, Dr. Scarlett served as Vice President, Clinical Affairs and headed the clinical development group at Greenwich Pharmaceuticals, Inc., a pharmaceutical company. From 1982 to 1985, Dr. Scarlett served as Associate Director and, subsequently, as Director, of Medical Research and Services at Ortho-McNeil Pharmaceuticals, a wholly owned subsidiary of Johnson & Johnson. Dr. Scarlett received his B.A. degree in chemistry from Earlham College and his M.D. from the University of Chicago, Pritzker School of Medicine.

*Ross G. Clark* has served as our Chief Technical Officer since May 2002 and as a member of our board of directors since December 2001. From December 2001 to August 2003, Dr. Clark served as Chairman of our board of directors. From December 2001 to February 2002, Dr. Clark served as our Chief Executive Officer and President. Dr. Clark founded Tercica Limited, our predecessor company in New Zealand, in September 2000, Dr. Clark served as Chief Scientist for NeuronZ Limited, a New Zealand biotechnology company. In July 1999, Dr. Clark served as a board member of ViaLactia Biosciences (NZ) Ltd, a biotechnology subsidiary of the New Zealand Dairy Board. From 1990 to 1997, Dr. Clark served as a senior scientist for Genentech, Inc., a biotechnology company. Dr. Clark received his B.Sc., Dip.Sci. and Ph.D. degrees in veterinary physiology from Massey University, New Zealand.

*Susan Wong* has served as our Vice President of Finance and Chief Accounting Officer since March 2006 and Acting Chief Financial Officer since June 2005; and Vice President, Finance and Controller from January 2004 to March 2006. From November 2001 to December 2003, Ms. Wong was an independent financial services consultant. From August 2000 to October 2001, she served as Senior Vice President and Corporate Controller at innoVentry Corp., a privately-held provider of fee-based financial services. From September 1993 to July 2000, Ms. Wong served as Vice President and Corporate Controller at Ocular Sciences, Inc., a publicly-held manufacturer and distributor of soft contact lenses. From September 1989 to 1993, Ms. Wong served as Director of Corporate Accounting and Financial Reporting, Planning & Analysis at Vanstar, Inc., a computer reseller. Ms. Wong held various positions in the audit group at Coopers & Lybrand from August 1985 to August 1989. Ms. Wong is a Certified Public Accountant, and received her B.S. degree in finance and accounting from University of California, Berkeley.

Stephen N. Rosenfield has served as our Executive Vice President of Legal Affairs, General Counsel and Secretary since March 2006; and Senior Vice President of Legal Affairs, General Counsel and Secretary since July 2004. From February 2003 to May 2004, Mr. Rosenfield served as Executive Vice President of Legal Affairs, General Counsel and Secretary of InterMune, Inc., a biopharmaceutical company. From February 2000 to February 2003, Mr. Rosenfield served as Senior Vice President of Legal Affairs, General Counsel and Secretary of InterMune, Inc. From February 1996 to March 2000, Mr. Rosenfield was as an attorney at Cooley Godward LLP and served as outside counsel for biotechnology and technology clients. Mr. Rosenfield received his B.S. degree from Hofstra University and his J.D. degree from Northeastern University School of Law.

*Andrew Grethlein* has served as our Senior Vice President, Pharmaceutical Operations since August 2005 and Vice President, Manufacturing from April 2003 to August 2005. From December 2000 to April 2003, Dr. Grethlein served as Senior Director, South San Francisco Operations for Elan Corporation, plc, a pharmaceutical company. From November 1998 to December 2000, he served as Director, Biopharmaceutical Operations for Elan Corporation, plc. From 1997 to November 1998, Dr. Grethlein served as Associate Director, Neurotoxin Production for Elan Corporation, plc. From 1997, Dr. Grethlein served as Manager, Biologics Development and Manufacturing for Athena Neurosciences, Inc., a biotechnology company. From 1991 to 1995, Dr. Grethlein served in various engineering positions for Michigan Biotechnology Institute, a non-profit technology research and business development corporation, and its wholly-owned subsidiary, Grand River Technologies, Inc. Dr. Grethlein received his B.S. degree in biology from Bates College and his Ph.D. in chemical engineering from Michigan State University.

*Chris E. Rivera* has served as our Senior Vice President of Commercial Operations since April 2005. From September 2003 through December 2004, Mr. Rivera served as Vice President, Sales, at Corixa Corporation, a biopharmaceutical company. From April 2003 until September 2003, Mr. Rivera served as Vice President, Business Development for GeneCraft, Inc. (currently Trubion), also a biopharmaceutical company. From June 1998 until April 2003, Mr. Rivera served at Genzyme Corporation in various commercial positions with increasing responsibilities, the most recent as Senior Vice President, Therapeutics, where he was responsible for the U.S. commercialization of Genzyme Corporation s renal division. From April 1996 until May 1998, Mr. Rivera served as Vice President, Sales for Genzyme Tissue Repair. Prior to serving at Genzyme Corporation, Mr. Rivera helped to build the original commercial organizations at Cephalon, Inc. from 1993 through 1995 and at Centocor, Inc. from 1991 through 1993. Mr. Rivera began his career at E.R. Squibb and Sons (currently known as Bristol Myers-Squibb) in 1986 in a sales capacity, and was promoted to Seattle District Manager in 1989. Mr. Rivera received his B.S. degree in Business Administration at Northwestern Oklahoma State University and his M.S. degree in Audiology at the University of Oklahoma Health Sciences Centery. Mr. Rivera also attended the M.B.A. program at Seattle University s Albers School of Business and Economics, where he studied marketing and management.

*Thorsten von Stein* has served as our Chief Medical Officer and Senior Vice President of Clinical and Regulatory Affairs since January 2005. From August 2003 to January 2005, Dr. von Stein served as Chief Medical Officer at NeurogesX, Inc., a pharmaceutical company. From December 2001 to July 2003, Dr. von Stein served as Vice President, Clinical Development at Neurogesx. From 1994 to 2001, Dr. von Stein held positions of increasing responsibility in medical research, global clinical development and project management for Roche Palo Alto and F. Hoffman-La Roche AG in Basel, Switzerland. Dr. von Stein served as Director of Medical Research at Roche Palo Alto from 1998 to December 2001. Dr. von Stein received his M.D. degree from Munich University, Germany, and his Ph.D. degree in computer science from the University of Hamburg, Germany.

### **Corporate Information**

Tercica, Inc. was formed in December 2001 as a Delaware corporation. In early 2002, Tercica, Inc. acquired all the intellectual property rights and assumed specified liabilities of Tercica Limited, which was formed in October 2000 as a New Zealand company. Tercica Limited was subsequently liquidated.

### **Available Information**

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

### Item 1A. Risk Factors.

We have identified the following additional risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. Investors should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and investors may lose all or part of their investment.

#### **Risks Related to Our Business**

# We are a development stage company with a limited operating history and may not be able to successfully market and sell any products, generate significant revenues or attain profitability.

We are a development stage company focused on the development and commercialization of Increlex for the treatment of short stature and other endocrine disorders. From our inception in October 2000 through December 31, 2005, we have accumulated a deficit of \$165.7 million. We have not generated and may not be able to generate significant revenues from operations and may not be able to attain profitability. We incurred a net loss of \$46.2 million during the year ended December 31, 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, market and sell 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 that 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 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.

Prior to our January 2006 commercial launch of Increlex in the United States for the treatment of severe Primary IGFD, rhIGF-1 had never been commercialized in the United States or Europe for any indication. Even though the FDA has approved Increlex for sale in the United States, physicians may choose not to prescribe it, 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;

reimbursement adoption;

product price;

the effectiveness of our sales and marketing efforts;

storage requirements and ease of administration;

dosing regimen;

safety and efficacy;

prevalence and severity of side effects; and

competitive products.

#### 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 Increlex, and the timing of reimbursement decisions by these payors, 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 assumptions regarding the timing of reimbursement decisions or the level of reimbursement for Increlex are incorrect, our expected revenues may be delayed or substantially reduced. 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 market and sell 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 severe Primary IGFD and Primary IGFD are incorrect, the market opportunity for Increlex therapy for the treatment of severe Primary IGFD may be substantially reduced.

In recent years, officials have made numerous proposals to change the health care system in the United States. These proposals include measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. If our product becomes subject to government legislation that limits or prohibits payment for Increlex, or that subjects the price of our product to governmental control, we may not be able to generate revenues, attain profitability or

market and sell 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.

#### 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:

acceptance of Increlex by physicians and patients as a safe and effective treatment;

reimbursement adoption;

product price;

manufacturing costs;

the effectiveness of our sales and marketing efforts;

storage requirements and ease of administration;

dosing regimen;

safety and efficacy;

prevalence and severity of side effects; and

competitive products.

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.

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Insmed Incorporated s combination product, when launched commercially, will compete with Increlex for the treatment of patients with severe Primary IGFD. Insmed s combination product was recently approved by the FDA for the treatment of patients with severe Primary IGFD or with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone.

Growth hormone products will likely compete with Increlex for the treatment of patients with Primary IGFD if Increlex is also approved for that indication. The major suppliers of commercially available growth hormone

products 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. Eli Lilly and Company and Genentech have received FDA approval for their respective growth hormone products for the treatment of children with ISS. Accordingly, we expect that growth hormone products will compete directly with Increlex for the treatment of children with Primary IGFD who may be diagnosed as having ISS.

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.

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. Insmed has also conducted clinical trials using a product that contains rhIGF-1 for the treatment of diabetes. It is possible that there are other products currently in development or that exist on the market that may compete directly with Increlex.

### 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. Although we have submitted a marketing authorization application in Europe for severe Primary IGFD, there is no assurance that we will receive marketing approval in Europe for either severe Primary IGFD or Primary IGFD. If we fail to obtain European marketing 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 market and sell 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 for the treatment of severe Primary IGFD. As an example, Cambrex Bio Science Baltimore, Inc. 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 market and sell Increlex or maintain Increlex in the marketplace, which would adversely affect our ability to generate revenues.

# Our inability to enter into a commercial agreement on commercially reasonable terms with a single-source manufacturer to fill-finish our approved product could adversely affect our commercial supply and ability to grow revenues.

We currently source all of our fill-finish manufacturing and portions of release testing through a single-source third-party supplier. This single-source supplier is the only approved supplier currently available to us, and could only be replaced by qualification of a new site for the same operations. We are currently negotiating a commercial agreement with this fill-finish manufacturer, which has agreed to provide commercial product under an existing agreement. However, if we are unable to enter into such a commercial agreement with this single-source third-party supplier, we may be unable to fill-finish our commercial product until we could move our process to another fill-finish manufacturer. It would take a significant amount of time and expense to arrange for an alternative manufacturer. If we need to change to another commercial fill-finish manufacturer, this manufacturer s facilities and processes, prior to our use, would have to undergo pre-approval and/or cGMP compliance inspections. In addition, we would need to transfer and validate the processes and certain analytical methods necessary for the production and testing of rhIGF-1 to this new manufacturer. Such a transfer may result in a shortage of our commercial product and a loss of revenues.

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

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 as a result of the 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, business restructuring or insolvency, 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 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 IGFD 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.

# If other companies overcome our U.S. orphan drug marketing exclusivity or obtain marketing exclusivity in Europe, they 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. 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. For example, the FDA recently approved Insmed Incorporated s combination product for the treatment of severe Primary IGFD and granted Insmed s product orphan drug designation. Accordingly, notwithstanding our orphan drug designation for rhIGF-1, Insmed s combination product for rhIGF-1 and BP-3 was deemed by the FDA to be a different drug than ours, and therefore, it will compete with Increlex for the treatment of patients with severe Primary IGFD, when it is launched commercially.

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 other companies are able to overcome our U.S. orphan drug exclusivity, they will be able to compete with us, and our revenues will be diminished.

We believe that Insmed 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. If Insmed s or another company s drug product is granted orphan drug marketing exclusivity for severe Primary IGFD in Europe before ours and is considered to be the same drug as ours, we would not be able to market or sell Increlex for severe Primary IGFD in Europe, and our revenues would be diminished.

# 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.

### 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. For example, 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. In the event there are other rhIGF-1 products approved by the FDA to treat indications other than those covered by Increlex, physicians may elect to prescribe a competitor s product containing rhIGF-1 to treat the indications for which Increlex has received and may receive approval. This is commonly referred to as off-label use. While under FDA regulations a competitor is not allowed to promote off-label use of its product, the FDA does not regulate the practice of medicine and as a result cannot direct physicians as to what product containing rhIGF-1 to 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.

# Competitors could challenge our patents and file an Abbreviated New Drug Application (ANDA) or a 505(b)(2) new drug application for an IGF-1 product and adversely affect the competitive position of Increlex.

Products approved for commercial marketing by the FDA are subject to the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Act. The Hatch-Waxman Act

provides companies with marketing exclusivity for varying time periods during which generic or modified versions of a drug may not be marketed and allows companies to apply to extend patent protection for up to five additional years. It also provides a means for approving generic versions of a drug once the marketing exclusivity period has ended and all relevant patents have expired. The period of exclusive marketing, however, may be shortened if a patent is successfully challenged and defeated. Competitors with a generic IGF-1 product or a modified version of IGF-1 may attempt to file an ANDA or a 505(b)(2) NDA and challenge our patents and marketing exclusivity. Such applications would have to certify that one of the patents in the Increlex NDA is invalid or not infringed by the manufacture, use, or sale of the product described in that ANDA or 505(b)(2) application under the Hatch-Waxman Act. If successful, a competitor could come to market at an earlier time than expected. We can provide no assurances that we can prevail in a challenge or litigation related to our patents or exclusivity.

### 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 Insmed Incorporated in the United Kingdom and against Insmed in the United States to enforce patent rights we licensed from Genentech. We cannot predict the outcome of such litigation. These actions have required a substantial diversion of financial and personnel resources and could 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 patents. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do so. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

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

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

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

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

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

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

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

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

We have licensed intellectual property rights and technology from Genentech, under our U.S. and International License and Collaboration agreements with Genentech. Under each agreement, Genentech has the right to terminate our license if we are in material breach of our obligations under that agreement and fail to cure that breach. Under the terms of the agreements, we are obligated, among other things, to use reasonable business efforts to meet specified milestones, including filing for regulatory approval in the United States for either a diabetes indication or a substitute indication by December 31, 2008. 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, market and sell Increlex for any indication. This may prevent us from continuing our business.

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

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

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

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

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

patients do not enroll in clinical trials at the rate we expect (for example, in one of our current Phase III clinical trials of rhIGF-1 in Primary IGFD, 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.

# 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 market and sell Increlex on a timely basis, if at all.

### We may need others to market and sell Increlex in Europe.

We may need others to market and sell Increlex in Europe. If we receive marketing approval for Increlex in Europe and decide to sell Increlex in Europe through one or more third parties, 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 market and sell 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 market and sell Increlex for indications other than severe Primary IGFD or Primary IGFD. 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.

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

In October 2005, we entered into a committed equity financing facility, or CEFF, with Kingsbridge Capital Limited, or Kingsbridge, which 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, filed by us with the U.S. Securities and Exchange Commission, or SEC, 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 the entering into of the CEFF; 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 filed by us with the SEC 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 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 and prohibit Kingsbridge from selling shares under the registration statement. 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 fail to obtain the capital necessary to fund our operations, we will be unable to execute our business plan.

We believe that our existing cash, cash equivalents and short-term investments as of December 31, 2005, together with the net proceeds from our public offering of common stock in January 2006 and our CEFF, will be sufficient to meet our projected operating and capital expenditure requirements through at least the end of 2007 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 Increlex;

the status of competing products;

the commercial status of the Increlex bulk drug manufacturing operations at Cambrex Baltimore, including the success of our cGMP production activities;

the success of Increlex final drug product manufacturing;

the costs, timing and scope of additional regulatory approvals for Increlex;

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, 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.

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

Our ability to implement our business plan requires an effective planning and management process. As of December 31, 2005, we had 89 full-time employees, and we expect 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 market and sell 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 Increlex for an average of 4.4 years, with some patients being treated for over 12 years. None of the children withdrew from the study 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.

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, market and sell Increlex 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 have 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. Section 404 requires annual management assessments of the effectiveness of our internal control over financial reporting and a report by our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal controls confidence in the reliability of our internal control over financial reporting, which could adversely affect our stock price.

# If we are unable to attract and retain additional qualified personnel, our ability to market and sell 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 the assessment of two quarters of product sales. 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 entitled Risks Related to Our Business above. 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.

# 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 December 31, 2005, our directors, executive officers and principal stockholders and their affiliates beneficially owned approximately 66.7% 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 9.7%; MedImmune, Inc., which beneficially owned 9.5%; entities affiliated with Rho Ventures, which beneficially owned 9.5%; The Bank of New York, which beneficially owned 5.9%; and State of Wisconsin Investment Board, which beneficially owned 5.6%. 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 and at our election, 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 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:

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

estimates of our business potential and earnings prospects;

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

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 February 1, 2006, we had 37,422,622 outstanding shares of common stock. Of these shares, the 18,975,000 shares sold in our public offerings that were outstanding as of February 1, 2006 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, and other than shares subject to lock-up agreements that the holders of these shares entered into with the underwriter of our public offering in January 2006. These lock-up agreements expired on March 11, 2006. The remaining 18,447,622 shares outstanding as of February 1, 2006 were freely tradable (subject to certain restrictions on sales by affiliates and vesting in the case of early exercised options) other than the shares subject to the lock-up agreements referred to above.

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, 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. In November 2005, we also filed a registration statement 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.

Item 1B. Unresolved Staff Comments. None.

#### Item 2. Properties.

Our facilities consist of approximately 28,000 square feet of office space located in Brisbane, California that is leased to us until October 2011. We have no laboratory or research facilities. We believe that our Brisbane facilities will be adequate for our near-term needs and that suitable additional space will be available on commercially reasonable terms to accommodate expansion of our operations, if any.

#### Item 3. Legal Proceedings.

On December 20, 2004, we initiated patent infringement proceedings against Avecia Limited and Insmed Incorporated as co-defendants in the High Court of Justice (Chancery Division Patents Court) in the United Kingdom. There is no trial date set for this action. On December 23, 2004, we, with Genentech, initiated patent infringement proceedings against Insmed Incorporated in the U.S. District Court for the Northern District of California. We initiated these proceedings because we believe that Insmed and Avecia are infringing and/or have infringed on our patents that cover Insmed s product s use and manufacture. The trial date is November 6, 2006; however on March 8, 2006, we filed a motion to accelerate the trial date.

We cannot predict the outcome of our litigation against Avecia and Insmed in the United Kingdom or the outcome of our litigation against Insmed in the United States. Moreover, we cannot predict the cost of such litigation, which has required and will continue to require a substantial diversion of our financial assets and other resources, and which may have a material adverse effect on our business. In addition, if the outcome of our litigation in the United Kingdom is not favorable to us, we are likely to be found liable for the opposing parties costs incurred in connection with the litigation, and we could be found liable for an award of additional damages to the opposing parties if the court decides that our claims of patent infringement are without sufficient merit or not pursued in good faith. If in our litigation in the United States, the court decides that a defendant prevails, and the defendant establishes by clear and convincing evidence that the case is exceptional (e.g., our claims of patent infringement were not pursued in good faith), we could be liable for an award of the opposing party s costs and legal fees incurred in connection with the litigation and/or an award of other damages. Any such award or awards to the opposing parties could substantially increase our costs and exacerbate the negative impact that an unfavorable outcome in the case(s) could have on our business. Further, it is not uncommon in cases of this kind for a defendant to assert counterclaims, which could significantly increase our costs, potential liability for damages, and other risks arising from these lawsuits, and a court could find us liable for any such damages caused by Genentech as well.

Insmed and Avecia have challenged the validity of European Patent No. 0 571 417 in our litigation in the United Kingdom, and it is likely that Insmed will challenge the validity of U.S. Patent Nos. 5,187,151, 6,331,414 and/or 5,258,287 in our litigation in the United States. Even if we voluntarily drop our claims of patent infringement in our litigation in the United States and/or the United Kingdom, the opposing party or parties may pursue counterclaims for a declaratory judgment of invalidity against the asserted patent or patents in such action(s). If in our litigation in the United States the court awards a declaratory judgment finding invalid one or more of the claims of U.S. Patent No. 5,187,151, one or more of the claims of U.S. Patent No. 5,258,287, and/or one or more of the claims of U.S. Patent No. 6,331,414, and if the court s finding of invalidity in such declaratory judgment is upheld in whole or in part on appeal or if no appeal is taken, we would be unable to exclude others from using the affected claim or claims in the United States, which may decrease our ability to generate significant revenue from our rhIGF-1 programs and/or render any further development and commercialization of rhIGF-1 commercially infeasible for us. If in our litigation in the United Kingdom, the court awards a declaratory judgment finding invalid one or more of the claims of European Patent No. 0 571 417, and if the court s finding of invalidity in such declaratory judgment finding invalid one or more of the claims of European Patent No. 0 571 417, and if the court s finding of invalidity in such declaratory judgment is upheld in whole or in part on appeal or if no appeal is taken, we would be unable

to exclude others from using the affected claim or claims in the United Kingdom, and any such finding of invalidity may have a similar adverse impact on the enforceability of the affected claim or claims in one or more of the other European countries in which European Patent No. 0 571 417 would otherwise be in force, which may decrease our ability to generate significant revenue from our rhIGF-1 programs and/or render any further development and commercialization of rhIGF-1 commercially infeasible for us.

On December 6, 2005, we filed a complaint against Insmed for False Advertising and Unfair Competition, Case No. C-05-5027 SBA, in the U.S. District Court, Northern District of California. The complaint alleges that Insmed made false, misleading and deceptive statements about Increlex and its product. We are seeking monetary and injunctive relief. We filed an amended complaint on December 15, 2005. Defendant Insmed filed a Motion to Dismiss on January 13, 2006. The motion is scheduled to be heard on March 28, 2006. Discovery has not commenced, and no trial date has been set.

#### Item 4. Submission of Matters to a Vote of Security Holders.

There were no matters submitted to a vote of security holders during the quarter ended December 31, 2005.

#### PART II

#### Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock has been traded on the Nasdaq National Market under the symbol TRCA since March 17, 2004. The following table sets forth for the periods indicated the high and low closing sale prices of our common stock, as reported by the Nasdaq National Market.

	Р	rices
	High	Low
Fiscal 2005:		
First Fiscal Quarter	\$ 10.55	\$ 7.63
Second Fiscal Quarter	9.21	7.14
Third Fiscal Quarter	12.65	8.41
Fourth Fiscal Quarter	11.94	6.74
Fiscal 2004:		
First Fiscal Quarter (beginning March 17, 2004)	\$ 10.22	\$ 8.42
Second Fiscal Quarter	11.90	7.78
Third Fiscal Quarter	9.45	7.70
Fourth Fiscal Quarter	10.97	8.47

There were approximately 46 holders of record of our common stock as of February 24, 2006. In addition, we believe that a significant number of beneficial owners of our common stock hold their shares in street name.

#### **Dividend Policy**

We have never declared or paid any cash dividends on our common stock. We currently expect to retain any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future.

#### **Use of Proceeds From Registered Securities**

On March 22, 2004, we completed our initial public offering of 5,500,000 shares of our common stock at a public offering price of \$9 per share. On April 2, 2004, we received net cash proceeds from the issuance of 825,000 shares of common stock in connection with the underwriters exercise of the over-allotment option. The shares of common stock sold in the offering were registered under the Securities Act of 1933, as amended, on a Registration Statement on Form S-1 (File No. 333-108729) that was declared effective by the SEC on March 16, 2004. The aggregate purchase price of the offering was \$56,925,000. The net offering proceeds to us after deducting total expenses and underwriting discounts and commissions were \$50,021,000.

None of the expenses were paid, directly or indirectly, to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates

We are using, and intend to continue to use, these proceeds for general corporate purposes, including research and development expenses, manufacturing expenses, clinical trials and selling, general and administrative expenses. No such payments were made to directors, officers of persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for Board or Board committee service.

The amount and timing of our actual expenditures may vary significantly depending on numerous factors, such as the progress of our product development and commercialization efforts and the amount of cash used by our operations.

#### **Issuer Purchases of Equity Securities**

The following table sets forth information regarding our repurchases of common stock during the quarter ended December 31, 2005:

			Total Number of	Maximum Number
			Shares Purchased	of Shares that May
			as Part of Publicly	Yet Be Purchased
			Announced	Under the
Period	Total Number of Shares Purchased	Average Price Paid per Share		Programs
October 1 through October 31, 2005	22,136	\$ 0.40		
November 1 through November 30, 2005				
December 1 through December 31, 2005				
	22,136	\$ 0.40		

The repurchase of shares of common stock indicated in the table above was not made pursuant to a publicly announced program. The shares were repurchased from the purchaser upon termination of the purchaser s employment with us pursuant to our right to repurchase shares that had not yet vested as of the termination date. The repurchase price was equivalent to the purchase price paid by the purchaser for the shares.

## Item 6. Selected Financial Data.

The following selected financial data should be read in conjunction with, and are qualified by reference to, our financial statements and related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations. The selected statements of operations data for the period from October 1, 2000 (inception) through December 31, 2005, for each of the three years in the period ended December 31, 2005, and the selected balance sheet data as of December 31, 2005 and 2004 are derived from, and qualified by reference to, the audited financial statements included in Item 8 of this Form 10-K. The selected statements of operations for the nine months ended December 31, 2001 and for the year ended December 31, 2002, and the selected balance sheet data as of December 31, 2003, 2002 and 2001, are derived from audited financial statements not included in this Form 10-K. The historical results are not necessarily indicative of results to be expected in any future period. In October 2001, we changed our fiscal year end from March 31 to December 31.

		Period From					
							October 1,
							2000
					Nine	Months	(Inception)
					Ended		Through
					Dece	mber 31,	December 31,
	2005	2004	2003	2002	2	2001	2005
Statements of Operations Data (in thousands, except per share data):							
Costs and expenses:							
Research and development	\$ 21,587	\$ 27,918	\$ 19,246	\$ 1,974	\$	307	\$ 71,212
Selling, general and administrative	25,913	12,552	4,834	1,978		510	45,903
Acquired in-process research and development		1,417	1,670	5,071			8,158
Total costs and expenses	(47,500)	(41,887)	(25,750)	(9,023)		(817)	(125,273)
Interest expense	(1,080)			(106)			(1,186)
Interest and other income, net	2,347	885	327	177		9	3,746
Net loss	(46,233)	(41,002)	(25,423)	(8,952)		(808)	(122,713)
Deemed dividend related to beneficial conversion	( - , ,			(-) /		()	
features of convertible preferred stock			(44,153)				(44,153)
Net loss allocable to common stockholders	\$ (46,233)	\$ (41,002)	\$ (69,576)	\$ (8,952)	\$	(808)	\$ (166,866)
Basic and diluted net loss per share allocable to common stockholders(1)	\$ (1.51)	\$ (2.12)	\$ (38.59)	\$ (5.76)	\$	(0.90)	
Shares used in computing basic and diluted net loss per share allocable to common stockholders(1)	30,590	19,302	1,803	1,555		895	

	December 31,									
	2005	2004	2003	2002	2001	1				
Balance Sheet Data (in thousands):										
Cash, cash equivalents and short-term investments	\$ 58,626	\$ 52,001	\$ 37,313	\$ 15,870	\$ 1	68				
Working capital	54,210	45,542	33,346	15,707		29				

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Total assets	66,316	55,022	42,484	16,348	198
Total liabilities	9,518	7,345	7,045	568	149
Convertible preferred stock			68,637	24,693	
Deficit accumulated during the development stage	(165,741)	(119,508)	(78,506)	(8,930)	(1,103)
Total stockholders equity (deficit)	56,798	47,677	(33,198)	(8,913)	48

(1) See Note 3 to the financial statements for information regarding the computation of per share amounts.

## **Changes in Results From Reported Earnings**

On February 15, 2006, we reported preliminary unaudited financial results for the fourth quarter and year ended December 31, 2005. The financial results in this report on Form 10-K differ from those preliminary results as follows:

Subsequent to February 15, 2006, we revised the accounting for the warrant issued to Kingsbridge Capital Limited in connection with our \$75 million Committed Equity Financing Facility (CEFF). The value assigned to the warrant was previously reported as a transaction cost associated with accessing the CEFF and thus was recorded to non-operating expense. The value of this warrant is now accounted for in stockholders equity. This revised accounting resulted in a decrease in non-operating expense and an increase in additional-paid-in-capital included in Total stockholders equity (deficit), of \$1,196,000 in the accompanying financial statements for the year ended December 31, 2005.

This was a non-cash transaction.

The revised accounting discussed above had no impact on 2005 operating loss.

Net loss for 2005 decreased from \$47,429,000 to \$46,233,000.

Basic and diluted net loss per share for 2005 decreased from \$1.55 to \$1.51.

#### Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations.

This report includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended. All statements other than statements of historical facts are forward-looking statements for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statement of the plans and objectives of management for future operations, any statements concerning proposed new products or licensing or collaborative arrangements, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as may, will, expects, plans, anticipates, e potential, or continue or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that such expectations or any of the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including but not limited to the Risk Factors set forth under Item 1A above, and for the reasons described elsewhere in this report. All forward-looking statements and reasons why results may differ included in this report are made as of the date hereof, and we assume no obligation to update these forward-looking statements or reasons why actual results might differ.

#### Overview

We are a biopharmaceutical company focused on the development and commercialization of new therapeutics for the treatment of short stature and other endocrine disorders. Our first commercial product is Increlex, a DNA-derived recombinant human insulin-like growth factor-1, or rhIGF-1. We obtained approval of long-term Increlex replacement therapy for severe primary insulin-like growth factor deficiency, or severe Primary IGFD, from the FDA in August 2005, and Increlex was granted seven years of orphan drug marketing exclusivity for the long-term treatment of growth failure in children with severe Primary IGFD. See the section entitled Risks Related to our Business under Item 1A above for further details related to our orphan drug marketing exclusivity. In January 2006, we launched Increlex in the United States. We also submitted a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMEA, for approval to market Increlex in the European Union for the long-term treatment of growth failure in children with severe Primary IGFD or with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone, or GH. 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 current focus is on marketing and selling Increlex for the treatment for severe Primary IGFD, and 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 are developing Increlex for use in the broad population of children with Primary IGFD. We are currently conducting two late-stage clinical trials for the use of rhIGF-1 in Primary IGFD. We are assessing our Increlex development strategy for other indications.

Tercica, Inc. s predecessor, Tercica Limited, a New Zealand Company, was formed in October 2000. Tercica Medica, Inc. was incorporated in Delaware in December 2001, adopted the calendar year as its fiscal year and subsequently changed its name to Tercica, Inc. In early 2002, Tercica, Inc. acquired (at amounts approximating Tercica Limited s historical net book value) an immaterial amount of assets, including intellectual property rights, from Tercica Limited as its operations were moved from New Zealand to California. In March 2002, Tercica Limited made a final, immaterial distribution to its stockholders in connection with its legal liquidation.

estimates

In April 2002, we licensed from Genentech intellectual property to develop and commercialize rhIGF-1 for a broad range of indications, including short stature and diabetes in the United States. In December 2002, we entered into a development and commercial supply contract for the manufacture of bulk rhIGF-1 drug substance with Cambrex Bio Science Baltimore, Inc., or Cambrex Baltimore. In July 2003, we signed an international license and collaboration agreement with Genentech obtaining its rights to develop and commercialize rhIGF-1 products outside of the United States for all indications other than diseases and conditions of the central nervous system. In addition, we must enter into a written agreement with another company if we desire to commercialize Increlex for the treatment of diabetes outside of the United States.

In January 2005, we entered into a loan agreement with Venture Leasing & Lending IV, Inc., or VLL, under which we had the option to draw down funds in the aggregate principal amount of up to \$15.0 million. This facility expired on December 31, 2005 with no borrowings from this facility.

In October 2005, we entered into a committed equity financing facility, or CEFF, with Kingsbridge Capital Limited, or Kingsbridge, which entitles us to sell and obligates Kingsbridge to purchase a maximum of approximately 6.0 million newly issued shares of our common stock over a three-year period for cash up to an aggregate of \$75.0 million, subject to certain conditions and restrictions. See the discussion below under Committed Equity Financing Facility for further details on the CEFF. As of December 31, 2005, we had not issued any shares under this facility.

As of December 31, 2005, we had approximately \$58.6 million in cash, cash equivalents and short-term investments. We have funded our operations since inception through the private placement of equity securities and public offerings of our common stock. In 2002, we raised \$20.0 million through the sale of shares of our Series A preferred stock. In 2003, we raised \$43.8 million through the sale of shares of our Series B preferred stock. On March 22, 2004, we completed our initial public offering of common stock in which we raised net cash proceeds of approximately \$43.1 million and received an additional \$6.9 million of net cash proceeds on April 2, 2004 in connection with the underwriters exercise of their option to purchase additional shares. On February 11, 2005, we completed a follow-on public offering of common stock in which we raised net cash proceeds of approximately \$51.1 million. On January 27, 2006, we completed another follow-on public offering of common stock in which we raised net cash proceeds of approximately \$34.1 million.

#### Revenues

We began generating revenue from the sale of our current product, Increlex, in January 2006.

## **Research and Development Expenses**

Research and development expenses consist primarily of costs associated with manufacturing development activities and clinical and regulatory activities. Manufacturing development activities include pre-FDA approval preparation activities for current good manufacturing practices (cGMP), regulatory inspection preparation, technology transfer, process development and validation, quality control and assurance activities, analytical services, personnel and related benefits and depreciation. Clinical and regulatory activities include the preparation, implementation, management of our clinical trials and assay development, as well as regulatory compliance, data management and biostatistics. Our research and development activities are primarily focused on manufacturing development activities at our contract manufacturers, including clinical supplies manufacturing, manufacturing process development, validation and qualification activities, analytical development, and compliance-related support, inspection preparation and clinical and regulatory development activities related to severe Primary IGFD and Primary IGFD. Prior to receiving regulatory approval, we charged all drug supply production costs to research and development. Some of these drug supply costs incurred subsequent to August 2005 are included in inventory as our product received regulatory approval that month, and the subsequent cost of sales of these inventories may not be indicative of future costs of sales. Because we licensed non-clinical, clinical and manufacturing data and know-how related to rhIGF-1 from Genentech in 2002, we did not incur

significant development expenses prior to 2002. During 2003, our research and development activities were primarily focused on two projects: the transfer of our rhIGF-1 manufacturing process and the development project for Primary IGFD. At the end of 2003, we began to manage the development project for severe Primary IGFD as a separate project from the development project for Primary IGFD and completed the technology transfer of our manufacturing process to our contract manufacturers. Our primary focus in research and development in 2004 was associated with the establishment and validation of our rhIGF-1 manufacturing process at our contract manufacturers and preparations for the anticipated NDA filing for severe Primary IGFD. During 2005, our research and development activities primarily centered around our NDA filing, process validation, quality control and assurance, and analytical services in preparations for FDA inspections at our contract manufacturers and development projects for severe Primary IGFD and Primary IGFD. Development projects for severe Primary IGFD and Primary IGFD consists primarily of clinical and regulatory activities, including costs associated with clinical trials. 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 expect 2006 to be primarily focused on clinical activities in Primary IGFD. Our projects or intended projects may be subject to change from time to time as we evaluate our research and development priorities and available resources.

#### Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of payroll and related costs associated with sales and marketing personnel, executive management, corporate administration, legal fees, pre-launch commercial planning activities, facility costs, insurance, information technology and accounting services. During 2004, we continued to expand our corporate staffing and infrastructure and initiated planning for sales and marketing activities. During 2005, we expanded our corporate staffing and infrastructure, increased our pre-launch activities and implemented Section 404 of the Sarbanes-Oxley Act of 2002. We expect total selling, general and administrative expenses in 2006 to increase primarily due to commercial activities associated with marketing Increlex for severe Primary IGFD, partially offset by decreased legal costs associated with our litigation with Insmed Incorporate and Avecia Limited.

## Critical Accounting Policies and the Use of Estimates

Our management s discussion and analysis of our financial condition and results of operations are based on our financial statements which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of our financial statements requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. Actual results could differ materially from those estimates.

The items in our financial statements requiring significant estimates and judgments are as follows:

#### Stock Compensation

We account for employee stock options using the intrinsic-value method in accordance with Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, Financial Accounting Standards Board, or FASB, Interpretation No. 44, *Accounting for Certain Transactions involving Stock Compensation, an interpretation of APB No. 25*, and related interpretations and have adopted the disclosure-only provisions of Statement of Financial Accounting Standards, or SFAS, No. 123, *Accounting for Stock-Based Compensation*.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. SFAS No. 148 amends SFAS No. 123 to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. We have elected to continue to follow the intrinsic value method of accounting as prescribed by APB No. 25. The

information regarding net loss as required by SFAS No. 123 has been determined as if we had accounted for our employee stock options under the fair value method of that statement.

Stock compensation expense, which is a non-cash charge, results from stock option grants at exercise prices below the reassessed fair value of the underlying common stock resulting in our recording stock compensation associated with these grants. Stock compensation expense is amortized over the vesting period of the underlying option, generally four years. From inception through January 31, 2004, we recorded deferred stock compensation of \$10.9 million. At December 31, 2005, we had a total of \$2.6 million of deferred stock compensation remaining to be amortized over the vesting period of the stock options of approximately two years. In the year ended December 31, 2005, we reversed \$1.7 million of deferred stock compensation due to the forfeiture of unvested stock options from employee terminations. We have not recorded any additional deferred stock compensation subsequent to January 31, 2004.

The total unamortized deferred stock compensation recorded for all option grants through January 31, 2004, net of the amounts reversed associated with forfeited stock options will be amortized as follows: \$1.7 million for the year ending December 31, 2006 and \$0.9 million for the year ending December 31, 2007.

On December 16, 2004, the FASB issued an amendment to SFAS No. 123, *Share-Based Payment*, (SFAS No. 123R). We have adopted SFAS No. 123R as of January 1, 2006. SFAS No. 123R addresses the accounting for transactions in which an enterprise receives employee services in exchange for equity instruments of the enterprise or liabilities that are based on the fair value of the enterprise s equity instruments or that may be settled by the issuance of such equity instruments. SFAS No. 123R eliminates the ability to account for share-based compensation transactions using APB Opinion No. 25, and requires instead that such transactions be accounted for using a fair-value-based method. Companies are required to recognize an expense for compensation cost related to share-based payment arrangements including stock options and employee stock purchase plans. We have selected the Black-Scholes option-pricing model to be used for valuing share-based payments and will recognize compensation cost is recognized based on the requirements of SFAS No. 123R beginning with the effective date (a) for all share-based payments granted after the effective date and (b) for all awards granted to employees prior to the effective date of SFAS No. 123R that remain unvested on the effective date. We believe that the adoption of the new standard will have a material impact on our results of operations. We expect to continue to grant stock-based compensation to employees. Our estimate of future stock-based compensation expense is affected by our stock price, the number of stock-based awards our board of directors may grant in the future, as well as a number of complex and subjective valuation assumptions and the related tax effect. These valuation assumptions include, but are not limited to, the volatility of our stock price and employee stock option exercise behaviors.

#### Inventories

Inventories are stated at the lower of cost or market and consist of inventories for Increlex, which was approved by the FDA in August 2005. Cost is determined using the first-in, first-out basis. The valuation of inventory requires us to estimate obsolete or excess inventory. The determination of obsolete or excess inventory requires us to estimate the future demands for our products; however, if our current assumptions about future production or inventory levels, demand or competition were to change or if actual market conditions are less favorable than those we have projected, inventory write-downs may be required that could negatively impact our product gross margins and results of operations.

#### **Clinical Trial Expenses**

We contract with third-party clinical research organizations to perform various clinical trial activities. We recognize research and development expenses for these contracted activities based upon a variety of factors, including actual and estimated patient enrollment rates, clinical site initiation activities, labor hours and other

activity-based factors. We match the recording of expenses in our financial statements to the actual services received and efforts expended. Depending on the timing of payments to the service providers, we record prepaid expenses and accruals relating to clinical trials based on our estimate of the degree of completion of the event or events as specified in each clinical study or trial contract. We monitor each of these factors to the extent possible and adjust estimates accordingly.

## Acquired In-Process Research and Development

Acquired in-process research and development relates to in-licensed technology, intellectual property and know-how. The nature of the efforts for completion of research and development activities surrounding rhIGF-1 generally include completion of clinical trials, completion of manufacturing validation, interpretation of clinical and preclinical data and obtaining marketing approval from the FDA and other foreign regulatory bodies, the cost, length and success of which are extremely difficult to determine. Numerous risks and uncertainties exist with timely completion of development projects, including clinical trial results, manufacturing process development results, and ongoing feedback from regulatory authorities, including obtaining marketing approval. In addition, products under development may never be successfully commercialized due to the uncertainties associated with the pricing of new pharmaceuticals, the cost of sales to produce these products in a commercial setting, changes in the reimbursement environment, or the introduction of new competitive products. As a result of the uncertainties noted above, we charge in-licensed intellectual property and licenses for unapproved products to acquired in-process research and development.

## **Results of Operations**

## Year Ended December 31, 2005 Compared to Year Ended December 31, 2004

*Revenues.* We did not generate any revenues from Increlex for the years ended December 31, 2005 and 2004. We began generating revenue from the sale of Increlex in January 2006.

*Research and Development Expenses.* Research and development expenses decreased to \$21.6 million for the year ended December 31, 2005, from \$27.9 million for the same period in 2004. The \$21.6 million in expenses for the year ended December 31, 2005 were comprised primarily of personnel and related costs of \$10.5 million, costs associated with the process validation, quality control and assurance, analytical services and preparations for pre-approval inspections at our contract manufacturers totaling \$5.9 million, costs related to our development projects for Primary IGFD and severe Primary IGFD, which consists primarily of costs associated with the implementation and management of our clinical trials totaling \$4.1 million and a milestone payment of \$1.0 million to Genentech upon receiving FDA approval of Increlex.

In the year ended December 31, 2005, total research and development expenses decreased by \$6.3 million over the same period in 2004. This decrease was primarily due to lower costs related to manufacturing activities, which decreased by \$8.8 million from the same period in 2004. Manufacturing development expenses in 2004 included establishment and validation of our rhIGF-1 manufacturing process at our contract manufacturers and cGMP preparations for the anticipated NDA filing in severe Primary IGFD, neither of which were required in 2005. Costs in 2005 associated with our development projects for Primary IGFD and severe Primary IGFD decreased by \$1.3 million due primarily to the timing of certain start up clinical trial expenses incurred in 2004. These decreases were partially offset by higher personnel costs of \$2.3 million and a milestone payment to Genentech of \$1.0 million. We expect 2006 to be primarily focused on clinical activities in Primary IGFD.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses increased to \$25.9 million for the year ended December 31, 2005, from \$12.6 million for the same period in 2004. The \$13.3 million increase was attributable to increased legal fees primarily associated with our litigation with Insmed and Avecia of \$7.0 million, increased personnel costs of \$2.8 million and increased corporate administration expenses including consulting, professional fees, insurance, facilities and other expenses of \$3.5 million. We

expect total selling, general and administrative expenses in 2006 to increase primarily due to increased personnel and commercial activities associated with marketing Increlex for severe Primary IGFD, partially offset by decreased legal costs associated with our litigation with Insmed and Avecia.

Acquired In Process Research and Development. Acquired in-process research and development expense was \$1.4 million in the year ended December 31, 2004. We did not incur acquired in-process research and development expenses in the same period in 2005. The costs in 2004 resulted from a \$1.2 million payment to Genentech related to the exclusive license to Genentech s worldwide rights, including the United States, to IGF-1 combined with IGFBP-3 for all indications, other than diseases and conditions of the central nervous system, and \$250,000 of costs resulting from the execution of a patent license.

*Interest Expense.* Interest expense was \$1.1 million for the year ended December 31, 2005. We did not incur any interest expense in the comparable period in 2004. Interest expense in 2005 represented the value of 112,500 shares of common stock we issued in 2005 in connection with our loan agreement with VLL of \$1.0 million and \$75,000 of commitment fees related to our loan agreement with VLL.

*Interest and Other Income, net.* Interest and other income, net, increased to \$2.3 million for the year ended December 31, 2005, from \$0.9 million for the same period in 2004. The increase was primarily due to interest income on higher average cash, cash equivalents and short-term investment balances as a result of the cash proceeds received from our initial public offering in March 2004 and our follow-on public offering in February 2005 and the impact of higher interest rates in 2005 compared to 2004.

#### Year Ended December 31, 2004 Compared to Year Ended December 31, 2003

*Research and Development Expenses.* Research and development expenses increased to \$27.9 million for the year ended December 31, 2004, from \$19.2 million for the same period in 2003. The \$27.9 million in expenses for the year ended December 31, 2004 were comprised of project costs associated with the establishment and validation of our rhIGF-1 manufacturing process at Cambrex Baltimore totaling \$14.7 million, internal personnel and other costs totaling \$8.2 million, and our development projects for severe Primary IGFD and Primary IGFD totaling \$5.0 million.

In the year ended December 31, 2004, project costs for the establishment and validation of our rhIGF-1 manufacturing process increased \$1.5 million from the same period in 2003, and were driven primarily by production and validation activities at Cambrex Baltimore. The costs associated with our development projects for severe Primary IGFD and Primary IGFD for the year ended December 31, 2004 increased by approximately \$3.5 million from the same period in 2003. The severe Primary IGFD and Primary IGFD project costs related primarily to conducting several small studies, the analyses of clinical trial data, NDA filing preparations for severe Primary IGFD and start-up costs related to the trials in Primary IGFD. Personnel costs for the year ended December 31, 2004 increased \$3.6 million from the same period in 2003.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses increased to \$12.6 million for the year ended December 31, 2004, from \$4.8 million for the same period in 2003. This increase of \$7.7 million was attributable to increased personnel costs of \$4.8 million, increased sales and marketing expenses of \$1.6 million and increased corporate administration expenses such as legal, insurance, information technology and other expenses of \$1.3 million.

Acquired In-Process Research and Development. Acquired in-process research and development expense decreased to approximately \$1.4 million for the year ended December 31, 2004 from \$1.7 million in the same period in 2003. The costs in 2004 resulted from a \$1.2 million payment to Genentech related to the exclusive license to Genentech s worldwide rights, including the United States, to IGF-1 combined with IGFBP-3 for all indications, other than diseases and conditions of the central nervous system, and \$250,000 of costs resulting from the execution of a patent license. The costs in 2003 resulted from the execution of our International License

and Collaboration Agreement with Genentech and were comprised of cash of \$1.7 million. This agreement allows us to market and sell Increlex outside of the United States for all indications other than diseases or conditions of the central nervous system.

*Interest and Other Income, net.* Interest and other income, net, increased to \$0.9 million for the year ended December 31, 2004, from \$0.3 million for the same period in 2003. The increase was due to interest income on higher average cash, cash equivalents and short-term investment balances as a result of the cash proceeds received from the issuance of Series B preferred stock in July 2003 and from our initial public offering in March 2004.

*Preferred Stock Dividend.* In July 2003, we sold 8,830,646 shares of Series B preferred stock at \$5.00 per share, for total cash proceeds of approximately \$43.8 million. The difference between the preferred stock sales price and the reassessed value per share of common stock on the transaction date resulted in a beneficial conversion feature in the amount of \$44.2 million. The beneficial conversion feature has been reflected as a preferred stock dividend in the statement of operations for the year ended December 31, 2003.

#### Liquidity and Capital Resources

#### Sources of Liquidity

As of December 31, 2005, we had an accumulated deficit of \$165.7 million, which was primarily comprised of \$122.7 million of accumulated net losses and \$44.2 million of a non-cash deemed dividend related to the beneficial conversion feature of convertible preferred stock. We have funded our operations and growth from inception through December 31, 2005 with net cash proceeds of \$66.0 million in private equity financings and \$101.2 million from our public offerings of common stock.

On January 27, 2006, we completed a public offering of our common stock under a shelf registration, in which we raised net cash proceeds of approximately \$34.1 million.

We believe that our cash, cash equivalents and short-term investments as of December 31, 2005 of \$58.6 million, together with the net proceeds of our public offering completed in January 2006 and our CEFF, will be sufficient to meet our projected operating and capital expenditure requirements through at least the end of 2007 based on our current business plan.

#### Senior Credit Facility

Pursuant to our loan agreement with VLL, we had the option to draw down funds in the aggregate principal amount of up to \$15.0 million. We paid a \$75,000 fee as part of this loan agreement and issued a total of 112,500 shares of our common stock to an affiliate of VLL. The facility expired on December 31, 2005, and we did not borrow any funds under this facility.

#### Committed Equity Financing Facility

Under the terms of the CEFF, Kingsbridge committed to purchase a maximum of approximately 6.0 million newly issued shares of our common stock over a three-year period beginning in October 2005, for cash up to an aggregate of \$75.0 million, subject to certain conditions. We may draw down under the CEFF in tranches of up to the lesser of \$7.0 million or 2% of our market capitalization at the time of the draw down of such tranche, subject to certain conditions. The common stock to be issued for each draw down will be issued and priced over an eight-day pricing period at discounts ranging from 6% to 10% from the volume weighted average price of our common stock during the pricing period. During the term of the CEFF, Kingsbridge may not short our stock, nor may it enter into any derivative transaction directly related to our stock. The minimum acceptable purchase price, prior to the application of the appropriate discount for any shares to be sold to Kingsbridge during the eight-day

pricing period, is determined by the greater of \$3.00 or 90% of our closing share price on the trading day immediately prior to the commencement of each draw down. In connection with the CEFF, we issued a warrant to Kingsbridge to purchase up to 260,000 shares of our common stock at an exercise price of \$13.12 per share. 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 our common stock under the CEFF provide an appropriate means of raising capital. However, we are not obligated to sell any of the \$75.0 million of common stock available under the CEFF, and there are no minimum commitments or minimum use penalties.

## Cash Flow

Cash, cash equivalents and short-term investments totaled \$58.6 million at December 31, 2005, compared to \$52.0 million at December 31, 2004, and \$37.3 million at December 31, 2003. The increase in 2005 was primarily due to net proceeds of \$51.1 million from the issuance of common stock in a follow-on public offering, partially offset by cash used in operating activities of \$43.4 million. Cash used in operating activities in 2005 includes the receipt of a \$1.0 million reimbursement from our landlord for facility improvements which was recognized as deferred rent. The increase in 2004 was primarily due to net proceeds of \$50.0 million. The increase in 2005 operating activities from 2004 was primarily due to the increase of \$34.7 million. The increase in net cash used in 2005 operating activities from 2004 was primarily due to the increase of our net loss in 2005 compared to 2004, which is discussed above in the results of operations, and the capitalization of inventory after we obtained FDA approval of Increlex, offset by the recognition of the leasehold improvement allowance received from our landlord. The increase in net cash used in operating activities in 2004 was due to increased personnel and infrastructure costs, the establishment and validation of our rhIGF-1 manufacturing process at Cambrex Baltimore, and our development projects for severe Primary IGFD and Primary IGFD.

Net cash used in investing activities totaled \$7.7 million in the year ended December 31, 2005, compared to \$3.4 million in the year ended December 31, 2004 and \$38.2 million in the year ended December 31, 2003. Net cash used in investing activities represent purchases, sales and maturities of investments and purchases of property and equipment net against proceeds received from the sale of equipment. Net purchases of short-term investments were \$5.2 million in 2005, an increase of \$2.2 million from 2004. Due to the relatively short-term maturities of our investment portfolio during 2004 and 2005, the increases and decreases in net purchases of short-term investments were primarily due to timing of maturities, sales and purchases of short-term investments. Net purchases of short-term investments were \$3.0 million in 2004, a decrease of \$32.8 million from 2003. The decrease in net purchases of short-term investments in 2004 compared to 2003 was due primarily to the relatively short-term maturities of our investment portfolio during 2004 resulting in lower net purchases of short-term investments and the increased cash inflows from our Series B financing in 2003 resulting in higher net purchases of short-term investments. Purchases of property and equipment were \$2.8 million in 2005, an increase of \$2.4 million from 2004. The increase in purchases of property and equipment in 2005 primarily relate to the purchase of leasehold improvements and office furniture for our new offices located in Brisbane, California, and the purchase of computer equipment and software for new employees hired in 2005. Proceeds received from the sale of equipment was \$0.3 million in 2005, compared to \$0 in 2004. Purchases of property and equipment were \$0.4 million in 2004, a decrease of \$1.9 million from 2003. The decrease in purchases of property and equipment were \$0.4 million in 2004, a decrease of \$1.9 million from 2003. The decrease in purchases of property and equipment were \$0.4 million in 2004, a decrease of \$1.9 million from 200

Net cash provided by financing activities for the year ended December 31, 2005 was \$51.8 million, compared to \$50.3 million for the year ended December 31, 2004, and \$44.5 million for the year ended December 31, 2003. Net cash provided by financing activities primarily relate to net proceeds received from our public offerings of common stock and proceeds received from the issuance of common stock under our stock plans. Net proceeds received from our public offerings of common stock were \$51.1 million and \$50.0 million in 2005 and 2004, respectively. Proceeds from the issuance of common stock under our equity compensation plans were \$0.8 million, \$0.3 million and \$0.5 million for 2005, 2004 and 2003, respectively.

## Litigation

On December 20, 2004, we initiated patent infringement proceedings against Avecia Limited and Insmed Incorporated as co-defendants in the High Court of Justice (Chancery Division Patents Court) in the United Kingdom. There is no trial date set for this action. On December 23, 2004, we, with Genentech, initiated patent infringement proceedings against Insmed Incorporated in the U.S. District Court for the Northern District of California. We initiated these litigations because we believe that Insmed and Avecia are infringing and/or have infringed on our patents that cover Insmed s product s use and manufacture. The trial date is November 6, 2006; however, on March 8, 2006, we filed a motion to accelerate the trial date.

We cannot predict the outcome of our litigation against Avecia and Insmed in the United Kingdom or the outcome of our litigation against Insmed in the United States. Moreover, we cannot predict the cost of such litigation, which may require a substantial diversion of our financial assets and other resources and consequently prevent us from allocating sufficient resources to the development of our rhIGF-1 programs, and which may have a material adverse effect on our business. In addition, if the outcome of our litigation in the United Kingdom is not favorable to us, we are likely to be found liable for the opposing parties costs incurred in connection with the litigation, and we could be found liable for an award of additional damages to the opposing parties if the court decides that our claims of patent infringement are without sufficient merit or not pursued in good faith. If in our litigation in the United States, the court decides that a defendant prevails, and the defendant establishes by clear and convincing evidence that the case is exceptional (e.g., our claims of patent infringement were not pursued in good faith), we could be liable for an award of the opposing party s costs and legal fees incurred in connection with the litigation and/or an award of other damages. Any such award or awards to the opposing parties could substantially increase our costs and exacerbate the negative impact that an unfavorable outcome in the case(s) could have on our business. Further, it is not uncommon in cases of this kind for a defendant to assert counterclaims, which could significantly increase our costs, potential liability for damages, and other risks arising from these lawsuits, and a court could find us liable for any such damages caused by Genentech as well.

On December 6, 2005, we filed a complaint against Insmed for False Advertising and Unfair Competition, Case No. C-05-5027 SBA, in the U.S. District Court, Northern District of California. The complaint alleges that Insmed made false, misleading and deceptive statements about Increlex and its product. We are seeking monetary and injunctive relief. We filed an amended complaint on December 15, 2005. Defendant Insmed filed a Motion to Dismiss on January 13, 2006. The motion is scheduled to be heard on March 28, 2006. Discovery has not commenced, and no trial date has been set.

#### **Contractual Obligations and Commercial Commitments**

Our contractual obligations as of December 31, 2005 were as follows (in thousands):

		Less than		More than	
	Total	1 Year	1-3 Years	3-5 Years	5 Years
Operating lease commitments	\$ 3,742	\$ 116	\$ 1,450	\$ 1,545	\$ 631
Our commitments for operating leases include leases for our present office	facility and offic	e equinment	In 2005 we o	htained a \$3/	0 000

Our commitments for operating leases include leases for our present office facility and office equipment. In 2005, we obtained a \$340,000 irrevocable letter of credit in conjunction with the lease agreement covering our present facility. This irrevocable letter of credit is collateralized for the same amount by cash, cash equivalents and short-term investments held in a Company bank account and has been recorded as restricted cash.

We also have contractual payment obligations, the timing of which is contingent on future events. Under our license agreements with Genentech, aggregate payments of up to \$0.5 million would be due if milestones relating to the initial product approval of rhIGF-1 for severe Primary IGFD in Europe are achieved. Additional milestone payments would be due for subsequent indication approvals, including for approvals of products consisting of rhIGF-1 or IGF binding protein 3, in the United States or Europe.

Under our agreement with Cambrex Baltimore, we have a non-cancelable obligation to reimburse Cambrex Baltimore on a time and materials and per batch basis in connection with the commercial production of Increlex. We estimate that our total purchase commitment to Cambrex Baltimore is approximately \$4.5 million through December 31, 2006. Further, as we reach certain milestones, we will be committed to make certain future purchases.

#### **Operating Capital and Capital Expenditure Requirements**

We believe that our cash, cash equivalents and short-term investments as of December 31, 2005 of \$58.6 million, together with the net proceeds from our public offering of common stock in January 2006 of approximately \$34.1 million and our CEFF, will be sufficient to meet our projected operating and capital expenditure requirements through at least the end of 2007 based on our current business plan. We plan to make significant expenditures to support our marketing, sales, clinical trial, regulatory, and manufacturing development activities. We expect to focus on commercial launch activities for severe Primary IGFD and continue to expand our development projects for severe Primary IGFD and Primary IGFD. We also expect to make significant legal expenditures for our ongoing litigations.

We obtained approval for the long-term treatment of growth failure in children with severe Primary IGFD or with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone from the FDA in August 2005, and we are marketing Increlex for those indications. In addition, we submitted an MAA to EMEA seeking approval to market Increlex in the European Union for an indication that is similar. We are also conducting two late-stage clinical trials for the use of Increlex in Primary IGFD as well as other clinical activities. Our projects may be subject to change from time-to-time as we evaluate our research and development priorities and available resources. These projects may also yield varying results that could delay, limit or change the timing of a project s advancement through various stages of product development and significantly impact the costs to be incurred in bringing a project to completion. As a result, the costs to complete such projects, as well as the timing of net cash outflows, are not reasonably estimable.

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.

Due to the significant risks and uncertainties inherent in the manufacturing, clinical development and regulatory approval processes, the costs to complete our projects through product commercialization are not accurately predictable. Results from regulatory review, manufacturing operations and clinical trials may not be favorable. Further, data from clinical trials is subject to varying interpretation, and may be deemed insufficient by the regulatory bodies reviewing applications for marketing approvals. As such, our development projects are subject to risks, uncertainties and changes that may significantly impact cost projections and timelines. As a result, our capital requirements may increase in future periods.

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 the CEFF. However, there is no assurance that additional funding will be available to finance our operations when needed or on acceptable terms. Additional funding may also result in dilution to our stockholders.

## Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and short-term investments in a variety of securities, including auction rate debt securities, commercial paper, federal agency bonds, repurchase agreements and money market funds. Our cash and cash equivalents through December 31, 2005 included liquid money market accounts. Our short-term investments included readily marketable debt securities. Due to the short-term nature of these instruments, a 10% movement in market interest rates would not have a significant negative impact on the total value of our portfolio as of December 31, 2005.

Item 8. Financial Statements and Supplementary Data.

## TERCICA, INC.

# (A DEVELOPMENT STAGE COMPANY)

# INDEX TO FINANCIAL STATEMENTS

Reports of Independent Registered Public Accounting Firm	Page 57
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Statements of Stockholders Equity (Deficit)	61
Statements of Cash Flows	64
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#### **Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of

Tercica, Inc.

We have audited the accompanying balance sheets of Tercica, Inc. (a development stage company) as of December 31, 2005 and 2004, and the related statements of operations, stockholders equity (deficit), and cash flows for each of the three years in the period ended December 31, 2005, and for the period from October 1, 2000 (inception) through December 31, 2005. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Tercica, Inc. at December 31, 2005 and 2004, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2005, and for the period from October 1, 2000 (inception) through December 31, 2005, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Tercica, Inc. s internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 13, 2006 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California

March 13, 2006

#### **Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of

Tercica, Inc.

We have audited management s assessment, included in the accompanying Management s Annual Report on Internal Control over Financial Reporting at Item 9A, that Tercica, Inc. (a development stage company) maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Tercica, Inc. s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of the company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management s assessment that Tercica, Inc. maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Tercica, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets as of December 31, 2005 and 2004, and the related statements of operations, stockholders equity (deficit), and cash flows for each of the three years in the period ended December 31, 2005, and for the period from October 1, 2000 (inception) through December 31, 2005 of Tercica, Inc. (a development stage company) and our report dated March 13, 2006 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California

March 13, 2006

## TERCICA, INC.

# (A DEVELOPMENT STAGE COMPANY)

#### **BALANCE SHEETS**

## (In thousands, except share and per share data)

		Decer 2005	December 31,		
Assets		2005		2004	
Current assets:					
Cash and cash equivalents	\$	14,817	\$	14,126	
Short-term investments	Ŷ	43,809	Ψ	37,875	
Inventories		1,636		.,	
Prepaid expenses and other current assets		1,673		705	
Total current assets		61,935		52,706	
Property and equipment, net		4,021		2,266	
Restricted cash		340			
Other assets		20		50	
Total assets	\$	66,316	\$	55,022	
Liabilities and stockholders equity					
Current liabilities:					
Accounts payable	\$	2,245	\$	3,967	
Accrued expenses		5,750		3,032	
Liability for early exercise of stock options		70		165	
Total current liabilities		8,065		7,164	
Deferred rent		1,429			
Other liabilities		24		181	
Total liabilities		9,518		7,345	
Commitments and contingencies					
Stockholders equity: Preferred stock, \$0.001 par value: 5,000,000 shares authorized, no shares issued and outstanding at December 31, 2005 and 2004					
Common stock, \$0.001 par value: 100,000,000 shares authorized; 31,578,859 and 24,172,162 shares issued		22		24	
and outstanding at December 31, 2005 and 2004, respectively Additional paid-in capital		32 225,100		24 173,621	
Deferred stock compensation		(2,591)		(6,388)	
Accumulated other comprehensive loss		(2,391)		(0,388)	
Deficit accumulated during the development stage		(165,741)	(	(72)	
Total stockholders equity		56,798		47,677	
Total liabilities and stockholders equity	\$	66,316	\$	55,022	

See accompanying notes.

# TERCICA, INC.

## (A DEVELOPMENT STAGE COMPANY)

#### STATEMENTS OF OPERATIONS

(In thousands, except per share data)

Year Ended December 31, Period From

October 1,

2000

(Inception)

Through

December 31,

	2005	2004	2003	2	2005
Costs and expenses:					
Research and development*	\$ 21,587	\$ 27,918	\$ 19,246	\$	71,212
Selling, general and administrative*	25,913	12,552	4,834		45,903
Acquired in-process research and development		1,417	1,670		8,158
Total costs and expenses	(47,500)	(41,887)	(25,750)	(	125,273)
Interest expense	(1,080)				(1,186)
Interest and other income, net	2,347	885	327		3,746
Net loss	(46,233)	(41,002)	(25,423)	(	122,713)
Deemed dividend related to beneficial conversion feature of convertible preferred stock			(44,153)		(44,153)
SIOCK			(44,155)		(++,155)
Net loss allocable to common stockholders	\$ (46,233)	\$ (41,002)	\$ (69,576)	\$ (	166,866)
Basic and diluted net loss per share allocable to common stockholders	\$ (1.51)	\$ (2.12)	\$ (38.59)		
Shares used to compute basic and diluted net loss per share allocable to common stockholders	30,590	19,302	1,803		
* Includes non-cash stock-based compensation expense as follows:					
Research and development	\$ 1,188	\$ 1,386	\$ 791	\$	3,369
Selling, general and administrative	1,006	1,455	256		2,719
Total	\$ 2,194	\$ 2,841	\$ 1,047	\$	6,088

See accompanying notes.

## TERCICA, INC.

## (A DEVELOPMENT STAGE COMPANY)

# STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

## (In thousands, except share and per share data)

	Class A	Class A and B Common Stock		ck							
Balances et October 1, 2000 (incerting)	Shares	Amount	Shares		l ount(	Paid-in Capi <b>t</b> ab	Stock	Inco intion(Lo	A hensiv ome D	Deficit Accumulated Ye During S Development Stage \$	tockholders Equity (Deficit)
Balances at October 1, 2000 (inception)		\$		\$		\$	\$	\$		\$	\$
Issuance of Tercica Limited Class A shares to founders for cash and intellectual property in March 2001	162,360	67									67
Issuance of Tercica Limited Class B shares to founders for	102,300	07									07
cash and intellectual property in March 2001	725,449	465									465
Comprehensive loss:	725,449	405									405
Foreign currency translation adjustment									(5)		(5)
Net loss									(5)	(294)	(294)
10011055										(2)4)	(2)4)
											(= = = =)
Comprehensive loss											(299)
Balances at March 31, 2001	887,809	532							(5)	(294)	233
Issuance of Tercica Limited Class B shares at \$16.12 per											
share to founders for cash in July 2001	37,282	601									601
Comprehensive loss:											
Foreign currency translation adjustment									22		22
Net loss										(808)	(808)
Comprehensive loss											(786)
											(, 00)
B. L	025 001	1 1 2 2							17	(1.100)	40
Balances at December 31, 2001	925,091	1,133							17	(1,102)	48
Issuance of common stock to founders at \$0.0062 per share in			1 400 127		1	8					9
February 2002			1,480,137		1	8					9
Liquidating distribution to shareholders and retirement of all	(025.001)	(1.122)								1.124	( <b>0</b> )
outstanding Tercica Limited shares in March 2002	(925,091)	(1,133)								1,124	(9)
Issuance of common stock to a founder and employee at \$0.0062 per share in February and May 2002			333,598		1	1					2
Issuance of stock options to consultants in exchange for			555,596		1	1					2
services						6					6
Comprehensive loss:						0					0
Reversal of foreign currency translation adjustment upon											
liquidation of Tercica Limited									(17)		(17)
Net loss									(17)	(8,952)	(8,952)
										(0,752)	(0,752)
Comprehensive loss											(8,969)
Balances at December 31, 2002 (carried forward)		\$	1,813,735	\$	2	\$ 15	\$	\$		\$ (8,930)	\$ (8,913)
	See aci	companyin		Ŧ	_		Ŧ	Ŧ		(0,200)	(0,2-0)
	See all	panyin	0 110100.								

# TERCICA, INC.

## (A DEVELOPMENT STAGE COMPANY)

# STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)

## (In thousands, except share and per share data)

	Class A and B	Common	Stock					Def	icit	
							Accumulate	d		Total
							Other	Accum		
				1	Additional Paid-in	Deferred Stock	Comprehens Income		0	Stockholders
	Shares Amount	Shares	Amour	nt		Compensatio		Sta	pment age	Equity (Deficit)
Balances at December 31, 2002 (brought		Sharts	11100		cupitui	compensatio	(1000)		·8·	(2 011010)
forward)	\$	1,813,735	\$ 2	2 :	\$ 15	\$	\$	\$	(8,930)	\$ (8,913)
Vesting of common stock from early exercises										
of stock options		255,739			102					102
Issuance of common stock		14,267			6					6
Deferred stock compensation					6,888	(6,888	5)			
Amortization of deferred stock compensation						904	Ļ			904
Issuance of stock options to consultants in										
exchange for services					144					144
Beneficial conversion feature related to										
issuance of Series B convertible preferred										
stock					44,153					44,153
Deemed dividend related to beneficial										
conversion feature of convertible preferred										
stock								(4	44,153)	(44,153)
Comprehensive loss:										
Unrealized loss on marketable securities							(18	)		(18)
Net loss							, ,		25,423)	(25,423)
Comprehensive loss										(25,441)
Balances at December 31, 2003		2,083,741	2	2	51,308	(5,984	) (18	) (7	78,506)	(33,198)
Issuance of common stock upon net exercise		_,,.			,	(*,***	(	, (,	, )	(,-,-)
of warrants		139,750								
Conversion of Series A convertible preferred		,								
stock to common stock		6,466,662	7	7	24,846					24,853
Conversion of Series B convertible preferred		.,,			,					,
stock to common stock		8,830,646	9	)	43,775					43,784
Issuance of common stock upon initial public		0,020,010			10,110					15,701
offering at \$9.00 per share in March and April										
2004, net of underwriting discount and										
offering expenses of \$6,905		6,325,000	6	ń	50,014					50,020
Vesting of common stock from early exercises		0,525,000	, in the second s	,	50,011					50,020
of stock options		258,913			173					173
Issuance of common stock		67,450			260					260
Deferred stock compensation, net of		07,150			200					200
forfeitures					3,138	(3,138	0			
Amortization of deferred stock compensation					5,150	2,734	<i>i</i>			2,734
Issuance of stock options to consultants in						2,754				2,734
exchange for services					107					107
Comprehensive loss:					107					107
Unrealized loss on marketable securities							(54	)		(54)
Net loss							(34	/	41,002)	(41,002)
								(-	.1,002)	(11,002)

Comprehensive loss

(41,056)

# Table of Contents

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Balances at December 31, 2004 (carried												
forward)	\$	24,172,162 \$	24	\$ 173,621	\$	(6,388)	\$	(72)	\$	(119,508)	\$	47,677
See accompanying notes.												

#### TERCICA, INC.

# (A DEVELOPMENT STAGE COMPANY)

# STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)

## (In thousands, except share and per share data)

	Class A and B	Common Stock				Асси	unulated	Deficit			Total		
	Shares Amount	Shares	Amou		Additional Paid-in Capital		Deferred Stock mpensation	Comp Ir	Other	Ac e	cumulated During velopment Stage		ckholders Equity Deficit)
Balances at December 31, 2004 (brought forward)	\$	24,172,162	¢	1	\$ 173,621	\$	(6,388)	¢	(72)	¢	(110 509)	¢	47,677
Issuance of common stock upon initial public offering at \$8.00 per share in February 2005, net of underwriting discount	Φ					ò	(0,388)	Φ	(72)	\$	(119,508)	ф	ć
and offering expenses of \$4,058		6,900,000		7	51,135								51,142
Vesting of common stock from early exercises of stock options Issuance of common stock		201,373 192,824		1	140 806								141 806
Reversal of deferred stock compensation due to forfeitures		172,024			(1,695)	1	1,695						000
Amortization of deferred stock compensation							2,102						2,102
Issuance of stock options to consultants in exchange for services					72								72
Stock-based compensation recognized due to stock option modifications					20								20
Issuance of common stock in connection with senior credit facility, net of issuance													
costs of \$1 Financing cost of warrant issued in		112,500			1,001								1,001
connection with committed equity financing facility					(1,196)	1							(1,196)
Issuance of warrant in connection with committed equity financing facility					1,196								1,196
Comprehensive loss: Unrealized gain on marketable securities									70				70
Net loss									70		(46,233)		(46,233)
Comprehensive loss													(46,163)
Balances at December 31, 2005	\$	31,578,859	\$ 3	2	\$ 225,100	\$	(2,591)	\$	(2)	\$	(165,741)	\$	56,798

See accompanying notes.

## TERCICA, INC.

# (A DEVELOPMENT STAGE COMPANY)

# STATEMENTS OF CASH FLOWS

## (In thousands)

	Year E	Period From October 1, 2000 (Inception) Through December 31,		
	2005	2004	2003	2005
Cash flows from operating activities:	2002	2001	2000	2000
Net loss	\$ (46,233)	\$ (41,002)	\$ (25,423)	\$ (122,713)
Adjustments to reconcile net loss to net cash used in operating activities:	+ (,)	+ (,)	+ (,)	÷ (,;)
Depreciation and amortization	707	446	92	1,264
Loss on sale of equipment	76			76
Property and equipment written-off		9		17
Amortization of deferred stock compensation, net of forfeitures	2,102	2,734	904	5,740
(Accretion) / Amortization of (discounts) /premiums relating to available-for-sale securities	(701)	454	471	224
Amortization of debt issuance costs	1,002			1,002
Commitment fee written-off due to termination of senior credit facility	75			75
Stock compensation to consultants in exchange for services	72	107	143	328
Issuance of warrants in connection with convertible note		10,	110	105
Issuance of stock in exchange for intellectual property				130
Acquired in-process research and development				4,071
Other	23			23
Changes in operating assets and liabilities:	20			20
Prepaid expenses and other assets	(938)	2,101	(2,486)	(1,693)
Inventories	(1,636)	2,101	(2,100)	(1,636)
Restricted cash	(340)			(340)
Accounts payable	(1,722)	(1,384)	4,943	2,246
Accrued expenses	2,718	1,818	1,125	5,750
Deferred rent	1,429	-,	-,	1,429
Net cash used in operating activities	(43,366)	(34,717)	(20,231)	(103,902)
Cash flows from investing activities:				
Purchases of property and equipment	(2,838)	(407)	(2,298)	(5,678)
Proceeds received from sale of equipment	300			300
Purchases of available-for-sale securities	(110,641)	(113,184)	(63,653)	(287,478)
Proceeds from maturities and sales of available-for-sale securities	105,475	110,165	27,800	243,440
Net cash used in investing activities	(7,704)	(3,426)	(38,151)	(49,416)
Cash flows from financing activities:				
Net proceeds from issuance of Class A and B shares				1,004
Liquidating distribution to Tercica Limited shareholders				(9)
Net proceeds from issuance of preferred stock			43,784	63,800
Proceeds from issuance of convertible note			43,764	500
			160	
Proceeds from issuance of Series A convertible preferred stock for exercise of warrants	806	260		160
Proceeds from issuance of common stock, excluding early exercised options	800	260 40	6 511	1,083 622
Proceeds from early exercised options	(111)	40	511	
Repurchases of unvested early exercised options	(111)			(111)
Payment of commitment fees for senior credit facility	(76)	50.020		(76)
Net proceeds from public offerings of common stock	51,142	50,020		101,162
Net cash provided by financing activities	51,761	50,320	44,461	168,135

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Net increase (decrease) in cash and cash equivalents		691	12,177	(	(13,921)	14,817
Cash and cash equivalents, beginning of period			1,949		15,870	
Cash and cash equivalents, end of period	\$	14,817	\$ 14,126	\$	1,949	\$ 14,817
Supplemental schedule of noncash activities:						
Cash paid during the year for:						
Interest expense	\$	75	\$	\$		\$ 75
Non-cash investing and financing activities:						
Issuance of stock in exchange for intellectual property	\$		\$	\$		\$ 129
Issuance of Series A convertible preferred stock to a collaboration partner in exchange for acquired						
in-process research and development	\$		\$	\$		\$ 4,071
Issuance of warrants in connection with convertible note	\$		\$	\$		\$ 106
Issuance of warrants as commissions in connection with Series A preferred stock financing	\$		\$	\$		\$ 41
Conversion of convertible note into Series A convertible preferred stock	\$		\$	\$		\$ 500
Issuance of common stock from vesting of early exercises of stock options	\$	140	\$ 173	\$	102	\$ 415
Issuance of common stock for senior credit facility	\$	1,001	\$	\$		\$ 1,001
Issuance of warrant in connection with committed equity financing facility	\$	1,196	\$	\$		\$ 1,196
Deferred stock compensation, net of forfeitures	\$	(1,695)	\$ 3,138	\$	6,888	\$ 8,331
Deemed dividend related to beneficial conversion feature of convertible preferred stock	\$		\$	\$	44,153	\$ 44,153
Conversion of Series A and B convertible preferred stock into common stock	\$		\$ 68,637	\$		\$ 68,637

See accompanying notes.

#### TERCICA, INC.

#### (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS

#### 1. Company and Basis of Presentation

#### **Basis of Presentation**

Tercica, Inc. (the Company ) is a biopharmaceutical company focused on the development and commercialization of new therapeutics for the treatment of short stature and other endocrine disorders. The Company s first commercial product is Increlex, a DNA-derived recombinant human insulin-like growth factor-1 (rhIGF-1). The Company obtained approval for the long-term treatment of growth failure in children with severe primary insulin-like growth factor deficiency, or severe Primary IGFD, or with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone from the U.S. Food and Drug Administration (FDA) in August 2005, and Increlex was granted seven vears of orphan drug marketing exclusivity for the long-term treatment of growth failure in children with severe Primary IGFD. In January 2006, the Company launched Increlex in the United States. The Company also submitted a Marketing Authorization application (MAA) in the European Union for the long-term treatment of growth failure in children with severe Primary IGFD or with growth hormone gene deletion who have developed neutralizing antibodies to growth hormone. The Company licensed the rights of Genentech to develop, manufacture and commercialize rhIGF-1 products for a broad range of indications, including short stature, worldwide. The Company s current focus is on marketing and selling Increlex for the treatment severe Primary IGFD, and developing Increlex as a replacement therapy for primary IGF-1 deficiency, or Primary IGFD. The Company defines the indication Primary IGFD to mean a child who has a height standard deviation score (Height SDS) and an IGF-1 standard deviation score (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. The Company is developing Increlex for use in the broad population of children with Primary IGFD. The Company is currently conducting two late-stage clinical trials for the use of rhIGF-1 in Primary IGFD. The Company is also assessing their Increlex development strategy for other indications.

The Company s predecessor, Tercica Limited, a New Zealand Company, was formed in October 2000. Tercica Medica, Inc. was incorporated in Delaware in December 2001, adopted the calendar year as its fiscal year and subsequently changed its name in September 2003 to Tercica, Inc. In early 2002, the Company acquired (at amounts approximating Tercica Limited s historical net book value) an immaterial amount of assets, including intellectual property rights, from Tercica Limited as its operations were moved from New Zealand to California. In March 2002, Tercica Limited made a final, immaterial distribution to its stockholders in connection with its legal liquidation.

These development stage financial statements and accompanying notes include the results of operations from the inception of Tercica Limited in October 2000 as both entities were under common control as evidenced by the following factors: (i) all of the investors of Tercica Limited were founding stockholders of the Company, (ii) substantially all of the employees of Tercica Limited became employees of the Company, (iii) the nearly identical business plans adopted by both entities and (iv) the commencement of negotiations to obtain the license for recombinant human insulin-like growth factor-1 ( rhIGF-1 ) from Genentech, Inc. by Tercica Limited, and the completion of those negotiations by the Company.

The Company is considered to be in the development stage at December 31, 2005, as its primary activities since incorporation have been establishing its facilities, recruiting personnel, conducting research and development, business development, business and financial planning, preparing for the commercialization of Increlex and raising capital.

#### TERCICA, INC.

#### (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS (Continued)

#### **Initial Public Offering**

On March 22, 2004, the Company completed its initial public offering of 5,500,000 shares of its common stock, at \$9.00 per share. Net cash proceeds of the initial public offering were approximately \$43,116,000, after deducting underwriter discounts, commissions and other offering expenses. In conjunction with the closing of the initial public offering, all of the Company s outstanding shares of Series A and Series B convertible preferred stock outstanding at the time of the offering were automatically converted into 15,297,308 shares of common stock.

On March 30, 2004, the underwriters of the Company s initial public offering exercised in full their over-allotment option for 825,000 shares of its common stock. On April 2, 2004, the Company received the net cash proceeds of approximately \$6,905,000, after deducting underwriter discounts, commissions and other offering expenses.

In connection with the Company s initial public offering, all outstanding warrants to purchase 146,250 shares of common stock were net exercised resulting in 139,750 shares of common stock issued, with the warrant for the remaining 6,500 shares relinquished as non-cash payment.

#### **Follow-on Public Offerings**

On February 11, 2005, the Company completed a follow-on public offering of 6,900,000 shares of its common stock, at a price to the public of \$8.00 per share, including the exercise of the over-allotment option by the underwriters. Net cash proceeds from this offering were approximately \$51,100,000 after deducting underwriter discounts and other offering expenses.

On September 9, 2005, the Company filed a shelf registration statement with the SEC pursuant to which the Company may, from time to time, offer and sell shares of the Company s 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 \$75,000,000, at prices and on terms to be determined by market conditions at the time of any offering made under the shelf registration statement. The SEC declared the shelf registration statement effective on December 1, 2005. On January 27, 2006, the Company completed the sale of 5,750,000 shares of its common stock under this shelf registration statement, at a price to the public of \$6.40 per share, including the exercise of the over-allotment option by the underwriters. Net cash proceeds from this offering were approximately \$34,100,000 after deducting underwriter discounts and other offering expenses.

#### Need to Raise Additional Capital

The Company has incurred significant net losses and negative cash flows from operations since its inception. At December 31, 2005, the Company had an accumulated deficit of \$165,741,000. After considering the net cash proceeds obtained in January 2006, as described above, management believes that currently available resources, including cash, cash equivalents and short-term investments and the Committed Equity Financing Facility (See Note 8), will provide sufficient funds to enable the Company to meet its projected operating and capital expenditure requirements through at least the end of 2007 based on the Company s current business plan. If anticipated operating results are not achieved, however, management believes that planned expenditures may need to be reduced, extending the time period over which the currently available resources will be adequate to fund the Company s operations. The Company intends to raise additional funds through the issuance of equity securities, if available on terms acceptable to the Company.

## TERCICA, INC.

#### (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS (Continued)

#### 2. Summary of Significant Accounting Policies

#### **Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

#### Concentrations

Financial instruments that potentially subject the Company to credit risk consist of cash, cash equivalents and short-term investments to the extent of the amounts recorded on the balance sheets. The Company s cash, cash equivalents and short-term investments are placed with high credit-quality financial institutions and issuers. The Company believes its established guidelines for investment of its excess cash maintain safety and liquidity through its policies on diversification and investment maturity.

The Company sources all if its bulk manufacturing and fill-finish manufacturing through single-source third-party suppliers and contractors and the Company obtains specific components and raw materials used to manufacture Increlex from either single-source or sole-source suppliers. If these contract facilities, suppliers or contractors become unavailable to the Company for any reason, the Company may be delayed in manufacturing Increlex or may be unable to maintain validation of Increlex, which could delay or prevent the supply of commercial and clinical product, or delay or otherwise adversely affect revenues. The Company believes that it has established guidelines to maintain an adequate level of inventory to mitigate this potential negative impact.

#### Cash, and Cash Equivalents, Short-Term Investments and Restricted Cash

The Company considers all highly liquid investments with a remaining maturity of 90 days or less at the date of purchase to be cash equivalents. Cash equivalents are carried at cost, which approximates fair value. The Company s cash equivalents include interest-bearing money market funds. The Company s short-term investments primarily consist of readily marketable debt securities with remaining maturities of more than 90 days at the time of purchase.

The Company has classified its entire investment portfolio as available-for-sale. These securities are recorded as either cash equivalents or short-term investments and are carried at fair value with unrealized gains or losses included in accumulated other comprehensive income (loss) in the stockholders equity (deficit). The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest and other income, net. Realized gains and losses are also included in interest and other income, net. The cost of all securities sold is based on the specific identification method.

The Company obtained a \$340,000 irrevocable letter of credit in conjunction with a lease agreement for its facility. The letter of credit is collateralized for the same amount by cash, cash equivalents and short-term investments held in a Company bank account and has been recorded as restricted cash (see Note 6) in the accompanying balance sheet.

## TERCICA, INC.

## (A DEVELOPMENT STAGE COMPANY)

## NOTES TO FINANCIAL STATEMENTS (Continued)

The following is a summary of available-for-sale securities (in thousands):

	December 31, 2005			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Available-for-sale debt securities maturing within 1 year:				
Auction market preferred	\$ 36,150	\$	\$	\$ 36,150
Commercial paper	13,468	3		13,471
Federal agency bonds	5,477		(5)	5,472
Repurchase agreements	3,000			3,000
Total available-for-sale debt securities	\$ 58,095	\$ 3	\$ (5)	\$ 58,093

	December 31, 2004					
	Amortized Cost	Gross Unrealized Gains	Gros Unreal Loss	ized		timated Fair Value
Available-for-sale debt securities maturing within 1 year:						
Corporate bonds	\$ 5,815	\$	\$	(14)	\$	5,801
Commercial paper	9,346			(2)		9,344
Federal agency bonds	19,759			(26)		19,733
Municipal bonds	9,753			(30)		9,723
Total available-for-sale debt securities	\$ 44,673	\$	\$	(72)	\$	44,601

The Company s financial instruments are classified as follows (in thousands):

	Decem 2005	ıber 31, 2004
Cash	\$ 873	\$ 7,400
Cash equivalents	13,944	6,726
Cash and cash equivalents	14,817	14,126
Short-term investments	43,809	37,875
Long-term restricted cash	340	
Total	\$ 58,966	\$ 52,001

Realized losses on the sale of available-for-sale securities for the years ended December 31, 2005 and 2004 were immaterial.

#### **Fair Value of Financial Instruments**

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The carrying amounts of financial instruments, which include cash equivalents, short-term investments, restricted cash, accounts payable, accrued expenses and long-term obligations approximate their fair values due to the relatively short maturities.

## TERCICA, INC.

#### (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS (Continued)

#### Inventories

Inventories are stated at the lower of cost or market and consist primarily of contract manufacturing costs for the production of Increlex that were incurred subsequent to the approval for marketing by the FDA. Cost is determined using the first-in, first-out basis. The valuation of inventory requires the Company to estimate obsolete or excess inventory based on analysis of future demand for Increlex. If inventory costs exceed expected market value due to obsolescence or lack of demand, reserves may be recorded as deemed necessary by management for the difference between the cost and the market value. These reserves are determined based on significant estimates by management and will be recorded as a write-down to net realizable value in the period that impairment is first recognized.

#### **Research and Product Development Costs**

In accordance with Statement of Financial Accounting Standards (SFAS) No. 2, *Accounting for Research and Development Costs*, research and development costs are expensed as incurred. Research and development expenses consist primarily of contract manufacturing expenses associated with manufacturing development activities, clinical activities, regulatory activities, payroll and related costs, non-cash stock compensation, laboratory supplies and certain allocated costs. Manufacturing development primarily includes costs associated with process development and validation, quality control and assurance activities, analytical services and preparation for current good manufacturing practices (cGMP) in order to provide clinical drug supply.

#### **Acquired In-Process Research and Development**

Acquired in-process research and development relates to in-licensed technology, intellectual property and know-how. The nature of the remaining efforts for completion of research and development activities surrounding rhIGF-1 generally include completion of clinical trials, completion of manufacturing validation, interpretation of clinical and preclinical data and obtaining marketing approval from the FDA and other foreign regulatory bodies, the cost, length and success of which are extremely difficult to determine. Numerous risks and uncertainties exist with timely completion of development projects, including clinical trial results, manufacturing process development results, ongoing feedback from regulatory authorities, including obtaining marketing approval. In addition, products under development may never be successfully commercialized due to the uncertainties associated with the pricing of new pharmaceuticals, the cost of sales to produce these products in a commercial setting, changes in the reimbursement environment, or the introduction of new competitive products. As a result of the uncertainties noted above, the Company charges in-licensed intellectual property and licenses for unapproved products to acquired in-process research and development.

#### **Clinical Trial Expenses**

The Company contracts with third-party clinical research organizations to perform various clinical trial activities. The Company recognizes research and development expenses for these contracted activities based upon a variety of factors, including actual and estimated patient enrollment rates, clinical site initiation activities, labor hours and other activity-based factors. The Company matches the recording of expenses in the financial statements to the actual services received and efforts expended. Depending on the timing of payments to the service providers, the Company records prepaid expenses and accruals relating to clinical trials based on the estimate of the degree of completion of the event or events as specified each clinical study or trial contract. The Company monitors each of these factors to the extent possible and adjusts estimates accordingly.

### **Promotional and Advertising Expenses**

The Company expenses the costs of promotional and advertising expenses, as incurred. Promotional and advertising expenses consist primarily of promotional materials and activities, design and layout costs of

## TERCICA, INC.

#### (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS (Continued)

promotional materials, and direct mail advertising. Promotional and advertising expenses were \$1,069,000, \$75,000 and \$0 in the years ended December 31, 2005, 2004 and 2003, respectively.

#### **Property and Equipment**

Property and equipment are stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, but not more than:

Description	Estimated Useful Lives
Computer equipment and software	3 years
Office equipment	5 years
Furniture and fixtures	7 years
Manufacturing equipment	10 years
Leasehold improvements	Shorter of useful life or life of
	lease

#### Impairment of Long-Lived Assets

The Company reviews its long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss is recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Impairment, if any, is assessed using discounted cash flows.

#### **Income Taxes**

The Company utilizes the liability method of accounting for income taxes as required by SFAS No. 109, *Accounting for Income Taxes*. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Currently, there is no provision for income taxes as the Company has incurred operating losses to date.

#### **Stock Compensation**

Through December 31, 2005, the Company accounted for employee stock options using the intrinsic-value method in accordance with Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, Financial Accounting Standards Board Interpretation (FIN) No. 44, *Accounting for Certain Transactions involving Stock Compensation, an interpretation of APB No. 25*, and related interpretations and adopted the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation,* as amended.

The information regarding net loss as required by SFAS No. 123 has been determined as if the Company had accounted for its employee stock options under the fair value method of that Statement.

## TERCICA, INC.

### (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS (Continued)

The fair value of each option grant is estimated at the date of grant using the Black-Scholes method with the following weighted-average assumptions:

	Year E	Year Ended December 31,		
	2005	2004	2003	
Risk-free interest rate	3.8%	2.9%	2.8%	
Volatility	0.5	0.8	0.8	
Weighted-average expected life of options (years)	3.6	3.8	4.0	
Dividend yield	0.0%	0.0%	0.0%	

During the period from February 1, 2003 through January 31, 2004, certain stock options were granted with exercise prices that were below the reassessed fair value of the common stock at the date of grant. Total deferred compensation of \$6,888,000 was recorded in accordance with APB Opinion No. 25, and is being amortized over the related vesting period of the options. The Company recorded employee stock-based compensation expense of \$2,102,000, \$2,734,000 and \$904,000 for the years ended December 31, 2005, 2004 and 2003, respectively. During the years ended December 31, 2005 and 2004, the Company reversed \$1,695,000 and \$847,000, respectively, of deferred stock compensation due to forfeitures of unvested stock options resulting from employee terminations.

The following table illustrates the effect on net loss allocable to common stockholders had the Company applied the fair value provisions of SFAS No. 123 to employee stock compensation (in thousands, except per share data):

	Year Ended December 31,			Oct (Incep	eriod From ober 1, 2000 otion) Through ecember 31,
	2005	2004	2003		2005
Net loss allocable to common stockholders, as reported	\$ (46,233)	\$ (41,002)	\$ (69,576)	\$	(166,866)
Plus: Employee stock compensation expense based on intrinsic value method	2,102	2,734	904		5,740
Less: Employee stock compensation expense determined under the fair value method for all awards	(4,424)	(3,307)	(976)		(8,728)
Pro forma net loss allocable to common stockholders	\$ (48,555)	\$ (41,575)	\$ (69,648)	\$	(169,854)
Net loss per share allocable to common stockholders:					
Basic and diluted, as reported	\$ (1.51)	\$ (2.12)	\$ (38.59)		
Basic and diluted, pro forma	\$ (1.59)	\$ (2.15)	\$ (38.63)		

Stock compensation arrangements to non-employees are accounted for in accordance with SFAS No. 123, as amended by SFAS No. 148, and Emerging Issues Task Force (EITF) No. 96-18, Accounting for Equity Instruments that Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services, using a fair value approach. The compensation costs of these arrangements are subject to remeasurement over the vesting terms as earned.

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On December 16, 2004, the FASB issued an amendment to SFAS No. 123, *Share-Based Payment*, (SFAS No. 123R). The Company adopted SFAS No. 123R as of January 1, 2006. SFAS No. 123R addresses the accounting for transactions in which an enterprise receives employee services in exchange for equity instruments

### TERCICA, INC.

#### (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS (Continued)

of the enterprise or liabilities that are based on the fair value of the enterprise s equity instruments or that may be settled by the issuance of such equity instruments. SFAS No. 123R eliminates the ability to account for share-based compensation transactions using APB Opinion No. 25, and requires instead that such transactions be accounted for using a fair-value-based method. Companies are required to recognize an expense for compensation cost related to share-based payment arrangements including stock options and employee stock purchase plans. The Company has selected the Black-Scholes option-pricing model to be used for valuing share-based payments. The Company has also selected the modified prospective transition method, whereby compensation cost is recognized based on the requirements of SFAS No. 123R beginning with the effective date (a) for all share-based payments granted after the effective date and (b) for all awards granted to employees prior to the effective date of SFAS No. 123R that remain unvested on the effective date. The Company believes that the adoption of the new standard will have a material impact on the Company s results of operations. The Company expects to continue to grant stock-based compensation to employees. The estimate of the Company s future stock-based compensation expense is affected by the Company s stock price, the number of stock-based awards the Company s board of directors may grant in the future, as well as a number of complex and subjective valuation assumptions and the related tax effect. These valuation assumptions include, but are not limited to, the volatility of the Company s stock price and employee stock option exercise behaviors.

#### **Comprehensive Loss**

Comprehensive loss is comprised of net loss, foreign currency translation adjustment and unrealized gains/losses on available-for-sale securities in accordance with SFAS No. 130, *Reporting Comprehensive Income*. The following table presents the calculation of comprehensive loss (in thousands):

	Year Ended December 31,			
	2005	2004	2003	
Net loss, as reported	\$ (46,233)	\$ (41,002)	\$ (25,423)	
Change in unrealized losses on marketable securities	70	(54)	(18)	
Comprehensive loss	\$ (46,163)	\$ (41,056)	\$ (25,441)	

#### **Foreign Currency Translation**

The functional currency of Tercica Limited was New Zealand Dollars. Accordingly, through December 31, 2001, the Company s assets and liabilities were translated into U.S. dollars using the exchange rates in effect at each balance sheet date, while income and expense items were translated using average rates of exchange during each period. Gains or losses from translation were included in accumulated other comprehensive loss. Net gains and losses resulting from foreign currency transactions were recorded in net loss in the period incurred and were not significant for any period presented.

#### Reclassifications

Certain other amounts in prior periods have been reclassified to conform to the current period presentation.

## TERCICA, INC.

## (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS (Continued)

#### 3. Net Loss Per Share

Basic net loss per share allocable to common stockholders is calculated by dividing the net loss allocable to common stockholders by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share allocable to common stockholders is computed by dividing the net loss allocable to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by the Company, preferred stock, options, and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share allocable to common stockholders when their effect is dilutive.

	Year Ended December 31,		
	2005 (In thousar	2004 ids, except per s	2003 share data)
Historical			
Numerator:			
Net loss allocable to common stockholders	\$ (46,233)	\$ (41,002)	\$ (69,576)
Denominator:	20 (10	10.077	1.020
Weighted-average common shares outstanding	30,619	19,377	1,928
Less: Weighted-average unvested common shares subject to repurchase	(29)	(75)	(125)
Denominator for basic and diluted net loss per share allocable to common stockholders	30,590	19,302	1,803
Basic and diluted net loss per share allocable to common stockholders	\$ (1.51)	\$ (2.12)	\$ (38.59)

	Year Ended December 31,		
	2005	2004 (In thousands)	2003
Historical outstanding dilutive securities not included in diluted net loss per share allocable to			
common stockholders calculation			
Preferred stock			15,297
Options to purchase common stock	2,851	2,077	1,202
Warrant	260		146
	3,111	2,077	16,645

## 4. Balance Sheet Details

Inventories consisted of the following (in thousands):

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	2005
Raw materials	\$ 319
Work-in-process	1,229
Finished goods	88
Total	\$ 1,636

## TERCICA, INC.

## (A DEVELOPMENT STAGE COMPANY)

## NOTES TO FINANCIAL STATEMENTS (Continued)

Property and equipment, net, consists of the following (in thousands):

	Decemb	ber 31,
	2005	2004
Office equipment	\$ 292	\$ 292
Furniture and fixtures	628	197
Computer equipment and software	1,683	800
Manufacturing equipment	1,004	
Leasehold improvements	1,450	168
Construction in progress	175	1,352
Less accumulated depreciation and amortization	(1,211)	(543)
Property and equipment, net	\$ 4,021	\$ 2,266

Depreciation expense was \$707,000, \$446,000 and \$92,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

Accrued liabilities consist of the following (in thousands):

	Decem	ber 31,
	2005	2004
Accrued compensation and related liabilities	\$ 2,626	\$ 1,555
Accrued professional fees	1,577	460
Accrued contract manufacturing expenses	543	946
Clinical trial costs	276	
Other accrued liabilities	728	71
	\$ 5,750	\$ 3,032

## 5. License and Collaboration Agreement

On April 15, 2002, the Company entered into a license and collaboration agreement (the U.S. License and Collaboration Agreement ) with Genentech under which it obtained licenses to certain technology, know-how, and intellectual property rights to develop and commercialize rhIGF-1 in the U.S.

In connection with the U.S. License and Collaboration Agreement, the Company paid \$1,000,000 in cash and issued 1,017,666 shares of Series A convertible preferred stock valued at the time of issuance at \$4,071,000. The Company is required to make cash payments based on the achievement of certain milestones and royalties on future sales. Genentech has certain Opt-In rights to participate in the commercialization of certain rhIGF-1 products. If Genentech elects to exercise its Opt-In Right for a particular indication, Genentech will pay the Company more than 50% of the past development costs associated with that indication, which would have a one-time positive impact on the Company s operating results. In addition, after Genentech exercises its Opt-In Right for a particular indication, the Company would share with Genentech the ongoing net operating losses and profits resulting from the joint development and commercialization effort for that indication. Pursuant to this arrangement, the Company would fund less than 50% of such operating losses and the Company would receive less than 50% of any profits. In 2004 and early 2006, the Company paid Genentech cash of \$1,100,000 and \$100,000, respectively, under this agreement.

## TERCICA, INC.

### (A DEVELOPMENT STAGE COMPANY)

### NOTES TO FINANCIAL STATEMENTS (Continued)

On July 25, 2003, the Company entered into an international license and collaboration agreement (the International License and Collaboration Agreement ) with Genentech, obtaining certain rights to develop and commercialize rhIGF-1 for a broad range of indications, including short stature, outside of the United States. The Company paid Genentech cash of \$1,670,000 upon the execution of this license in 2003 and \$167,000 in 2004. The Company also agreed to pay to Genentech royalties on the sales of rhIGF-1 products and certain one-time payments upon the occurrence of specified milestone events. As the Company was several years away from having an approved product to market, the amount paid for this license was charged to acquired in-process research and development expense.

In addition to the amounts already paid to Genentech, if the Company achieves all of the additional milestones for rhIGF-1 under the U.S. and International License and Collaboration Agreements, the Company will owe Genentech up to an aggregate of approximately \$33,000,000 in milestone payments. If the Company develops rhIGF-1 in combination with IGF binding protein-3, the Company would be subject to these same milestone events and, upon achievement of all of the milestones, would owe Genentech up to an additional aggregate of approximately \$32,500,000 in milestone payments. In connection with the U.S. License and Collaboration Agreement, the Company paid a \$1,000,000 milestone payment to Genentech in the year ended December 31, 2005.

### 6. Commitments and Contingencies

The Company leases approximately 28,000 square feet of office space in Brisbane, California. The lease expires in October 2011 with an option to renew for five years. This lease agreement includes scheduled rent increases over the lease term and rent abatement for the first 15 months. The Company recognizes rent expense on a straight-line basis over the term that the facility is physically utilized, taking into account the scheduled rent increases, rent abatement, rent holidays and the leasehold improvement reimbursement. In September 2005, the Company received a \$1,046,000 reimbursement from the landlord for facility improvements, which was recorded as deferred rent and is being amortized to offset rent expense over the remaining life of the lease. Under the lease agreement, the Company originally provided the landlord with irrevocable letters of credit amounting to \$790,000, which were subsequently reduced to \$340,000 in September 2005 after the FDA approved Increlex for marketing in late August 2005. The remaining irrevocable letter of credit is collateralized for the same amount by cash, cash equivalents and short-term investments held in a Company bank account. The Company has recorded the collateralized bank account balance as restricted cash.

At December 31, 2005, future minimum lease commitments under operating leases were as follows (in thousands):

Year ending December 31,	
2006	\$ 116
2007	710
2008	740
2009	756
2010	789
Thereafter	631

\$ 3,742

Rent expense was \$641,000, \$453,000 and \$238,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

## TERCICA, INC.

#### (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS (Continued)

#### **Manufacturing Services Agreement**

In December 2002, the Company entered into a development and commercial supply agreement (the Manufacturing Agreement ) with Cambrex Bio Science Baltimore, Inc. (Cambrex Baltimore). At that time, the Company began to transfer its manufacturing technology to Cambrex Baltimore in order for them to establish the process for rhIGF-1 fermentation and purification. Further, under the terms of the Manufacturing Agreement, Cambrex Baltimore is obligated to annually provide the Company with certain minimum quantities of bulk rhIGF-1 drug substance. The Company has a non-cancelable obligation to reimburse Cambrex Baltimore on a time and materials and per batch basis in connection with the commercial production of Increlex of approximately \$4,482,000 through December 31, 2006. Further, as the Company reaches certain milestones, the Company will be committed to make certain future purchases. Payments under this agreement were \$6,887,000, \$11,699,000 and \$7,203,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

#### **Guarantees and Indemnifications**

In November 2002, the FASB issued Interpretation No. 45, *Guarantor s Accounting and Disclosure Requirements for Guarantees, including Indirect Guarantees of Indebtedness of Others* (FIN No. 45). FIN No. 45 requires that upon issuance of a guarantee, the guarantor must recognize a liability for the fair value of the obligations it assumes under that guarantee.

The Company, as permitted under Delaware law and in accordance with its Bylaws, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company s request in such capacity. The term of the indemnification period is for the officer s or director s lifetime. The Company may terminate the indemnification agreements with its officers and directors upon 90 days written notice, but termination will not affect claims for indemnification relating to events occurring prior to the effective date of termination. The maximum amount of potential future indemnification is unlimited; however, the Company has a director and officer insurance policy that limits its exposure and may enable it to recover a portion of any future amounts paid. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recorded any liabilities for these agreements as of December 31, 2005.

### Contingencies

On December 20, 2004, the Company initiated patent infringement proceedings against Avecia Limited and Insmed Incorporated as co-defendants in the High Court of Justice (Chancery Division Patents Court) in the United Kingdom. There is no trial date set for this action. On December 23, 2004, the Company, with Genentech, initiated patent infringement proceedings against Insmed Incorporated in the U.S. District Court for the Northern District of California. The Company initiated these litigations because it believes that Insmed and Avecia are infringing and/or have infringed on the Company s patents that cover Insmed s product s use and manufacture. The trial date is November 6, 2006; however, on March 8, 2006, we filed a motion to accelerate the trial date.

The Company cannot predict the outcome of its litigation against Avecia and Insmed in the United Kingdom or the outcome of its litigation against Insmed in the United States. Moreover, the Company cannot predict the cost of such litigation, which may require a substantial diversion of the Company s financial assets and other resources and consequently prevent the Company from allocating sufficient resources to the development of its rhIGF-1 programs, and which may have a material adverse effect on the Company s business. In addition, if the outcome of the Company s litigation in the United Kingdom is not favorable to the Company, the Company is likely to be found liable for the opposing parties costs incurred in connection with the litigation, and the

## TERCICA, INC.

### (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS (Continued)

Company could be found liable for an award of additional damages to the opposing parties if the court decides that the Company s claims of patent infringement are without sufficient merit or not pursued in good faith. If in the Company s litigation in the United States, the court decides that a defendant prevails, and the defendant establishes by clear and convincing evidence that the case is exceptional (e.g., the Company s claims of patent infringement were not pursued in good faith), the Company could be liable for an award of the opposing parties could substantially increase the Company s costs and exacerbate the negative impact that an unfavorable outcome in the case(s) could have on the Company s business. Further, it is not uncommon in cases of this kind for a defendant to assert counterclaims, which could significantly increase the Company s costs, potential liability for damages, and other risks arising from these lawsuits, and a court could find the Company liable for any such damages caused by Genentech as well.

On December 6, 2005, we filed a complaint against Insmed for False Advertising and Unfair Competition, Case No. C-05-5027 SBA, in the U.S. District Court, Northern District of California. The complaint alleges that Insmed made false, misleading and deceptive statements about Increlex and its product. We are seeking monetary and injunctive relief. We filed an amended complaint on December 15, 2005. Defendant Insmed filed a Motion to Dismiss on January 13, 2006. The motion is scheduled to be heard on March 28, 2006. Discovery has not commenced, and no trial date has been set.

From time to time, the Company may become involved in claims and other legal matters arising in the ordinary course of business. Management is not currently aware of any other matters that may have a material adverse affect on the financial position, results of operations or cash flows of the Company.

### 7. Senior Credit Facility

On January 21, 2005, the Company entered into a Loan Agreement (the Loan Agreement ) with Venture Leasing & Lending IV, Inc. (VLL) under which the Company had the option to draw down funds in the aggregate principal amount of up to \$15,000,000 through December 31, 2005. The Company paid a \$75,000 fee as part of this Loan Agreement and issued a total of 112,500 shares of its common stock to an affiliate of VLL. The 112,500 shares of common stock issued were recorded at fair market value on the dates of issuance of \$1,002,000. As of December 31, 2005, the entire amount was recognized as interest expense. The facility expired on December 31, 2005, and the Company did not borrow any funds under this facility.

#### 8. Committed Equity Financing Facility

On October 14, 2005, the Company entered into a committed equity financing facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge), which entitles the Company to sell and obligates Kingsbridge to purchase, a maximum of approximately 6.0 million newly issued shares of the Company s common stock over a period of three years for cash up to an aggregate of \$75,000,000, subject to certain conditions and restrictions. The Company may draw down under the CEFF in tranches of up to the lesser of \$7,000,000 or 2% of the Company s market capitalization at the time of the draw down of such tranche, subject to certain conditions. The common stock to be issued for each draw down will be issued and priced over an eight-day pricing period at discounts ranging from 6% to 10% from the volume weighted average price of the Company s common stock during the pricing period. During the term of the CEFF, Kingsbridge may not short the Company s stock, nor may it enter into any derivative transaction directly related to the Company s stock. The minimum acceptable purchase price, prior to the application of the appropriate discount for any shares to be sold to Kingsbridge during the eight-day pricing period, is determined by the greater of \$3.00 or 90% of the Company s closing share

## TERCICA, INC.

### (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS (Continued)

price on the trading day immediately prior to the commencement of each draw down. In connection with the CEFF, the Company issued a warrant to Kingsbridge to purchase up to 260,000 shares of the Company s common stock at an exercise price of \$13.12 per share. The exercise term of the warrant is five years beginning on April 14, 2006. The warrant was valued on the date of grant using the Black-Scholes method using the following assumptions: a risk-free interest rate of 4.1%, a life of 5.5 years, no dividend yield and a volatility factor of 0.5. The estimated value of this warrant was \$1,196,000 and was recorded as a contra-equity amount in additional paid-in capital in 2005.

On November 9, 2005 the Company filed a shelf registration statement with the SEC relating to the resale of up to 6,296,912 shares of common stock that the Company may issue to Kingsbridge pursuant to a common stock purchase agreement and warrant agreement noted above. The Company will not sell common stock under this registration statement and will not receive any of the proceeds from the sale of shares by the selling stockholder.

#### 9. Stockholders Equity Tercica Limited

#### **Class A and B Shares**

At December 31, 2001, Tercica Limited was authorized to issue 162,360 shares of its Class A shares and 763,952 shares of its Class B shares.

Holders of the Tercica Limited Class A shares were entitled to 20% of dividends, if any, voting rights, and surplus in the event of a liquidation or winding up of the Company. A shareholder with 10% or more of the Class A shares had the right to appoint one director to the Board.

Holders of the Tercica Limited Class B shares were entitled to 80% of dividends, if any, voting rights, and surplus in the event of a liquidation or winding up of the Company.

#### 10. Stockholders Equity (Deficit) Tercica, Inc.

#### **Common Stock**

At December 31, 2004 and 2005, the Company was authorized to issue 100,000,000 shares of common stock.

On September 11, 2003, the Company changed the par value of its common stock from \$0.0064 per share to \$0.001 per share.

#### **Preferred Stock**

As of December 31, 2005 and 2004, the Company was authorized to issue 5,000,000 shares of preferred stock. The board of directors has the authority, without action by its stockholders, to designate and issue shares of preferred stock in one or more series. The board of directors may also designate the rights, preferences and powers of each series of preferred stock, any or all of which may be greater than the rights of the common stock including restrictions of dividends on the common stock, dilution of the voting power of the common stock, reduction of the liquidation rights of the common stock, and delaying or preventing a change in control of the Company without further action by the stockholders. To date, the board of directors has not designated any rights, preference or powers of any preferred stock and no shares have been issued.

## TERCICA, INC.

#### (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS (Continued)

#### **Restricted Stock Purchases and Early Exercise of Options**

In February 2002, 328,158 restricted shares of common stock were issued to an employee in exchange for \$2,000 in cash. As of December 31, 2004 and 2005, 50,623 and 3,895 of these shares, respectively, were subject to repurchase by the Company. These shares are subject to a repurchase option held by the Company at the original issuance price. This right lapses 25% on the first anniversary of the agreement and in 36 equal monthly amounts thereafter.

In December 2002, the Company issued 692,943 shares of its common stock to two employees under restricted stock purchase agreements pursuant to the early exercise of their stock options for \$71,000 in cash in December 2002 and \$206,000 in cash in January 2003. During 2003, the Company issued 237,500 shares of common stock under restricted stock purchase agreements to three employees pursuant to the early exercises of their stock options in exchange for \$305,000 in cash. In January 2004, the Company issued 10,000 shares of common stock under a restricted stock purchase agreement to a director pursuant to the early exercise of stock options in exchange for \$40,000 in cash. Under the terms of these agreements, these shares generally vest over a four-year period for employees and over a three-year period for the director. Total unvested shares, which amounted to 93,700 and 425,791 at December 31, 2005 and 2004, respectively, are subject to a repurchase option held by the Company at the original issuance price in the event the optionees employment or director s tenure is terminated either voluntarily or involuntarily. These repurchase terms are considered to be a forfeiture provision and do not result in variable accounting. During the year ended December 31, 2005, the Company repurchased 130,718 shares of its common stock for approximately \$111,350 under restricted stock purchase agreements due to employee forfeitures.

In accordance with EITF No. 00-23, *Issues Related to the Accounting for Stock Compensation under APB Opinion No. 25*, and FIN No. 44, the shares purchased by the employees pursuant to the early exercise of stock options are not deemed to be issued until those shares vest. Therefore, amounts received in exchange for these shares have been recorded as liability for early exercise of stock options on the balance sheet, and will be reclassified into common stock and additional paid-in capital as the shares vest. There were 201,374 shares at an original purchase price of \$141,000 reclassified into common stock and additional paid-in capital during the year ended December 31, 2005, 258,913 shares at an original purchase price of \$173,000 reclassified into common stock and additional paid-in capital during the year ended December 31, 2004 and 255,739 shares at an original purchase price of \$102,000 reclassified into common stock and additional paid-in capital during the year ended December 31, 2003.

#### Warrants

In January 2002, the Company entered into a bridge loan agreement with two investors in which the Company received \$500,000 in exchange for a note payable convertible into the Company s Series A convertible preferred stock. The note payable was converted into 125,000 shares of Series A convertible preferred stock in May 2002. The two investors also made available an additional \$1,000,000 equity line which expired on July 31, 2002. There was no stated interest associated with the bridge loan. In connection with the bridge loan, the Company issued warrants to purchase an aggregate of 40,000 shares of the Company s Series A convertible preferred stock at an exercise price of \$4.00 per share. The warrants were exercised in November 2003. In conjunction with the closing of the Company s initial public offering in March 2004, all outstanding shares of Series A convertible stock were automatically converted into shares of common stock on a one-for-one basis.

In accordance with EITF No. 96-18, these warrants were valued on the date of grant using the Black-Scholes method using the following assumptions: a risk-free interest rate of 3.5%, a life of 5.5 years, no dividend

## TERCICA, INC.

### (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS (Continued)

yield, and a volatility factor of 0.8. The estimated fair value of the warrants was \$106,000 and was recorded as interest expense in the year ended December 31, 2002.

Additionally, in April 2002, the Company issued warrants to purchase an aggregate of 146,250 shares of the Company s common stock at an exercise price of \$0.40 per share as commissions for a placement agent in connection with the Series A convertible preferred stock financing. The Company recorded the estimated fair value of the warrants of \$41,000 using the Black-Scholes method as an issuance cost of the Series A convertible preferred stock. The assumptions used in calculating the fair value of the warrants were as follows: a risk-free interest rate of 3.5%, a life of five years, no dividend yield, and a volatility factor of 0.8. The warrants are all outstanding as of December 31, 2003. In conjunction with the closing of the Company s initial public offering in March 2004, the outstanding warrants to purchase 146,250 shares of common stock were net exercised resulting in 139,750 shares of common stock issued with the warrant for the remaining 6,500 shares relinquished as non-cash payment.

In connection with the CEFF (see Note 8), the Company issued a warrant to Kingsbridge to purchase up to 260,000 shares of the Company s common stock at an exercise price of \$13.12 per share. The exercise term of the warrant is five years beginning on April 14, 2006. This warrant was valued on the date of grant using the Black-Scholes method using the following assumptions: a risk-free interest rate of 4.1%, a life of 5.5 years, no dividend yield and a volatility factor of 0.54. The estimated value of this warrant was \$1,196,000 and was recorded as a contra-equity amount in additional paid-in capital in 2005.

#### Shares Reserved for Issuance

The Company had reserved shares of common stock for future issuance as follows:

	December 31,	
	2005	2004
2004 Employee Stock Purchase Plan	152,101	71,706
Stock option plans:		
Shares available for grant	1,338,983	1,597,259
Options outstanding	2,945,163	2,054,666
Stock options outstanding (granted outside of stock plans)		22,500
Shares available for issuance under the CEFF	6,036,912	
Warrant outstanding to purchase common stock	260,000	
	10,733,159	3,746,131

#### 2004 Employee Stock Purchase Plan

The Company s Board of Directors adopted the 2004 Employee Stock Purchase Plan (formerly the 2003 Stock Purchase Plan) in September 2003 and the Company s stockholders approved it in October 2003. The 2004 Employee Stock Purchase Plan (Purchase Plan) became effective on March 16, 2004. The Company has reserved a total of 222,979 shares of common stock for issuance under the Purchase Plan. In addition, the Purchase Plan provides for annual increases in the number of shares available for issuance under the Purchase Plan beginning January 1, 2005. The number of additional shares to be reserved automatically will be equal to the lesser of 125,000 shares, 0.5% of the outstanding shares on the date of the annual increase or such amount as may be determined by the Board of Directors. The Purchase Plan permits eligible employees to purchase

## TERCICA, INC.

### (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS (Continued)

common stock at a discount through payroll deductions during defined offering periods. The price at which the stock is purchased is equal to the lower of 85% of the fair market value of the common stock at the beginning of an offering period or after a purchase period end. 42,584 and 28,294 shares were issued under the Purchase Plan during the years ended December 31, 2005 and 2004, respectively.

#### 2004 Stock Plan

The Company s Board of Directors adopted the 2004 Stock Plan (formerly the 2003 Stock Plan) in September 2003 and the Company s stockholders approved it in October 2003. The 2004 Stock Plan became effective on March 16, 2004. The 2004 Stock Plan provides for the grant of incentive and nonstatutory stock options to employees, directors and consultants. Shares reserved under the 2004 Stock Plan include (a) shares reserved but unissued under the 2002 Executive Stock Plan and the 2002 Stock Plan, (b) shares returned to the 2002 Executive Stock Plan and the 2002 Stock Plan as the result of termination of options or the repurchase of shares issued under the 2002 Executive Stock Plan and the 2002 Stock Plan, and (c) annual increases in the number of shares available for issuance on the first day of each year beginning on January 1, 2005, equal to the lesser of:

4% of the outstanding shares of common stock on the first day of the Company s fiscal year,

1,250,000 shares, or

an amount the Company s board may determine.

Under the 2004 Stock Plan, employees, directors, and consultants of the Company are able to participate in the Company s future performance through awards of nonqualified stock options, incentive stock options and restricted stock.

Incentive stock options may be granted with exercise prices not less than 100% of estimated fair value, and nonqualified stock options may be granted with an exercise price of not less than 85% of the estimated fair value of the common stock on the date of grant, as determined by the Board of Directors. Options granted to individuals owning over 10% of the total combined voting power of all classes of stock are exercisable up to five years from the date of grant. The exercise price of any option granted to a 10% stockholder will not be less than 110% of the estimated fair value of the common stock on the date of grant, as determined by the Board of Directors. Options granted under the 2004 Stock Plan expires no later than 10 years from the date of grant. Options granted under the 2004 Stock Plan vests over periods determined by the Board of Directors, generally over four years. The 2004 Stock Plan terminates automatically 10 years after the adoption by the Board of Directors.

#### 2002 Stock Plan and 2002 Executive Stock Plan

The terms of the 2002 Stock Plan and 2002 Executive Stock Plan (the Plans ) are similar to those of the Company s 2004 Stock Plan. The shares reserved but unissued under the Plans as of March 15, 2004 were reserved for issuance under the 2004 Stock Plan (see 2004 Stock Plan above). In addition, any shares returned to the Plans as a result of termination of options or repurchases of shares after March 16, 2004 that were issued under the Plans are added to the shares reserved for the 2004 Stock Plan. Effective March 16, 2004, no additional stock options are issuable under these Plans.

In January 2004, the Board of Directors increased the number of shares of common stock available for future grant under the 2002 Executive Stock Plan to 2,080,000 from 1,330,000, and decreased the number of shares of common stock available for future grant under the 2002 Stock Plan to 2,140,000 from 2,890,000.

## TERCICA, INC.

## (A DEVELOPMENT STAGE COMPANY)

## NOTES TO FINANCIAL STATEMENTS (Continued)

A summary of activity of all options are as follows:

		Options Ou	0
	Shares Available for Grant	Number of Shares	Weighted- Average Exercise Price
Balances at December 31, 2001			\$
Shares authorized	1,750,000		
Options granted	(777,662)	777,662	0.40
Balances at December 31, 2002 Shares authorized	972,338 2,470,000	777,662	0.40
Options granted	(694,750)	694,750	0.94
Options exercised		(270,006)	0.40
Options canceled	625	(625)	0.40
Balances at December 31, 2003	2,748,213	1,201,781	0.71
Options granted	(1,284,000)	1,284,000	7.38
Option granted outside of Plans		22,500	4.00
Options exercised		(298,069)	0.72
Options canceled	133,046	(133,046)	3.25
Balances at December 31, 2004	1,597,259	2,077,166	4.72
Shares authorized	983,834		
Option granted	(1,959,200)	1,959,200	9.13
Options exercised		(351,613)	1.76
Options canceled	586,372	(586,372)	8.18
Options canceled outside of Plans		(22,500)	4.00
Options Repurchased	130,718	(130,718)	0.85
Balances at December 31, 2005	1,338,983	2,945,163	\$ 7.49

Options presented as exercised in the table above for the years ended December 31, 2003, 2004 and 2005 includes the exercise of vested options and the vesting of early exercised options in previous periods.

The following table summarizes information concerning total outstanding and vested options as of December 31, 2005:

Options Outstanding Range of Weighted-Average				<b>Options</b>	Exercisable
Exercise	Number	Remaining	Weighted		Weighted
Prices	Outstanding	Contractual Life	Average Exercise Price	Number Exercisable	Average Exercise Price

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\$0.4	40	302,981	7.1	\$ 0.40	294,857	\$ 0.40
\$1.00	\$1.60	132,283	7.3	\$ 1.55	110,511	\$ 1.59
\$4.0	00	304,334	8.0	\$ 4.00	223,947	\$ 4.00
\$7.24	\$9.99	1,575,596	9.2	\$ 8.49	1,242,752	\$ 8.60
\$10.05	\$12.65	629,969	9.2	\$ 11.35	270,066	\$ 11.18
		2,945,163			2,142,133	

The weighted-average fair value per share of options granted during the years ended December 31, 2005, 2004 and 2003 were \$3.94, \$6.13 and \$10.23, respectively.

## TERCICA, INC.

### (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS (Continued)

#### **Stock Options Granted to Non-Employees**

During the year ended December 31, 2004, the Company granted 24,000 options to purchase shares of its common stock to non-employees. The Company did not grant any stock options to non-employees during the year ended December 31, 2005. These have been accounted for in accordance with SFAS No. 123 and EITF No. 96-18. Compensation expense of \$72,000, \$107,000 and \$143,000 was recorded for the years ended December 31, 2005, 2004 and 2003, respectively.

The following table illustrates the weighted average assumptions for the Black-Scholes model used in determining the fair value of options granted to non-employees:

		i cai chucu		
	December 31,			
	2005	2004	2003	
Risk-free interest rate	4.23%	4.28%	4.36%	
Volatility	0.5	0.6	0.8	
Maximum contractual life (years)	10.0	10.0	10.0	
Dividend yield	0.0%	0.0%	0.0%	

Vear ended

#### **Deferred Stock Compensation**

In connection with the grant of certain stock options to employees during the year ended December 31, 2003, the Company recorded deferred stock compensation within stockholders equity (deficit) of \$6,888,000, representing the difference between the reassessed fair value of the common stock and the option exercise price at the date of grant. Such amount is being amortized over the vesting period of the applicable options on a straight-line basis.

During the period from February 1, 2003 through January 31, 2004, certain stock options were granted with exercise prices that were below the reassessed fair value of the common stock at the date of grant. Deferred compensation was recorded in accordance with APB Opinion No. 25, and is being amortized over the related vesting period of the options. The deferred compensation balance was \$2,591,000 and \$6,388,000 as of December 31, 2005 and 2004, respectively. The Company recorded amortization of employee stock-based compensation expense of \$2,102,000, \$2,734,000 and \$904,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

The total unamortized deferred stock compensation recorded for all option grants through January 31, 2004, net of the amounts reversed associated with forfeited stock options, will be amortized as follows: \$1,681,000 for the year ending December 31, 2006; \$903,000 for the year ending December 31, 2007 and \$7,000 for the year ending December 31, 2008.

## TERCICA, INC.

#### (A DEVELOPMENT STAGE COMPANY)

#### NOTES TO FINANCIAL STATEMENTS (Continued)

#### 11. Income Taxes

There is no provision for income taxes because the Company has incurred losses. Deferred income taxes reflect the tax effects of net operating loss and tax credit carryovers and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company s deferred tax assets are as follows (in thousands):

	Decem	ber 31,
	2005	2004
Net operating loss carryforwards	\$ 30,403	\$ 20,855
Research tax credit carryforwards	3,948	2,753
Orphan drug credits	5,881	3,464
Capitalized license fees	3,168	3,043
Capitalized start-up costs	531	2,619
Other	2,029	1,383
Total deferred tax assets	45,960	34,117
Valuation allowance	(45,960)	(34,117)
Net deferred tax assets	\$	\$

Realization of the deferred tax assets is dependent upon the generation of future taxable income, if any, the amount and timing of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by approximately \$11,843,000, \$19,040,000 and \$11,379,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

As of December 31, 2005, the Company had federal net operating loss carryforwards of approximately \$99,919,000. The Company also had California net operating loss carryforwards of approximately \$76,146,000. The federal net operating loss carryforwards will expire at various dates beginning in 2022, if not utilized. The California net operating loss carryforwards expire beginning in 2013. The Company also has federal research, state research and federal orphan drug credit carryforwards of approximately \$2,115,000, \$2,821,000 and \$5,881,000, respectively. The federal research and orphan drug credits expire beginning in 2022 and the state research credits have no expiration date.

Utilization of the net operating loss carryforwards may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

#### 12. 401(k) Plan

Effective January 2005, the Company began sponsoring a 401(k) plan, which covers all eligible employees. Under this plan, employees may contribute specified percentages of their eligible compensation, subject to certain Internal Revenue Service restrictions. The plan does not currently allow for matching contributions by the Company.

## TERCICA, INC.

## (A DEVELOPMENT STAGE COMPANY)

## NOTES TO FINANCIAL STATEMENTS (Continued)

## 13. Quarterly Financial Data Unaudited

The following table presents unaudited quarterly financial data of the Company. The Company s quarterly results of operations for these periods are not necessarily indicative of future results of operations.

	Net Loss (In the	Al C Sto	Net Loss locable to Common ockholders s, except per sl	Dilu Loss I Allo Co Stocl	sic and nted Net Per Share cable to mmon kholders
Year ended December 31, 2005					
Fourth Quarter	\$ (13,206)	\$	(13,206)	\$	(0.42)
Third Quarter	\$ (11,518)	\$	(11,518)	\$	(0.37)
Second Quarter	\$ (12,401)	\$	(12,401)	\$	(0.40)
First Quarter	\$ (9,108)	\$	(9,108)	\$	(0.32)
Year ended December 31, 2004					
Fourth Quarter	\$ (11,189)	\$	(11,189)	\$	(0.46)
Third Quarter	\$ (10,677)	\$	(10,677)	\$	(0.45)
Second Quarter	\$ (11,447)	\$	(11,447)	\$	(0.48)
First Quarter	\$ (7,690)	\$	(7,690)	\$	(1.47)

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure. None.

#### Item 9A. Controls and Procedures. Evaluation of Disclosure Controls and Procedures

Based on their evaluation as of December 31, 2005, our Chief Executive Officer and Acting Chief Financial Officer, with the participation of management, have concluded that our disclosure controls and procedures (as defined in Rules 13a 15(e) and 15d 15(e) of the Securities Exchange Act of 1934) are effective to ensure that the information required to be disclosed by us in the reports that we file or submit under the Securities and Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

### Management s Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Securities and Exchange Act of 1934. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Acting Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2005 using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control Integrated Framework*. Based on this evaluation, our management concluded that as of December 31, 2005, our internal control over financial reporting was effective.

Ernst & Young LLP, our independent registered public accounting firm that has audited our financial statements included herein, has issued an attestation report on management s assessment of our internal control over financial reporting, which report is included under Item 8 of this Annual Report on Form 10-K and is incorporated herein by reference.

### Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2005 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### Limitations on the Effectiveness of Controls

Our disclosure controls and procedures provide our Chief Executive Officer and Acting Chief Financial Officer reasonable assurances that our disclosure controls and procedures will achieve their objectives. However, company management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting can or will prevent all human error. A control system, no matter how well designed and implemented, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Furthermore, the design of a control system must reflect the fact that there are internal resource constraints, and the benefit of controls must be weighed relative to their corresponding costs. Because of the limitations in all control systems, no evaluation of controls can provide complete assurance that all control issues and instances of error, if any, within our company are detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur due to human error or mistake. Additionally, controls, no matter how well designed,

could be circumvented by the individual acts of specific persons within the organization. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated objectives under all potential future conditions.

Item 9B. Other Information. None

#### PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because the registrant will file with the U.S. Securities and Exchange Commission a definitive proxy statement pursuant to Regulation 14A in connection with the solicitation of proxies for the Company s Annual Meeting of Stockholders to be held in June 2006 (the Proxy Statement) not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information included therein is incorporated herein by reference.

## Item 10. Directors and Executive Officers of the Registrant.

Information with respect to Directors and Executive Officers may be found under the caption Executive Officers of the Registrant in Item 1 of this Annual Report on Form 10-K, and in the section entitled Proposal 1 Election of Directors appearing in the Proxy Statement. Such information is incorporated herein by reference. Information with respect to our audit committee and audit committee financial expert may be found in the section entitled Proposal 1 Election of Directors appearing in the Proxy Statement. Such information with respect to compliance with Section 16(a) of the Securities Exchange Act of 1934 and our code of ethics may be found in the sections entitled Section 16(A) Beneficial Ownership Reporting Compliance and Proposal 1 Election of Directors Code of Business Conduct and Ethics, respectively, appearing in the Proxy Statement. Such information is incorporated herein by reference.

### Item 11. Executive Compensation.

The information required by this Item is incorporated herein by reference to the information from the Proxy Statement under the section entitled Executive Compensation.

#### Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item with respect to security ownership of certain beneficial owners and management is incorporated herein by reference to the information from the Proxy Statement under the section entitled Security Ownership of Certain Beneficial Owners and Management. The information required by this Item with respect to securities authorized for issuance under our equity compensation plans is incorporated herein by reference to the information from the Proxy Statement under the section entitled Equity Compensation Plan Information.

#### Item 13. Certain Relationships and Related Transactions.

The information required by this Item is incorporated herein by reference to the information from the Proxy Statement under the section entitled Certain Relationships and Related Transactions.

## Item 14. Principal Accountant Fees and Services.

The information required by this Item is incorporated herein by reference to the information from the Proxy Statement under the section entitled Proposal 2 Ratification of Selection of Independent Registered Public Accounting Firm.

### PART IV

### Item 15. Exhibits and Financial Statement Schedules (a) Documents filed as part of this report

1. Financial Statements

See Index to Financial Statements in Item 8 of this Annual Report on Form 10-K, which is incorporated herein by reference.

2. Financial Statement Schedules

The following schedule is filed as part of this Form 10-K:

Schedule II- Valuation and Qualifying Accounts for the years ended December 31, 2005, 2004 and 2003.

All other financial statement schedules are omitted because the information is inapplicable or presented in the Notes to Financial Statements.

3. The following exhibits are included herein or incorporated herein by reference:

Exhibit Number	Description
3.1	Certificate of Incorporation(2)
3.2	Bylaws(1)
4.1	Form of Specimen Stock Certificate(1)
4.3	Warrant issued to Kingsbridge Capital Limited, dated October 14, 2005(10)
10.1A	2002 Stock Plan, as amended(1)*
10.1B	Form of Stock Option Agreement under the 2002 Stock Plan(1)*
10.2A	2002 Executive Stock Plan, as amended(1)*
10.2B	Form of Stock Option Agreement under the 2002 Executive Stock Plan(1)*
10.3A	2004 Stock Plan(1)*
10.3B	Form of Stock Option Agreement under the 2004 Stock Plan(1)*
10.4A	2004 Employee Stock Purchase Plan(1)*
10.4B	Form of Subscription Agreement under the 2004 Employee Stock Purchase Plan(1)*
10.5	Form of Indemnification Agreement(1)*
10.6A	Sublease Agreement dated June 24, 2002 between Elan Pharmaceuticals, Inc. and the Registrant(1)
10.6B	Sublease Agreement dated March 21, 2003 between Elan Pharmaceuticals, Inc. and the Registrant(1)
10.6C	Lease Agreement dated July 24, 2003 between Gateway Center, LLC and the Registrant(1)
10.6D	First Amendment to Lease Agreement dated September 24, 2003 between Gateway Center, LLC and the Registrant(1)
10.6E	Second Amendment to Lease Agreement dated June 28, 2004 between Gateway Center, LLC and the Registrant(3)
10.6F	Lease Agreement dated March 7, 2005 between 2000 Sierra Point, LLC and the Registrant(4)

Exhibit Number	Description
10.7A	License and Collaboration Agreement, between Genentech, Inc. and the Registrant, dated as of April 15, 2002(1)
10.7B	First Amendment to the License and Collaboration Agreement, between Genentech, Inc. and the Registrant, dated as of July 25, 2003(1)
10.7C	International License and Collaboration Agreement, between Genentech, Inc. and the Registrant, dated as of July 25, 2003(1)
10.7D	Second Amendment to the License and Collaboration Agreement, between Genentech, Inc. and the Registrant, dated as of November 25, 2003(9)
10.8	Manufacturing Services Agreement between the Registrant and Cambrex Bio Science Baltimore, Inc., dated as of December 20, 2002(1)
10.9A	Key Employment Agreement for John A. Scarlett, M.D. dated February 27, 2002(1)*
10.9B	Amendment to Key Employment Agreement for John A. Scarlett, M.D. dated May 15, 2002(1)*
10.9C	Key Employment Agreement for Ross G. Clark dated May 15, 2002(1)*
10.9D	Intentionally omitted
10.9E	Intentionally omitted
10.9F	Intentionally omitted
10.9G	Employment Letter to Andrew Grethlein dated March 5, 2003(1)*
10.9H	Intentionally omitted
10.9I	Intentionally omitted
10.9J	Intentionally omitted
10.9K	Intentionally omitted
10.9L	Employment Letter to Stephen Rosenfield dated June 23, 2004(3)*
10.9M	Employment Letter to Thorsten von Stein dated December 3, 2004(5)*
10.9N	Amendment to Key Employment Agreement for John A. Scarlett, M.D. dated February 22, 2005(4)*
10.90	Amendment to Key Employment Agreement for Ross G. Clark dated February 22, 2005(4)*
10.9P	Amendment to Employment Letter for Thomas H. Silberg dated February 22, 2005(4)*
10.9Q	Amendment to Employment Letter for Timothy P. Lynch dated February 22, 2005(4)*
10.9R	Amendment to Employment Letter for Stephen N. Rosenfield dated February 22, 2005(4)*
10.9S	Executive Officer Compensation Arrangements(6)*
10.9T	Non-Employee Director Compensation Arrangements(7)
10.9U	Employment Letter to Christopher E. Rivera, dated March 31, 2005(8)*
10.9V	Separation Agreement and Release, dated May 13, 2005, between Thomas H. Silberg and the Registrant(9)*
10.9W	Tercica, Inc. Incentive Compensation Plan(6)
10.10	Amended and Restated Investors Rights Agreement dated July 9, 2003(1)
10.11	Amendment to Amended and Restated Investors Rights Agreement dated February 27, 2004(1)

Exhib Numb				
10.12	Loan Agreement, dated January 21, 2005, between Venture Lending & Leasing IV, Inc. and the Registrant(5)			
10.121	Common Stock Purchase Agreement, dated January 21, 2005, between Venture Lending & Leasing IV, LLC and the Registrant(5)			
10.13	Common Stock Purchase Agreement, by and between Kingsbridge Capital Limited and the Registrant, dated October 14, 2005(10)			
10.13	Registration Rights Agreement, by and between Kingsbridge Capital Limited and the Registrant, dated October 14, 2005(10)			
23.1	Consent of Independent Registered Public Accounting Firm			
24.1	Power of Attorney (included on the signature pages hereto)			
31.1	Certification of Chief Executive Officer of Tercica, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a).			
31.2	Certification of Chief Financial Officer of Tercica, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a).			
32.1	Certification by the Chief Executive Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).			
32.2	Certification by the Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).			
*	Management contract or compensation plan or arrangement. Confidential treatment has been granted with respect to certain portions of this exhibit. This exhibit omits the information subject to this confidentiality request. Omitted portions have been filed separately with the SEC.			
(1)	<ol> <li>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.</li> </ol>			
(2)				
(3) (4)	Incorporated by reference to the Registrant s quarterly report on Form 10-Q (File No. 000-50461) filed on August 16, 2004.			
(4) (5)				

(6) Incorporated by reference to the information under the heading, Item 1.01. Entry into a Material Definitive Agreement in the Registrant s current reports on Form 8-K (File No. 000-50461) filed on February 28, 2005, March 18, 2005, August 22, 2005 and February 28, 2006.

(9) Incorporated by reference to the Registrant s quarterly report on Form 10-Q (File No. 000-50461) filed on August 4, 2005.

<sup>(7)</sup> Incorporated by reference to the information under the heading Executive Compensation Compensation of Directors in the Registrant s definitive proxy statement filed pursuant to Regulation 14A (File No. 000-50461) on April 29, 2005.

<sup>(8)</sup> Incorporated by reference to the Registrant s quarterly report on Form 10-Q (File No. 000-50461) filed on May 16, 2005.

<sup>(10)</sup> Incorporated by reference to the Registrant s quarterly report on Form 10-Q (File No. 000-50461) filed on November 4, 2005.

#### SIGNATURES

Pursuant to Section 13 or 15(d) of the Securities Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TERCICA, INC.

By: /s/ JOHN A. SCARLETT, M.D. John A. Scarlett, M.D.

President, Chief Executive Officer and Director

Dated: March 15, 2006

## 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 Susan Wong, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution for him, and in his name in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and any of them or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1934, this report has been signed by the following persons on behalf of the Registrant in the capacities indicated on March 15, 2006:

Signature	Title
/s/ John A. Scarlett, M.D.	President, Chief Executive Officer and Director
John A. Scarlett, M.D.	(Principal Executive Officer)
/s/ Susan Wong	Acting Chief Financial Officer
Susan Wong	(Principal Accounting and Financial Officer)
/s/ Michael Astrue	Director
Michael Astrue	
/s/ Alexander Barkas, PH.D.	Director
Alexander Barkas, Ph.D.	
/s/ Ross G. Clark, PH.D.	Director
Ross G. Clark, Ph.D.	
/s/ Karin Eastham	Director

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## Karin Eastham

/s/ Dennis Henner, PH.D.	Director
Dennis Henner, Ph.D.	
/s/ Mark Leschly	Director
Mark Leschly	
/s/ David L. Mahoney	Director
David L. Mahoney	
/s/ Thomas Wiggans	Director
Thomas Wiggans	

#### Schedule II

## TERCICA, INC.

## VALUATION AND QUALIFYING ACCOUNTS

## Years Ended December 31, 2005, 2004 and 2003

## (In thousands)

		Addition		
	Balance at	Charged to		Balance at
	Beginning	Cost and		End of
	of Period	Expenses	Deductions(1)	Period
Inventory reserves:				
Year Ended December 31, 2005:	\$	\$ 45	\$	\$ 45
Year Ended December 31, 2004:	\$	\$	\$	\$
Year Ended December 31, 2003:	\$	\$	\$	\$

(1) Represents amounts written off or returned against the allowance or reserves, or returned against earnings.