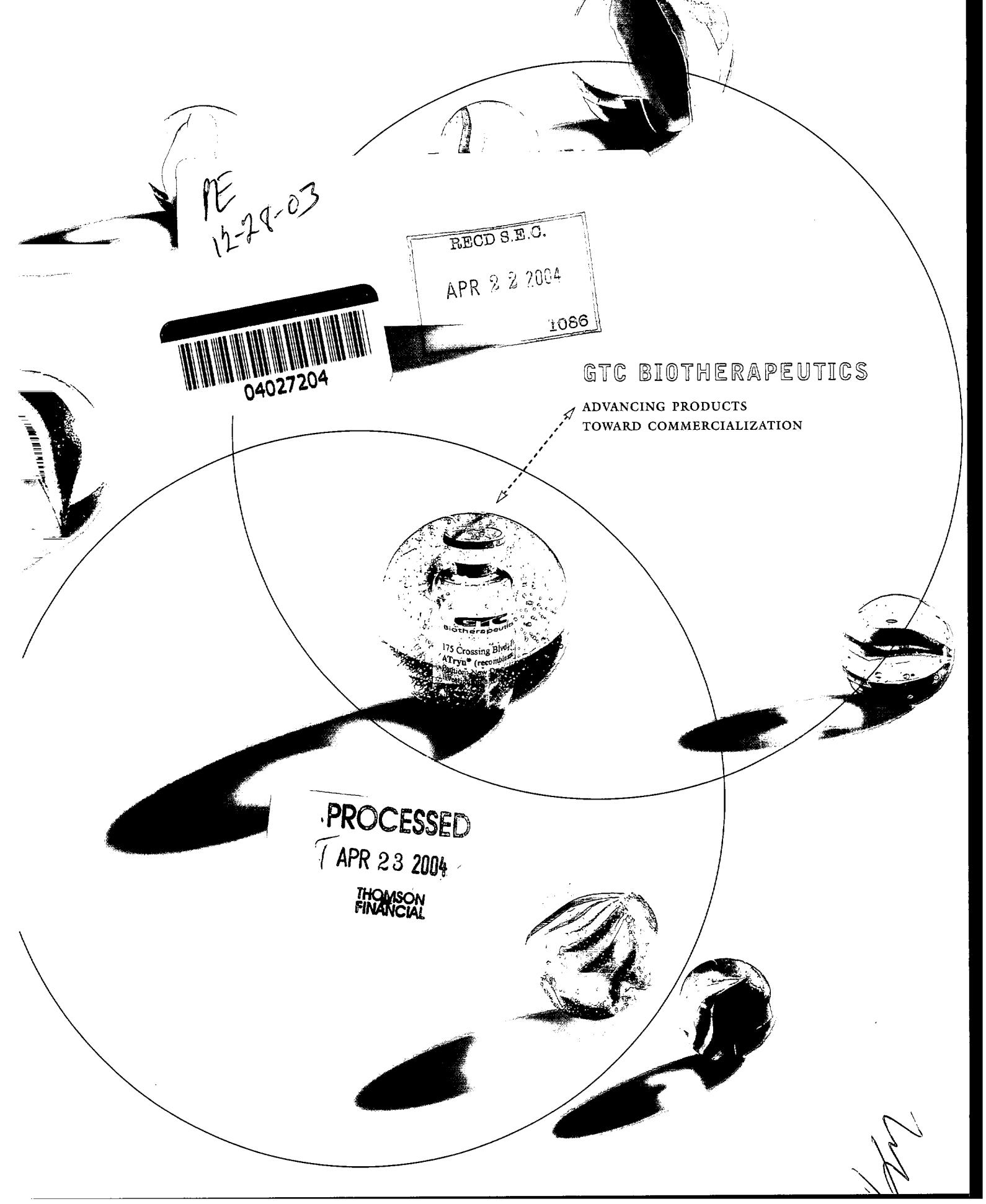
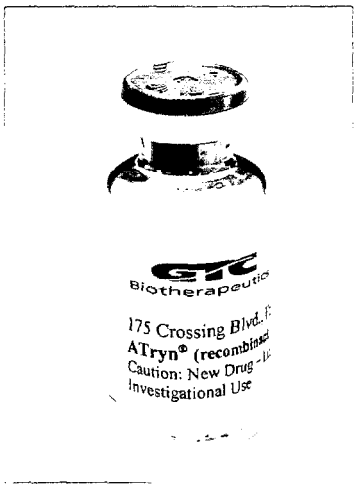




Dear Shareholders,

IN 2003, GTC BIOTHERAPEUTICS SUCCESSFULLY COMPLETED THE SINGLE MOST IMPORTANT MILESTONE IN ITS TWELVE-YEAR HISTORY, A CLINICAL TRIAL THAT TESTED THE SAFETY AND EFFECTIVENESS OF OUR RECOMBINANT HUMAN ANTITHROMBIN, TRADE NAME ATRYN®. THIS STUDY ASSESSED THE INCIDENCE OF DEEP VEIN THROMBOSES (DVTS) AND THROMBOEMBOLISMS IN PATIENTS WITH A HEREDITARY DEFICIENCY OF ANTITHROMBIN. THE STUDY WAS COMPLETED WELL WITHIN THE FORECASTED TIMELINES AND POSITIONED US WELL TO SUBMIT OUR MARKETING AUTHORIZATION APPLICATION (MAA) TO THE EUROPEAN MEDICINES EVALUATION AGENCY (EMEA) EARLY IN 2004. I AM HAPPY TO TELL YOU OUR SUBMISSION WAS ACCEPTED FOR REVIEW IN LATE FEBRUARY, FOUR MONTHS AHEAD OF OUR ORIGINAL SCHEDULE.

ATRYN® IS OUR FIRST PROGRAM TO BE SUBMITTED TO A REGULATORY AGENCY FOR MARKETING AUTHORIZATION. THIS IS A PIVOTAL MOMENT FOR GTC AS WE CONTINUE OUR IMPORTANT TRANSITION TO A COMMERCIAL PRODUCTS COMPANY. IT IS ALSO A PIVOTAL MOMENT FOR OUR INDUSTRY BECAUSE ATRYN® IS THE FIRST THERAPEUTIC PROTEIN PRODUCED USING TRANSGENIC TECHNOLOGY TO BE SUBMITTED TO ANY REGULATORY AGENCY ANYWHERE IN THE WORLD.

The Commercialization of ATryn® ⟩ GTC is especially pleased to be taking the lead in the commercialization of this important technology for the production of therapeutic proteins, helping to write the road map for the regulatory standards by which future products from this technology will be measured. GTC employees are proud of their achievements in the ATryn® program. I also want to take this opportunity to say a special thank you to the employees of GTC who have made this possible through an extraordinary combination of great science, dedication, experience and sheer hard work. Some of them have spent the best part of 20 years bringing this technology to commercial reality. GTC owes a special debt of gratitude to these employees and everyone associated with the program. One of these associations continues to be with Genzyme Europe B.V., who has collaborated with us on the clinical and regulatory development of ATryn®. We are indebted to this group for their extraordinary support throughout this process. I also thank the shareholders for their continuing support over many years which has enabled us to reach this milestone.

Let me provide some background to our MAA submission. The clinical study on which our submission was based was defined in scientific advice and guidance documents provided by the EMEA. The study was unusual in that it required only twelve evaluable patients in an open label study. The patients were subject to low levels of the antithrombin protein in their blood as a result of hereditary deficiency (HD). Antithrombin plays an important role in the control of blood coagulation, as well as having anti-inflammatory properties. HD patients are prone to develop thromboses from early adulthood, and are normally treated with blood thinners to prevent further thromboses. When patients with HD face surgery or childbirth, it is beneficial to restore their antithrombin levels to normal and stop the use of blood thinners prior to the procedure. Plasma-derived antithrombin has been used for many years in this treatment, particularly in Europe and Japan. Some of these plasma-derived products have had limited clinical development programs. A single supplier of plasma-derived antithrombin exists in the United States, but that product is only available in limited quantities. We believe our recombinant human antithrombin offers the assurance of a well-characterized, continuous supply of product, supported by a strong clinical development program.

Our clinical protocol required the patients to be treated by continuous infusion of ATryn® for at least three days up to a maximum of fourteen days, and to assess the incidence of DVTs by evidence of clinical symptoms and by independently reviewed duplex ultrasound scans. We recruited fourteen patients into our trial, a process which took the best part of a year. Those patients included nine childbirths, including Cesarean Sections, four hip replacements and a general surgery. No clinical symptoms of a DVT were observed in any patient at any time during the study. We are confident that two DVT observations resulting from ultrasound readings are explainable within the scope of the protocol, as required, with neither patient demonstrating any clinical symptoms.

Our MAA submission includes an expert opinion report that states that it is believed that ATryn® is a safe and efficacious prophylaxis for the prevention of thromboses in hereditary deficient patients undergoing surgery or childbirth. We are pleased with the clinical data submitted to the EMEA and we look forward to supporting the review process with the Agency. The review process is expected to take approximately one year and, if successful, we hope to be able to launch ATryn® in Europe in the middle of 2005.

Our separate dialogue with the Food and Drug Administration (FDA) is continuing as the EMEA review process proceeds. During 2003, the FDA informed us that they required a controlled study as the basis for submission in the United States. This type of study would be very challenging in any realistic time period for the HD indication. We have shared with the FDA much of the data submitted to the EMEA with the objective of establishing an acceptable clinical and regulatory strategy that can form the basis of a request for approval in the United States. At the time of writing, those discussions are still in progress.

Our strategy for establishing a significant market for ATryn® has several parts.) Once we have approval in Europe, we expect to capture an increasing share of the existing plasma-derived antithrombin market. We estimate this European market to be approximately $100 million. Together with the Japanese market, we believe that there is a total market for plasma-derived antithrombin products of approximately $250 million. The US market is significantly underserved and sales of the only available plasma-derived product are less than $5 million. This clearly underlines the importance of accessing the US market, potentially the largest and most valuable market in the world. Our plan will be to expand our clinical development program to support broader indications for ATryn® and thereby create and support a significantly larger market than that which exists today. ATryn® has potential applications ranging from the treatment of severe burns to sepsis and treatment for bowel perforation. We plan to initiate the clinical development of ATryn® in burns later this year, with the level of this commitment dependent on our financial resources.

We are continuing partnering discussions with several companies in Europe to assist us with the launch and marketing of ATryn® once we have approval. We are also maintaining a strategic option of marketing ATryn® in Europe ourselves with a small, highly-focused sales force. Clearly the remainder of 2004 will be a busy time as we develop and implement our launch strategy.

I have dedicated much of this letter to our progress with ATryn®. This is because ATryn® is at the heart of establishing the credibility and value of our technology platform across all our product programs as well as demonstrating leadership for the partners in our portfolio of external partnerships. I believe this leadership is helpful to our external partners as they reach the point of considering their clinical and commercial production options. I am pleased to tell you that our most advanced external program, recombinant human alpha-fetoprotein or MM-093, from Merrimack Pharmaceuticals entered the clinic in 2003 using product produced and purified entirely by GTC under Good Manufacturing Practices (GMP). GMP standards are requirements that the regulatory agencies monitor to ensure consistent, reliable, and safe manufacturing of medicinal products. Later in 2004, Merrimack is planning to take this product to the next stage of its clinical development program, again using product manufactured entirely by GTC. In addition, our program with Centocor for an undisclosed protein is moving forward into preclinical testing and hopefully a commitment for clinical testing later this year. With the catalyst of ATryn®, we look forward to further partnered programs moving to these next stages of development.

We entered into a strategic collaboration with Laureate Pharma L.P. in the first quarter of 2004. This collaboration allows both companies to offer a broad range of production technologies and manufacturing capabilities to external partners. In addition, this collaboration ensures that GTC has access to large-scale downstream purification for our own products. We look forward to working with Laureate to create value for both companies.

Proprietary Programs 〉 Before I close, let me tell you about the progress with our other proprietary programs. Our program for merozoite surface protein one, or MSP-1, is under development as an antigen for a malaria vaccine. This program, which is fully funded by the National Institute of Allergy and Infectious Diseases, made strong progress during the year and we now have transgenic animals expressing MSP-1 under evaluation. We expect to continue this program through to initiation of production later this year in preparation for the filing of an Investigational New Drug application with the FDA in 2005. Similarly, our recombinant human serum albumin (rhSA) program has continued its progress. We are developing rhSA initially as an excipient, that is a non-active component of a biological formulation that is used as a stabilizer. We plan to initiate production of qualification batches of rhSA in 2004 in preparation for filing a Drug Master File (DMF) in 2005. A DMF is a documentation system used by the FDA and EMEA to reduce the redundancy in filing information on materials or ingredients that can be used in multiple products. This program is already creating significant interest from potential customers.

To support the development strategies for ATryn® and the rest of our pipeline of internal programs, as well as ensure we can maintain momentum in our portfolio of external programs, GTC raised a net of $8.6 million through a private placement of common stock in August 2003 and an additional $13.9 million net through the direct placement of registered common stock in the first quarter of 2004. Our objective is to continue to run GTC in a prudent manner and focus our attention on our key value drivers.

Thank you for your continuing support which is so vital to our success. 2004 promises to be a year when our transition gains real momentum and I look forward to telling you about our progress and success next year.

Geoffrey F. Cox.

Leigh has a hereditary deficiency for antithrombin. She was treated with ATryn® while giving birth to her son three years ago during GTC's clinical trial program.

ATryn®— Moving Towards Commercialization

Focused on Regulatory Approval ⟩ GTC is rapidly moving towards becoming a commercial products company. A Marketing Authorization Application (MAA) for GTC's lead product, recombinant human antithrombin, trade name ATryn®, is under review by the European Medicines Evaluation Agency (EMEA). This application seeks authorization to market ATryn® for the treatment of patients with hereditary antithrombin deficiency (HD). The indication for ATryn® in HD patients is for prophylaxis of deep vein thrombosis (DVT) and thromboembolism in clinical risk situations such as surgical procedures or during labor and delivery.

This is a milestone event for GTC. ATryn® is the first recombinant protein produced using transgenic technology to be submitted to any regulatory agency anywhere in the world, and is also the first program GTC has submitted for regulatory review.

Production of a Consistent, Reliable Product ⟩ Antithrombin, a blood plasma protein with anti-inflammatory and anticoagulation properties is currently produced by the fractionation of human blood. Production of antithrombin using this method is highly dependent on the availability and quality of human donor blood. Worldwide supply is also hindered by the inability to pool donor blood between major demographic areas such as Europe and the United States. A recombinant antithrombin has the potential to resolve these supply issues. Up to now, antithrombin has been difficult to express using traditional recombinant production systems – as is typical for many human blood proteins. ATryn®, based on GTC's transgenic technology, may become the first recombinant antithrombin to offer an unlimited supply of highly characterized, consistent product in both the United States and Europe.

The Antithrombin Market ⟩ Currently, GTC estimates that the European market for antithrombin is approximately $100 million and together with the Japanese market there is a combined market of about $250 million. At this time, GTC believes that the United States is greatly underserved because it is supplied by a single plasma-derived product with sales of less than $5 million.

Market Opportunities for ATryn®

An unlimited supply of ATryn® greatly increases the prospects of using the therapeutic properties of antithrombin in a broad range of indications.

Estimated Maximum Annual Supply of Plasma-derived Antithrombin in the U.S. without Product Constraints

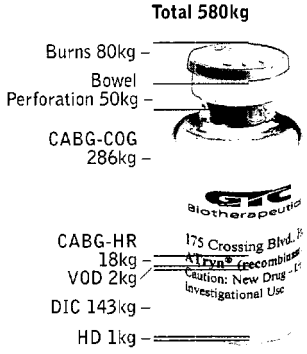
8 million donors* supply

- ➢ 14 million units of whole blood
- ➢ yields 2 million liters of recovered plasma
- ➢ yields 100 kilograms plasma-derived antithrombin

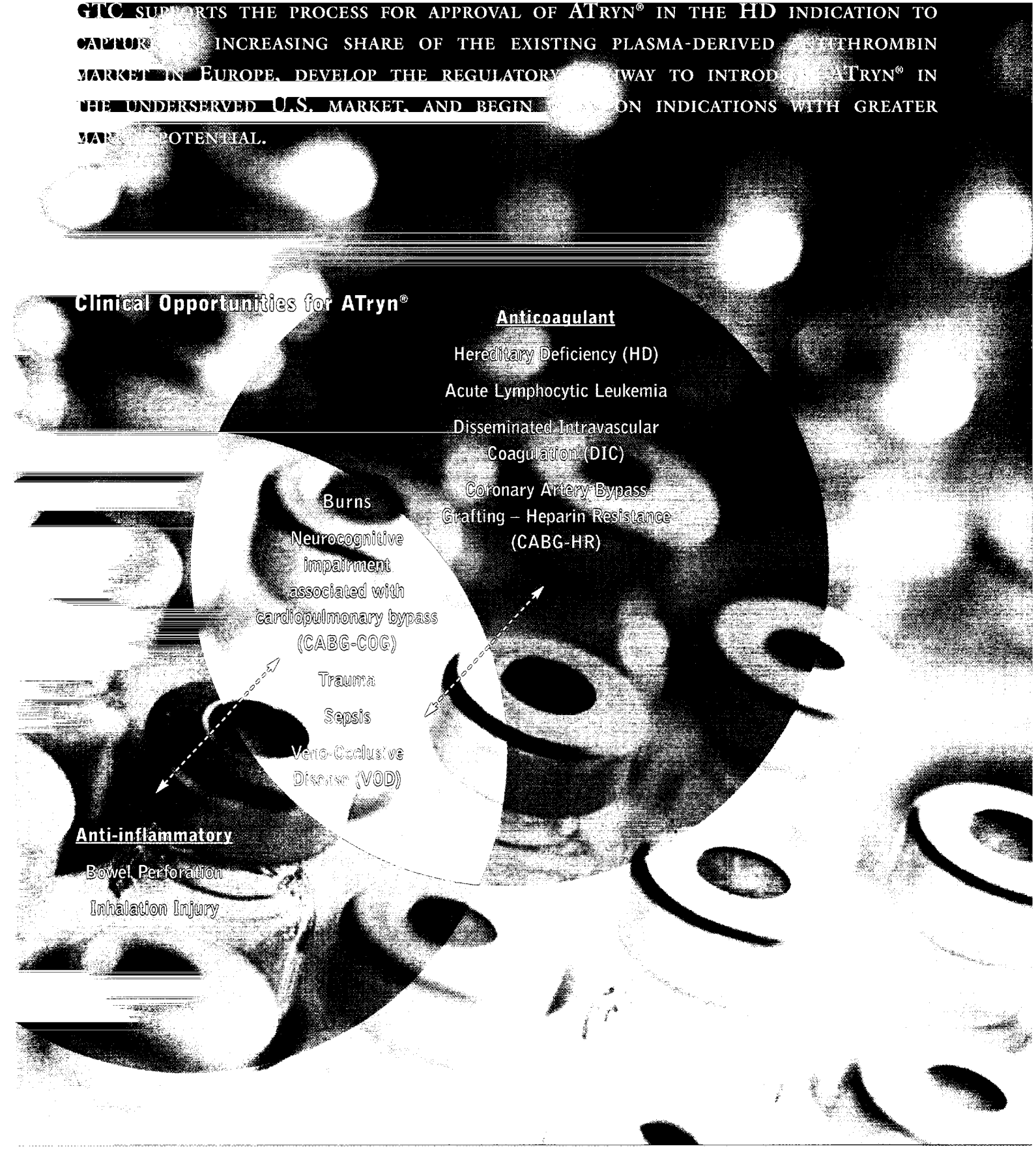
*American Association of Blood Banks

Estimated Potential Annual Uses for ATryn® in the U.S.

Assuming Appropriate Clinical and Regulatory Development



GTC SUPPORTS THE PROCESS FOR APPROVAL OF ATRYN® IN THE HD INDICATION TO CAPTURE INCREASING SHARE OF THE EXISTING PLASMA-DERIVED ANTITHROMBIN MARKET IN EUROPE, DEVELOP THE REGULATORY PATHWAY TO INTRODUCE ATRYN® IN THE UNDERSERVED U.S. MARKET, AND BEGIN EVALUATION INDICATIONS WITH GREATER MARKET POTENTIAL.



GTC has assembled capabilities from molecular biology through purification to provide products suitable for clinical use.

Moving Forward – A Portfolio of Products and Capabilities

A Portfolio of Products) GTC has established a robust set of opportunities to provide leadership through its internal product pipeline as well as participate in clinical and commercial production opportunities through its portfolio of external programs. The internal pipeline of products has significant commercial potential with each program having a strategy GTC believes can be successful. The portfolio of external programs represents multiple commercialization opportunities with the potential to be a very attractive business even if just a few partners successfully advance their products utilizing our platform technology.

GTC currently has three products in its internal program portfolio. The most advanced product, ATryn®, is being reviewed for marketing authorization approval in Europe. The second product, recombinant human serum albumin (rhSA), is being developed initially as an excipient, which provides stability to many drug formulations. Plans are in place for initiating qualification batches of rhSA this year and the filing of a Drug Master File (DMF) in 2005. The DMF system was developed by the health authorities to reduce redundancy in the filing of information for materials or ingredients that may be used in multiple drug formulations. MSP-1 is GTC's third internal product in development for use in a vaccine against malaria. This program is being funded by the National Institute of Allergy and Infectious Diseases (NIAID). GTC now has transgenic animals expressing MSP-1 under evaluation and plans to initiate production later this year to support the filing of an Investigational New Drug Application with the FDA in 2005.

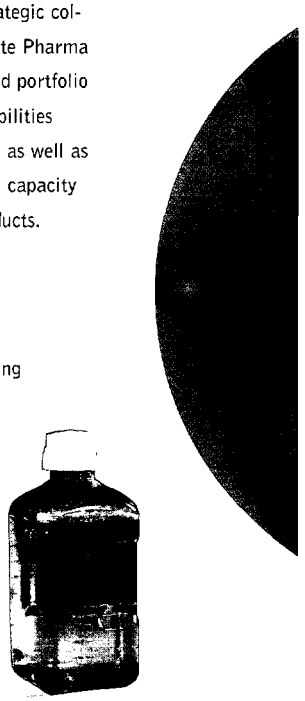
GTC's external program portfolio develops transgenic versions of its partner's products which are either needed in large volume or are difficult to express using traditional recombinant systems. The most advanced program, MM-093, a recombinant human alpha-fetoprotein for Merrimack Pharmaceuticals, entered the clinic in 2003 using product manufactured and purified at GTC facilities. GTC is also supplying product for Merrimack's next stage of clinical development. In addition, GTC's partnership with Centocor for an undisclosed protein is moving forward into preclinical testing with the hope of advancing to clinical testing later this year.

A Portfolio of Production Capability

GTC is well positioned to deliver the benefits of recombinant production for proteins that are needed in large amounts and/or difficult to express in traditional production systems. With the establishment of a fully integrated pilot purification facility in addition to its transgenic production facilities in central Massachusetts, and its recent announcement of a strategic collaboration with Laureate Pharma L.P., GTC offers a broad portfolio of manufacturing capabilities to its external partners as well as large-scale purification capacity to support its own products.

GTC Capabilities
- molecular biology
- bulk production
- downstream processing
- early-phase clinical production

Laureate Pharma Capabilities
- late-phase clinical production
- commercial-scale purification
- fill and finish



GTC HAS UTILIZED ITS PLATFORM TECHNOLOGY TO ESTABLISH ITS [illegible]ESS, COMPRISED OF INTERNAL AND EXTERNAL PROGRAMS, THAT PROVIDE M[illegible]NITIES TO ADVANCE PRODUCTS INTO COMMERCIAL DEVELOPMENT. IN ITS INTERNAL PROGRAMS, GTC DEVELOPS, PRO[illegible] INTENDS TO COMMERCIALIZE ITS OWN PROPRIETARY PROTEINS. IN ITS [illegible] PROGRAMS, GTC PARTNERS WITH PHARMACEUTICAL AND BIOTECHNOLOGY COMPANIES WHO REC[illegible]OTENTIAL OF TRANSGENIC TECHNOLOGY FOR THE PRODUCTION OF TH[illegible]RIETARY PROTEINS.

Platform Technology Drives Opportunities

Selected Financial Data (dollars in thousands except per share data)

	Fiscal Years Ended				
	December 28, 2003	December 29, 2002	December 30, 2001	December 31, 2000	January 2, 2000
Statement of Operations Data[1]					
Net Revenues	$ 9,764	$ 10,379	$ 13,740	$ 16,163	$ 13,825
Operating costs and expenses	40,081	36,288	37,584	32,749	26,764
Operating loss from continuing operations	(30,317)	(25,909)	(23,844)	(16,586)	(12,939)
Loss from continuing operations	(29,537)	(24,320)	(18,792)	(13,817)	(13,622)
Loss from discontinued operations	–	–	–	(324)	(5,139)
Gain from sale of discontinued operations	–	–	2,236	–	–
Net loss available to common shareholders	(29,537)	(24,320)	(16,556)	(14,215)	(20,258)
Net loss available per common share	(1.00)	(0.86)	(0.55)	(0.50)	(1.02)
Weighted average number of shares outstanding (basic and diluted)	29,562,152	28,353,490	29,975,167	28,373,283	19,876,904
Balance Sheet Data[1]					
Cash and cash equivalents	$ 6,733	$ 26,911	$ 26,850	$ 41,024	$ 7,813
Marketable securities	24,358	30,438	63,598	25,508	–
Working capital	24,152	47,682	74,458	88,389	16,715
Net assets of discontinued contract research operations held for sale	–	–	–	37,272	33,155
Total assets	71,072	95,373	120,443	134,403	58,518
Long-term liabilities	12,582	12,823	80	294	6,256
Shareholders' equity	48,161	68,772	101,950	114,843	26,206

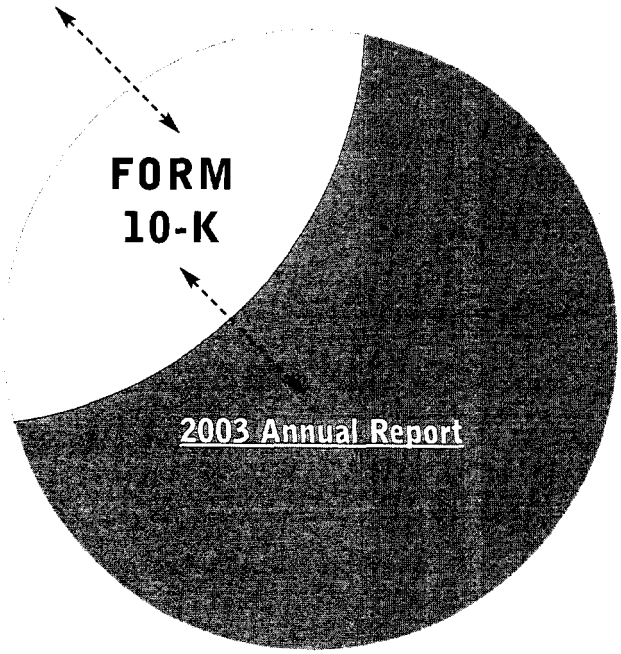
There were no cash dividends paid to common shareholders for any period presented.

(1) For all periods presented, the net results and assets of Primedica Corporation are shown as discontinued operations. Primedica was sold in February 2001.

Important Note to Investors

This document contains forward-looking information, including statements about research and development programs and the potential size of the markets for GTC Biotherapeutics' products and services. Actual results may differ materially from these statements because of a number of factors, including market acceptance of the Company's products and services; content and timing of decisions made by the U.S. Food and Drug Administration and other regulatory agencies; the accuracy of the Company's information about competitors, potential competitors, market sizes and the price-sensitivity of customers; and the Company's ability to obtain patents, to obtain adequate funding for research and development programs, and to recruit and retain adequate numbers of qualified employees. These and other risk factors are described or referenced to in more detail in the Company's most recent 10K filed with the Securities and Exchange Commission.

For the fiscal year ended
December 28, 2003



SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

☒ **FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 28, 2003

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 No. 0-21794

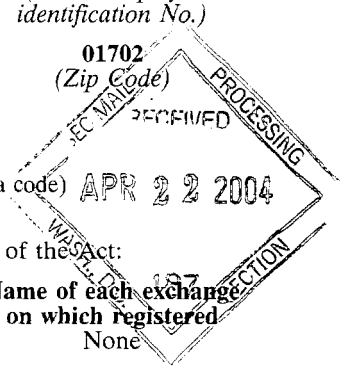
GTC BIOTHERAPEUTICS, INC.

(Exact name of Registrant as specified in its charter)

MASSACHUSETTS	**04-3186494**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer identification No.)*
175 CROSSING BOULEVARD FRAMINGHAM, MASSACHUSETTS	**01702**
(Address of principal executive offices)	*(Zip Code)*

(508) 620-9700

(Registrant's telephone number, including area code)



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

Title of Each Class	**Name of each exchange on which registered**
None	None

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

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, par value $0.01
(Title of each class)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or15(d) of the Securities Exchange Act of 1934 during the preceding twelve months and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes ☒ No ☐

Aggregate market value of voting stock held by non-affiliates of the Registrant as of June 27, 2003, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $89,828,281, based on the closing sale price of the Company's Common Stock as reported on the NASDAQ National Market.

Number of shares of the Registrant's Common Stock outstanding as of March 1, 2004: 32,241,425

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for the Annual Meeting of Stockholders to be held May 26, 2004 are incorporated by reference into Part III of this Form 10-K.

PART I

ITEM 1. BUSINESS

Overview

GTC Biotherapeutics, Inc., referred to as GTC or the Company, is a leader in the development, production, and commercialization of human therapeutic proteins in the milk of animals. Using a process known as transgenics, GTC inserts protein-specific DNA into an animal to enable it to produce that specific protein in its milk. The protein is then purified from the milk to obtain the therapeutic product, which is typically administered by injection.

GTC is developing its own proprietary proteins and providing leadership in obtaining regulatory and market approval for products produced transgenically. GTC uses transgenic technology to establish commercial production systems for products that are anticipated to require large production volume or are difficult to express in traditional recombinant protein production systems. The Company's technology platform is being used to create a pipeline of internal product programs and a portfolio of external clinical and commercial production opportunities.

The Company has three internal programs in active development. These programs are the recombinant human antithrombin program, which will be sold under the brand name ATryn® once regulatory approval is obtained, the recombinant human serum albumin program, known as rhSA, and a malaria vaccine program using one of the malaria parasite's surface proteins known as MSP-1 as an antigen. All of these programs involve products that are difficult-to-express proteins. The ATryn® and rhSA proteins are also required in large volumes. The ATryn® program has the potential to generate commercial product revenues in the next two to three years. The Company seeks partners for its internal programs to provide a source of funding for these programs as well as to augment its clinical or marketing expertise.

GTC's external programs use the Company's intellectual property and technology platform to develop transgenic production of a partner's proprietary protein. External programs generate current revenue through research funding and achievement of milestones. These programs provide GTC the opportunity for long-term product revenues as a result of GTC serving as the clinical and commercial manufacturing partner for the program product. This business has the potential to generate positive cash flow and eventually profits, helping support the continued development of the Company's internal programs and technology platform.

In GTC's portfolio of external programs, the most advanced is the program with Merrimack Pharmaceuticals, Inc. for production and purification of Merrimack's MM-093 (formerly named ABI.001), a recombinant human alpha-fetoprotein, or rhAFP. GTC has been producing MM-093 transgenically for use in Merrimack's ongoing human clinical studies. The rhAFP protein has been difficult to express in traditional recombinant protein production systems. GTC is also working with Centocor to develop transgenic protein production for an undisclosed protein. This program is moving forward to supply product for preclinical evaluation. Four of the other programs in the external portfolio, two with Abbott and two with Bristol-Myers Squibb, have concluded with the successful completion of founder status namely development of a transgenic animal capable of starting a production herd for a therapeutic protein. No further work will be undertaken in these programs unless the respective partner chooses to pursue transgenic production for preclinical or clinical testing.

Internal Programs

Recombinant Human Antithrombin (ATryn®)

Antithrombin is a blood plasma protein that has anticoagulant and anti-inflammatory properties. Antithrombin, as is typical of many blood plasma proteins, is difficult to express in traditional

recombinant production systems. In late 2001, GTC was granted permission by the European Medicines Evaluation Agency, known as EMEA, to conduct clinical studies of ATryn® in individuals who express a low level of antithrombin in their blood as a result of an hereditary deficiency of antithrombin, referred to as HD. ATryn® is a recombinant form of human antithrombin. There are approximately 1 in 5,000 people with an HD. In December 2001, GTC began dosing HD patients in a study to establish an appropriate dosing regimen for an efficacy study. GTC successfully completed this 15 patient study and began an efficacy study in HD patients in 2002, primarily based in Europe and including patients in the United States. The efficacy study was designed to assess the prevention of certain blood clots, known as deep vein thromboses, referred to as DVT, among HD patients that undergo surgery or childbirth. Based on EMEA guidance, GTC determined that at least 12 evaluable patients must be included in the efficacy study. A total of 14 patients were enrolled in the efficacy study. In the opinion of clinical experts who have reviewed these data, ATryn® offers safe and efficacious thromboprophylaxis for this difficult-to-manage group of patients. GTC submitted a Market Authorization Application, or MAA, to the EMEA in January 2004. The MAA submission includes data from this trial, as well as data from high-risk situations treated under the compassionate use program. The EMEA has accepted the MAA for review which will make a determination of the safety and efficacy of ATryn® in addition to assessing whether the product is approvable for commercial sale. GTC believes that ATryn® is the first transgenically produced therapeutic protein to be considered for approval by a regulatory agency in the U.S. or Europe. GTC is in discussions with the U.S. Food and Drug Administration, or FDA, regarding its clinical and regulatory strategy and the FDA's requirement that there be a controlled study of ATryn® for approval in the U.S.

Commercially available antithrombin protein is currently produced by human plasma fractionation for therapeutic use in hereditary and acquired antithrombin deficiencies, with worldwide annual sales of approximately $250 million. GTC believes that the U.S. market is underserved by a single producer with only limited supplies being available.

GTC is in discussions with potential partners for the ATryn® program to provide marketing and financial support. The Company is also considering the strategic option of adding a small sales force in Europe to support commercial sales of ATryn® for the hereditary antithrombin deficiency indication. GTC plans to expand the market opportunity for this product through one or more clinical studies in order to develop additional potential acquired deficiency indications in collaboration with potential partners. Acquired antithrombin deficiency occurs in a number of conditions, and may result from a decrease in the amount of antithrombin produced, an increase in the rate of antithrombin consumption or an abnormal loss of antithrombin in the circulatory system. Examples of conditions in which acquired antithrombin deficiency may occur are burns, heparin resistance, bowel perforation, acute liver failure, disseminated intravascular coagulation, sepsis and septic shock, multiple organ failure, pre-eclampsia, bone marrow or organ transplantation, and prevention of neurocognitive deficiency in patients undergoing cardio pulmonary bypass. GTC is focusing on the larger market potential indications for further clinical studies, such as developing the use of ATryn® to treat burns. Since antithrombin levels may be dramatically reduced in patients with severe thermal injury due to increased consumption and loss, GTC believes that antithrombin's anticoagulant and anti-inflammatory properties may be beneficial in reducing the intensive care hospitalization time for burns patients as well as helping to reduce the scarring that often results.

Recombinant Human Serum Albumin (rhSA)

Albumin is a plasma protein that is principally responsible for maintaining the osmotic pressure in the vascular system, as well as maintaining plasma volume and the balance of fluids in blood. It is critical to the transport of amino acids, fatty acids and hormones in the blood stream. Albumin is used as an excipient, which is a non-active component used to stabilize the active ingredient in biologic drug formulations. Human serum albumin produced from blood plasma has been used as an excipient to

maintain structural stability and activity in many biological drug formulations for long periods of time under a wide range of storage conditions. Albumin is also used therapeutically in situations of blood loss and/or decreased blood albumin levels which can result from shock, serious burns, pre- and post-operative conditions, congestive heart failure and gastric, liver and intestinal malfunctions (the blood expander indication).

GTC has a strategic interest in developing recombinant human serum albumin, or rhSA, in the excipient market where there is the potential for commercial sales within the next two to three years, sooner than is practical in the blood expander indication and with significantly lower capital investment. GTC believes that the recombinant nature of this product can lead to a well characterized protein and a stable single source of supply. This will provide drug manufacturers the opportunity to avoid plasma-derived human serum albumin as an excipient for their recombinant products and establish a universally acceptable supply. GTC believes this will allow rhSA to make substantial penetration into the existing excipient market. During 2004, GTC intends to initiate the production of qualification batches for evaluation as an excipient by its clients and for the development of a Drug Master File, which is a documentation system required by the health authorities to reduce redundancy in the filing of information related to ingredients or materials that may be used in multiple therapeutic products. The Company believes that under this timetable for development GTC has the opportunity to achieve commercial sales of rhSA within two to three years, depending primarily on the level of development funding devoted to this program. The Company expects that the timetable of development will be based on the financial resources available to the Company, as well as its ability to attract additional marketing or strategic partners to provide additional funding.

rhSA is another example of a difficult-to-express plasma protein under development by GTC, which is also required in large volumes. Albumin is currently produced by human plasma fractionation, with worldwide sales of approximately $1 billion. About $150 million to $200 million of this total is sold for excipient use. Since the total market is very large, requiring about 400 metric tons of production a year, GTC is developing this program in transgenic cattle to take advantage of the higher milk production of cattle compared to goats. The cattle in this program are maintained by Trans Ova Genetics in Iowa. GTC has developed and continues to add to the number of cattle that express rhSA in their milk. Bench scale purification of clinical grade quality has been achieved and the purification process is being scaled up for clinical production quantities. GTC estimates the total production volume to meet the needs of the excipient market is in the range of one to two metric tons per year.

In late 2002, Fresenius AG and GTC restructured their relationship for the therapeutic blood expander market into a joint venture, called Taurus hSA LLC or the Taurus Joint Venture, to include the development of rhSA as an excipient. The Taurus Joint Venture will manage development of GTC's rhSA program for both the excipient and blood expander markets. GTC currently has a 55% interest in the joint venture. Each party has the right, but not the obligation, to make future contributions to the Taurus Joint Venture. The joint venture structure allows the development of the excipient market with the potential to attract additional marketing or strategic partners that may also assist with the financing of the joint venture. Ownership interests will be adjusted based on future levels of financial participation from existing and new partners. The Company is engaged in ongoing discussions with third parties to obtain further financing for the Taurus Joint Venture and the Company has also developed alternative plans to advance the joint venture using its existing resources with limited external financing. GTC and Fresenius made available all relevant commercial licenses, manufacturing and marketing rights, and intellectual property to enable the joint venture to operate worldwide in both the excipient and blood expander markets. The existence of the Taurus Joint Venture is perpetual unless terminated or dissolved earlier in accordance with the terms of the agreement. Upon any liquidation, sale or other disposition of all, or substantially all of the assets of the Taurus Joint Venture, and after the payment of debts and liabilities, expenses of liquidation and any reserves for unforeseen liabilities or in-kind distributions, the net proceeds would be applied and distributed first to Fresenius

and then to the Company, each according to its percentage interest. Each member would also have reversion rights to any intellectual property it contributes to the Taurus Joint Venture. The Company consolidates the Taurus Joint Venture on GTC's financial statements for financial reporting purposes.

Malaria Vaccine

GTC is developing the merozoite surface protein 1, or MSP-1, for use as an antigen in a malaria vaccine. This protein is normally expressed by the malaria parasite. Malaria is a disease that has an annual incidence of more than 300 million people worldwide and results in several million deaths annually, primarily among children. GTC has been working with the National Institutes of Health, or NIH, and the Federal Malaria Vaccine Coordinating Committee to develop transgenic production of the MSP-1 protein as an antigen for a vaccine and to examine the options for commercializing the vaccine. During 1998, GTC achieved high level expression of the MSP-1 antigen in the milk of transgenic mice. To express the MSP-1 protein at high quantities, GTC's scientists modified the protein's gene sequence while conserving the overall amino acid sequence of the protein. A U.S. patent has been issued to GTC for this modification. The MSP-1 protein has been expressed at 2-4 mg/ml in the milk of mice that have incorporated this gene sequence. The MSP-1 protein produced by the mice successfully protected *Aotus nancymai* monkeys in a preclinical vaccine study conducted by and co-authored with the National Institute of Allergy and Infectious Diseases, or NIAID. This study, titled "A recombinant vaccine expressed in the milk of transgenic mice protects *Aotus* monkeys from a lethal challenge with *Plasmodium falciparum*", was published in the December 18, 2001 *Proceedings of the National Academy of Sciences.* MSP-1 is difficult to express in other recombinant systems, with those other systems producing it in very limited quantities or in forms that may not induce the necessary immune response. GTC has developed goats at its research facilities that express the MSP-1 protein. The NIAID has funded a contract for the development and production of clinical grade production of MSP-1, as a malaria vaccine. The development work is being performed under the existing NIAID Contract No. NO1-A1-05421 managed by Science Applications International Corporation. The scope of work includes developing founder goats that express the MSP-1 antigen in their milk as well as the downstream purification process and final product formulation. The approved scope of work also includes the submittal of an Investigational New Drug, or IND, application to the FDA. GTC's portion of this project will be supported completely with Federal funds amounting to at least $4.9 million.

External Program Portfolio

GTC follows a partnership strategy in its portfolio of external programs, where both the Company's unique intellectual property position and molecular biology expertise are used in the development of a transgenic version of the external partner's protein. The advantages to external partners of using GTC's production platform include enabling the development of proteins that are difficult to produce in traditional recombinant production systems, requiring significantly lower capital investment, assuring lower cost of goods, and providing for flexibility in capacity expansion. The external portfolio business area also provides GTC the opportunity for a revenue stream through milestone payments during the development phase and, assuming continuing clinical and development success, subsequent opportunities for long-term product revenues as the external partner's commercial manufacturing partner. GTC views this area as an operating business which currently contributes to the support of the production and regulatory infrastructure of the Company and has the potential to provide positive cash flow for investment in GTC's proprietary programs.

The most advanced program in the external portfolio is with Merrimack Pharmaceuticals, formerly known as Atlantic BioPharmaceuticals. The Merrimack program is for MM-093 (formerly ABI.001), a recombinant human alpha-fetoprotein, or rhAFP. The rhAFP protein has been difficult to express in traditional recombinant systems. GTC has developed goats that express this protein in their milk. In 2002, GTC and Merrimack agreed to expand their relationship to include production and purification

of MM-093. Merrimack completed a phase I study of MM-093 in 2003. GTC expects to deliver purified MM-093 during 2004 for use in further human clinical studies by Merrimack. Potential indications for MM-093 include autoimmune diseases such as rheumatoid arthritis, multiple sclerosis and myasthenia gravis. Assuming that MM-093 is found to be safe and efficacious as the clinical program develops, GTC expects to earn revenue totaling several million dollars for production of rhAFP to supply the clinical trials, as well as additional revenues for eventual commercial production. In December 2003, GTC exercised its option to convert $1.25 million of the receivable owed by Merrimack into Merrimack preferred stock at the same valuation as the other investors in Merrimack's recent financing. In addition, GTC agreed to defer the payment of up to $650,000 of receivables owed by Merrimack until June, 2004.

Monoclonal Antibodies (MAB) and Immunoglobulin (Ig) Fusion Proteins

GTC's believes that its technology platform is well suited to producing difficult-to-express proteins and to establish large volume production with low capital investment and an assured low cost of goods. Monoclonal antibodies, or MABs, are proteins generated by an immune system that bind to a specific target. MABs typically express at reasonable levels in traditional recombinant production systems, but are often required in large quantities due to their applications to chronic disease indications. Immunoglobulin, or Ig fusion proteins, which consists of a MAB fragment linked to a second protein fragment, may be difficult to express due to their complexity. For these reasons, GTC has attracted multiple MAB and Ig fusion protein production opportunities to its external program portfolio.

GTC is actively participating in the field of MABs and Ig fusion proteins. The Company has been granted several patents covering the production of MABs in the milk of transgenic mammals, along with other transgenic process patents, which it believes establish a strong proprietary position in the field.

GTC has two programs with Centocor. The second program with Centocor for its undisclosed MAB has begun expansion of production capacity to provide a supply of product for preclinical evaluation.

The two programs with Bristol-Myers Squibb and the two programs with Abbott have been successfully completed with the achievement of founder status. No further development work is expected in these four programs with Abbott and Bristol-Myers Squibb unless the respective partner chooses to pursue transgenic production for preclinical or clinical testing. Abgenix has discontinued clinical studies at this time for its ABX-IL8 MAB program.

Summary Chart of External Programs

The following chart contains a summary of the Company's portfolio of external programs: (Note that a founder is a transgenic animal capable of starting a production herd for a therapeutic protein.)

Product Name	Product Type	Indication	Development Stage of Cell Culture Product	Development Stage of Transgenic Product	Partner	Anticipated Next Steps
5G1.1	Monoclonal antibody	Rheumatoid Arthritis; Nephritis	Phase II clinicals	Preclinical; Transgenic goats in evaluation	Alexion Pharmaceuticals	To be determined
Remicade®	Monoclonal antibody	Crohn's Disease; Rheumatoid Arthritis	Marketed	Preclinical; Founder	Centocor	Maintain founder animals
Undisclosed	Monoclonal antibody	Undisclosed	Undisclosed	Undisclosed; Founder	Centocor	Preclinical production
Antegren®	Monoclonal antibody	Rheumatoid Arthritis; Crohn's Disease	Phase II & III clinicals	Preclinical; Founder	Elan Pharmaceuticals	To be determined
Undisclosed	Monoclonal antibody	Undisclosed	Undisclosed	Preclinical; Founder	Elan Pharmaceuticals	Maintain founder animals
huN901	Monoclonal antibody	Small Cell Lung Cancer	Phase II clinicals	Preclinical; Transgenic goats in evaluation	ImmunoGen	To be determined
MM-093	Recombinant protein	Rheumatoid Arthritis; Myasthenia Gravis; Multiple Sclerosis	Not feasible	Phase I clinical; Founder	Merrimack Pharmaceuticals	Additional production for clinical studies
PRO542	Immunoglobulin fusion protein	HIV/AIDS	Phase II clinicals	Preclinical; Founder	Progenics Pharmaceuticals	To be determined
Successfully Concluded Programs						
D2E7	Monoclonal antibody	Rheumatoid Arthritis	Marketed as Humira®	Preclinical; Founder	Abbott Laboratories	Program concluded; maintain capability
Undisclosed	Monoclonal antibody	Undisclosed	Undisclosed	Preclinical; Founder	Abbott Laboratories	Program concluded
ABX-IL8	Monoclonal antibody	Rheumatoid Arthritis	Clinical trials discontinued by Abgenix	Preclinical: Founder	Abgenix Inc.	Maintain capability
CTLA4Ig	Immunoglobulin fusion protein	Rheumatoid Arthritis	Phase II completed	Preclinical; Founder	Bristol-Myers Squibb	Program concluded; maintain capability
Undisclosed	Immunoglobulin fusion protein	Organ Transplant Rejection; Autoimmune Disorders	Phase II clinicals	Preclinical; Founder	Bristol-Myers Squibb	Program concluded; maintain capability

Transgenic Technology Platform

Overview

GTC's technology platform includes the molecular biology expertise and intellectual property to generate appropriate transgenic animals, primarily goats and in some cases cattle, that express a specific recombinant protein in their milk. The Company also has the capacity to perform downstream purification. This technology platform is supported by the quality systems and regulatory, clinical development, and information technology infrastructure necessary to bring therapeutic protein products through clinical trials to commercial scale.

The economic and technical advantages of GTC's technology make it well suited to large volume applications, particularly 100 kilograms or more per year, in comparison to traditional recombinant protein production systems. These advantages include significantly reduced capital expenditures, greater flexibility in capacity expansion and lower unit production costs. In the case of certain complex proteins that do not express well in traditional systems, transgenic production may represent the only technologically and economically feasible method of commercial production. Some immunoglobulin, or Ig, fusion proteins as well as some proteins found in human plasma are examples of recombinant proteins that may not express at practical levels in traditional systems.

GTC's technology platform has been established as an operating infrastructure in goat husbandry, breeding, milking and downstream purification. These operations occur at the Company's biopharmaceutical production facilities in central Massachusetts, where it has approximately 1,600 goats, and at its facilities in Framingham, Massachusetts. Goat husbandry includes veterinary care with a clinic and medicinal supplies, all established within the farm's biosecurity program. The biosecurity program includes barriers to provide separation of the animals from contact with wildlife, separation from people, and specified and quality control monitored feed. Milking is typically performed using modern milking and processing equipment. Clarification to the intermediate bulk material is typically performed using tangential flow filtration equipment that removes much of the fats and casein from the milk. Manufacturing to clinical grade purity under standards of good manufacturing practice occurs either in GTC's facilities, the facilities of GTC's partners, or in contracted facilities. During 2002, GTC established capacity in its Framingham facilities for the purification of recombinant proteins suitable for clinical studies.

The Company uses goats and cattle in its commercial development programs. A goat reaches sexual maturity in about twelve months and gestates in approximately five months. A typical goat will produce an average of approximately 2 liters of milk per day during most of its natural lactation cycle. A cow reaches sexual maturity in about eighteen months and gestates in about nine months. A typical cow will produce an average of approximately 20 liters of milk per day during most of its natural lactation cycle. The species selected for a particular program will depend on a variety of factors, including the expected market size, desired herd size, and anticipated productivity of the desired protein within the animal's mammary gland. GTC has obtained broad freedom to operate in cattle technology through a licensing agreement with Pharming Group N.V., which was obtained in 2002.

GTC is now using nuclear transfer technology in the development of transgenic animals. The first step in this technology involves the generation of a characterized cell line which has incorporated the specific DNA for expression of the target protein in milk. Individual cells from the cell line(s) are then fused to an animal's ovum after removal of the ovum's own DNA. Thus, the transgenic nucleus of the cell becomes the driver for further development of the embryo, which is then placed in a surrogate female animal. All animals that are born through this process are transgenic. Nuclear transfer may mitigate the impact of long gestation and maturation periods in cattle, by producing a larger number of transgenic animals in one generation. The U.S. Patent and Trademark Office, or PTO, has declared an interference proceeding between Advanced Cell Technologies, Inc., or ACT, and Geron Corporation for

one of the patents GTC licenses from ACT. The Company does not know at this time what impact, if any, this interference proceeding may have on its ability to practice nuclear transfer.

Advantages of Transgenic Technology

GTC believes that its current and future partners will elect to employ transgenic technology for the production of recombinant proteins in cases where transgenic technology either uniquely enables development of proteins that are hard to express with traditional methods or offers economic and technological advantages over other production systems. These advantages, any one of which may be critical to the decision to proceed with a particular development project, include:

- *Technological Enablement.* Transgenic technology offers the ability to produce certain biotherapeutics that cannot be made in a commercially feasible manner in any other system. The potential of transgenic production for high-volume proteins requiring more than 100 kilograms per year is widely acknowledged. In addition, GTC has achieved consistent expression rates with complex molecules, which may not be producible at commercial scale in cell culture systems. This accomplishment, in conjunction with the favorable economics of herd development, means that transgenics may be a viable production system for some complex proteins, regardless of the volume required.
- *Lower Capital Investment.* Developing a herd and providing appropriate production facilities can be accomplished with substantially lower investment than building a cell culture bioreactor facility.
- *Lower Cost of Goods.* Economic factors unique to transgenic production may lower the ultimate cost of goods in most cases. The lower amortization of the initial capital investment, the lower cost of consumable materials and the high productivity of operations result in the cost of transgenically produced products, in most cases, being substantially lower than that of a cell culture derived product.
- *Flexible Production.* Transgenic production offers the ability to rapidly match production capacity to the market demand, once the first appropriate animal is identified. If the product's market is larger than originally planned, the incremental investment to breed additional animals and expand capacity is relatively small. In contrast, traditional bioreactor methods are hard assets with a generally fixed capacity. If a bioreactor product's market will support sales significantly higher than the installed capacity can achieve, more bioreactor space needs to be built or acquired at unit costs similar to the original capital investment with construction times of generally three to five years.

Transgenic Development Process

GTC's development of a typical transgenic protein is designed to proceed in a logical sequence of three principal steps:

- *Development of Transgenic Animals.* In this first step, GTC takes the genetic material for a desired protein and establishes an appropriate expression vector by combining the genetic material with the appropriate coding and promoter sequences to ensure expression in the mammary gland. The Company then employs nuclear transfer techniques to initiate pregnancies to produce a transgenic animal. The first animals are then born after the appropriate gestation period.
- *Transgenic Evaluation.* GTC and its partner evaluate the genetic profile of the animal. The animal's production levels under induced or natural lactation are evaluated and the recombinant protein produced by the animal in its milk is characterized. Some initial process development work takes place in which pilot clarification and purification methods are examined.

- *Founder.* GTC and the partner select one or more appropriate transgenic animals as founders. A founder animal has the appropriate genetic profile and is the potential start of a herd of transgenic animals capable of producing a desired therapeutic protein. GTC and the partner may then begin a collaborative effort to establish a commercially robust purification process for the protein. This enables substantial amounts of material to be delivered for preclinical studies and initial human clinical studies. Thereafter, scale up of the herd to reach needed commercial production capacity is then planned.

Patents and Proprietary Rights

Currently, GTC holds 17 issued or allowed U.S. patents and 111 corresponding foreign patents. GTC's patents generally expire between 2013 and 2019, with the most significant patents expiring in 2015. Of the GTC patents expiring in 2015, two relate to transgenically produced antithrombin, its lead product. In accordance with ongoing research and development efforts, GTC has 40 pending U.S. patent applications and 174 corresponding foreign applications covering relevant and newly developed portions of its transgenic technology. Several of these pending applications are included in various cross-licensing or out-licensing arrangements with other companies that in turn provide access to their proprietary technologies. Specifically GTC has cross-licensed its proprietary technology for the production of proteins in milk to Pharming B.V. and PPL Therapeutics, while limited access has been granted to its technology related to the production of antibodies in milk to Pharming B.V. and the French company Bioprotein. Recently issued GTC U.S. patents provide claim coverage for protein purification from the milk of transgenic animals, the production of monoclonal and assembled antibodies at commercial levels in the milk of transgenic mammals, the production of recombinant antithrombin in the milk of transgenic goats and one covering the production of Prolactin in the milk of transgenic animals.

In addition, GTC holds exclusive and non-exclusive licenses from Genzyme Corporation, Biogen, and other individuals and corporations to rights under a number of issued patents and patent applications in the U.S. and the corresponding cases abroad for a variety of technologies enabling the transgenic production of proteins in the milk of non-human animals. GTC holds licenses to 35 issued U.S. patents and 19 pending U.S. applications. On an international basis, GTC holds licenses to 61 issued patents, and 99 pending applications. The in-licensed patents that are related to the transgenic platform begin to expire in 2009.

GTC also has exclusive and nonexclusive licenses to specific technologies owned by other parties. GTC has also concluded an extensive cross-licensing arrangement with Pharming providing broad access to the transgenic cattle platform as well as some additional nuclear transfer technology. GTC's relationship with ACT also focuses on intellectual property concerning cloning and nuclear transfer. Certain of the licenses require GTC to pay royalties on sales of products which may be derived from or produced using the licensed technology. The licenses generally extend for the life of any applicable patent. GTC has signed an exclusive, worldwide licensing agreement with ACT that allows GTC to utilize ACT's patented nuclear transfer technology for the development of therapeutic proteins in the milk of transgenic mammals. The majority of GTC's current programs have used, and most of its future programs are expected to use, this technology. The PTO has declared an interference proceeding between ACT and Geron Corporation for one of the patents GTC licenses from ACT. The Company does not know at this time what impact, if any, this interference proceeding may have on its ability to practice nuclear transfer. GTC has broadened its rights to practice nuclear transfer as part of its licensing agreement with Pharming, which was executed in 2002.

The Company also relies upon trade secrets, know how and continuing technological advances to develop and maintain its competitive position. In an effort to maintain the confidentiality and ownership of trade secrets and proprietary information, the Company requires employees, consultants

and certain collaborators to execute confidentiality and invention assignment agreements upon commencement of a relationship with the Company.

Competition

Many companies, including biotechnology and pharmaceutical companies, are actively engaged in seeking efficient methods of producing proteins for therapeutic or diagnostic applications. This includes companies that are developing transgenic technology using various plant and avian systems, as well as many companies that are building their own cell-culture-based production systems or other traditional protein production methods, and contract manufacturers who are using those systems to produce proteins for others.

The other companies known to GTC to be engaged in the application of transgenic technology in mammals for the production of proteins for therapeutic use in humans are Pharming Group N.V. and PPL. Based in the Netherlands, Pharming is primarily engaged in the development of recombinant proteins in the milk of transgenic cows and rabbits. Pharming has one product in clinical development that is in phase II studies. PPL, now in liquidation, is based in Scotland and utilizes primarily sheep for transgenic protein production. PPL has developed recombinant alpha-1 antitrypsyn into Phase II stage of clinical testing. There are also other companies seeking to develop transgenic technology in animals and in plants, which may be competitive with GTC's technology with respect to its patents and proprietary rights.

For ATryn®, a number of companies internationally produce and market antithrombin from the fractionation of human plasma. Aventis has approximately a 40% share of this market worldwide. Bayer is the only company that has commercially available fractionated antithrombin material that is approved for sale in the U.S., which sales represent only about 1% of the worldwide market.

There are a number of companies worldwide that produce and market human serum albumin from the fractionation of human plasma. We estimate that Bayer and Aventis sales represent approximately 30% and 10% market shares, respectively, of the worldwide market for human serum albumin. We are aware of two companies internationally that are developing recombinant forms of human serum albumin derived from yeast cultures. One company, Aventis, is developing its recombinant albumin product for the excipient market.

Government Regulation

The manufacturing and marketing of GTC's potential products and certain areas of research related to them are subject to regulation by federal and state governmental authorities in the U.S., including the FDA, the U.S. Department of Agriculture and the Environmental Protection Agency. Comparable authorities are involved in other countries, including the EMEA in Europe.

To GTC's knowledge, no therapeutic protein produced in the milk of a transgenic animal has been submitted to the FDA for final regulatory approval or, except for GTC's submission of Atryn® to the EMEA in January 2004, to any other regulatory agency for final regulatory approval. However, the FDA issued its Points to Consider in August 1995, addressing the Manufacture and Testing of Therapeutic Products for Human Use Derived from Transgenic Animals. Points to Consider, which are not regulations or guidelines, are nonbinding published documents that represent the current thinking of the FDA on a particular topic. Earlier in 1995, comparable guidelines were issued by European regulatory authorities. GTC believes that its programs satisfactorily address the topics identified in these documents and generally views them as a very positive milestone in the acceptance of the transgenic form of production. Nonetheless, obtaining required regulatory approvals for our transgenically produced products may take several years to complete and is expensive and uncertain.

Regulations in the U.S. setting forth legal requirements for the investigation and commercialization of drug products and medical devices are implemented in accordance with the Food, Drug and Cosmetic Act. Regulations mandating requirements for the development and licensure of biological products are implemented in accordance with the Public Health Service Act, or PHSA. With respect to therapeutic biological products, generally, the standard FDA approval process includes preclinical laboratory and animal testing, submission of an IND to the FDA and completion of appropriate human clinical trials to establish safety and effectiveness. The approval process is comparable in Europe and other countries.

GTC is in discussions with the FDA regarding its clinical and regulatory strategy for approval of ATryn® in the United States. In response to an IND filed with the FDA in 2003 for clinical development of ATryn® in the hereditary deficiency indication, the FDA has provided the Company guidance that it wishes to see a controlled study as a basis for approval, which may not be feasible for this indication. Such a study has not been required under the advice GTC has received from the EMEA for approval of ATryn® in the hereditary deficiency indication in Europe. The Company is in a continuing dialogue with the FDA to define an appropriate clinical and regulatory strategy for ATryn® approval in hereditary deficiency or another indication that meets the agency's requirements. The Company intends to move forward with its clinical development program for ATryn® in the United States in 2004 under an appropriate IND once agreement has been reached with the FDA. Until the Company knows the nature of any clinical program that may be agreed with the FDA, GTC is unable to estimate a timetable for filing a Biologics License Application on ATryn® in the United States. If the Company does not reach agreement with the FDA on an appropriate IND for ATryn®, the Company will not be able to proceed with its clinical development in the United States.

As a potential manufacturer of biological products, GTC will also be subject to regulation requiring it to successfully demonstrate that a given biological product meets PHSA standards, that is, that the product is safe, pure and potent and that the facility in which it is manufactured meets standards designed to ensure that the product continues to be safe, pure and potent. If it does so, then as the manufacturer GTC would receive a biological license to market the product in interstate commerce. It is possible, however, that the FDA may not act expeditiously or favorably on requests for approval of a biological license or will require additional data before granting approval. GTC is required to comply with these regulations to support development and commercialization of products produced in its internal programs and under its contracts with external partners.

Research and Development Costs

During its fiscal years ended December 28, 2003, December 29, 2002 and December 30, 2001, GTC spent in total, $29.2 million, $25 million and $22.4 million, respectively, on cost of revenue and research and development expense of which $11.1 million, $13.1 million and $15.1 million, respectively, was related to external programs. Of the total spent on research and development, $8.7 million, $5.1 million and $2.3 million, was spent on the ATryn® program in fiscal years 2003, 2002 and 2001, respectively. These costs include labor, materials, supplies and overhead, as well as certain subcontracted research projects. Also included are the costs of operating the transgenic production facility such as feed and bedding, veterinary costs and utilities.

Employees

As of December 28, 2003, GTC employed 159 people, including 6 part time and temporary employees. Of GTC's total employees, 102 were engaged in farm operations, clarification processes, quality assurance and control, 21 were engaged in research and development and 36 were engaged in administration, business development and marketing. Of GTC's employees, approximately 16 have Ph.D. degrees and 6 have D.V.M. degrees. None of GTC's employees are covered by collective bargaining agreements. GTC believes its employee relations are satisfactory. During the third quarter of

2003, the Company implemented a restructuring plan including a headcount reduction of 13%. Additionally in February 2004, the Company announced a further restructuring of its organization to control costs and to support its focus on clinical development and commercialization of its internal pipeline of proprietary products and its portfolio of external programs. This restructuring included a headcount reduction of approximately 20% from 159 to 127 full time equivalent employees.

Available Information

GTC's internet website is www.gtc-bio.com and through the "Investor Information" portion of the website, investors may access, free of charge, GTC's annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements on Schedule 14A and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after GTC electronically files such material with, or furnishes it to, the Securities and Exchange Commission.

ITEM 1A. EXECUTIVE OFFICERS OF THE REGISTRANT

The executive officers of the Company and their respective ages and positions as of March 1, 2004 are as follows:

Name	Age	Position
Geoffrey F. Cox, Ph.D.	60	Chairman of the Board, President and Chief Executive Officer
John B. Green	49	Senior Vice President, Chief Financial Officer and Treasurer
Gregory F. Liposky	49	Senior Vice President, Operations
Harry M. Meade, Ph.D.	57	Senior Vice President, Research and Development
Daniel S. Woloshen	56	Senior Vice President and General Counsel

Dr. Cox was appointed Chairman of the Board, President and Chief Executive Officer of GTC in July 2001. From 1997 to 2001, Dr. Cox was Chairman and Chief Executive Officer of Aronex Pharmaceuticals, Inc., a biotechnology company. In 1984, Dr. Cox joined Genzyme Corporation in the UK and, in 1988, became Senior Vice President of Operations in the United States. Subsequently, Dr. Cox was promoted to Executive Vice President for Genzyme, responsible for operations and the pharmaceutical, diagnostic and genetics business units until 1997. Prior to joining Genzyme, Dr. Cox was General Manager of the UK manufacturing operations for Gist-Brocades. Dr. Cox also serves as a director for Nabi Biopharmaceuticals and the Emerging Companies Section Governing Body of the Biotechnology Industry Organization.

Mr. Green was appointed Senior Vice President of GTC in May 2002, having had previously served as Vice President since 1994. Mr. Green has also served as Chief Financial Officer since December 1994 and Treasurer since August 1997. Prior to that, he was Vice President and Assistant Treasurer of TSI Corporation from December 1989 until its acquisition by GTC in 1994.

Mr. Liposky was appointed Senior Vice President, Operations in May 2002 and was previously Vice President, Operations since January 1999. Before joining GTC, Mr. Liposky served as Vice President, Contract Manufacturing for Creative Biomolecules, Inc. from 1992 through 1998 and Vice President, Bioprocessing and Operations and Projects Manager for Verax Corporation from 1987 to 1991.

Dr. Meade has been Senior Vice President of Research and Development since 2002. Prior to that time, he was Vice President of Transgenics Research for GTC since August 1994 after serving as Research Director since May 1993. Prior to joining GTC, Dr. Meade was a Scientific Fellow at Genzyme, where he was responsible for directing the transgenic molecular biology program. From 1981 to March 1990, Dr. Meade was a Senior Scientist at Biogen, Inc., a biotechnology company, where he

worked on the technology relating to the production of proteins in milk and was an inventor on the first issued patent covering this process.

Mr. Woloshen was appointed Senior Vice President and General Counsel in May 2002 and was previously Vice President and General Counsel since August 1999. Prior to that, Mr. Woloshen served as Vice President and General Counsel of Philips Medical Systems North America from April 1989 until July 1999.

ITEM 2. PROPERTIES

GTC's corporate headquarters is located in 12,468 square feet of office space in Framingham, Massachusetts under a lease which expires in March 2006. In 2002, the Company entered into a Sublease Agreement to use additional office and laboratory space at their existing location in Framingham. The sublease consists of approximately 19,888 square feet. GTC's research facility is located in approximately 3,900 square feet of laboratory, research and office space leased from Genzyme in Framingham, Massachusetts which automatically renews annually, on a year-to-year basis.

GTC owns a 383-acre facility in central Massachusetts. This facility contains 106,793 square feet of production, laboratory and administrative space and currently houses more than 1,600 goats. GTC believes its owned and leased facilities are adequate for significant further development of commercial transgenic products. GTC leased animal housing, care, treatment and research facilities operated by Tufts University School of Veterinary Medicine in Massachusetts until December 1, 2003, at which time GTC no longer needed such services. In January 2002, the Company completed the purchase of approximately 135 acres of farm land in eastern New York State for potential development as a second animal facility.

ITEM 3. LEGAL PROCEEDINGS

On November 13, 2001, two employees of one of the Company's former subsidiaries filed an action in the Court of Common Pleas for Philadelphia County in Pennsylvania against the Company seeking damages, declaratory relief and certification of a class action relating primarily to their Company stock options. The claims arise as a result of the Company's sale of Primedica Corporation to Charles River Laboratories International, Inc. in February 2001, which the Company believes resulted in the termination of Primedica employees' status as employees of the Company or its affiliates and termination of their options. The plaintiffs contend that the sale of Primedica to Charles River did not constitute a termination of their employment with the Company or its affiliates for purposes of the Company's equity incentive plan and, therefore, that the Company breached its contractual obligations to them and other Primedica employees who had not exercised their stock options. The complaint demands damages in excess of $5 million, plus interest. GTC has filed an answer denying all material allegations in the complaint, and is vigorously defending the case. The Company believes that it has meritorious defenses and that, although the ultimate outcome of the matters cannot be predicted with certainty, the disposition of the matter should not have a material adverse effect on the financial position of the Company.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

During the fourth quarter of fiscal year 2003, no matter was submitted to a vote of the security holders of the Company.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

The Company's Common Stock commenced trading on the NASDAQ National Market System in 1993. The stock's ticker symbol was changed to GTCB on June 3, 2002, in conjunction with changing the name of the Company to GTC Biotherapeutics, Inc. Quarterly high and low sales prices for the Common Stock as reported by the NASDAQ National Market are shown below.

		High	Low
2002:			
1st	Quarter	$6.25	$3.25
2nd	Quarter	3.88	1.25
3rd	Quarter	1.61	0.61
4th	Quarter	1.25	0.73
2003:			
1st	Quarter	$1.58	$1.01
2nd	Quarter	4.34	1.17
3rd	Quarter	3.90	2.14
4th	Quarter	4.00	2.50

The records held by the transfer agent indicate that on March 1, 2004 there were approximately 914 shareholders of GTC of record.

The Company has never paid a cash dividend on its Common Stock and currently expects that future earnings will be retained for use in its business.

ITEM 6. SELECTED FINANCIAL DATA

The selected financial data set forth below as of December 28, 2003 and December 29, 2002 and for each of the three fiscal years in the period ended December 28, 2003 are derived from the Company's consolidated financial statements included elsewhere in this Report, which have been audited by PricewaterhouseCoopers LLP, independent accountants. The selected financial data set forth below as of December 30, 2001, December 31, 2000 and January 2, 2000, and for the years ended December 31, 2000 and January 2, 2000 are derived from audited consolidated financial statements not included in this Report.

This data should be read in conjunction with the Company's consolidated financial statements and related notes thereto under Item 8 of this Report and "Management's Discussion and Analysis of Financial Condition and Results of Operations" under Item 7 of this Report.

SELECTED FINANCIAL DATA

(Dollars in thousands except per share data)

	For the Fiscal Years Ended				
	December 28, 2003	December 29, 2002	December 30, 2001	December 31, 2000	January 2, 2000
Statement of Operations Data:					
Revenues:					
Revenue	$ 9,640	$ 10,379	$ 12,152	$ 12,880	$ 9,334
Revenue from joint venture and related party	124	—	1,588	3,283	4,491
	9,764	10,379	13,740	16,163	13,825
Costs of revenue and operating expenses:					
Cost of revenue	11,116	13,100	15,075	15,619	11,402
Research and development	18,036	11,869	7,353	3,357	3,690
Selling, general and administrative	10,929	11,319	11,078	9,148	7,875
Equity in loss of joint venture	—	—	4,078	4,625	3,797
	40,081	36,288	37,584	32,749	26,764
Operating loss from continuing operations	(30,317)	(25,909)	(23,844)	(16,586)	(12,939)
Other income and (expenses):					
Interest income	1,103	2,028	3,478	3,770	65
Interest expense	(508)	(439)	(746)	(1,001)	(1,232)
Realized gain on sale of CRL stock	—	—	2,320	—	—
Other income	185	—	—	—	484
Loss from continuing operations	$ (29,537)	$ (24,320)	$ (18,792)	$ (13,817)	$ (13,622)
Discontinued operations					
Income (loss) from discontinued contract research operations, net of taxes	—	—	—	(324)	(5,139)
Gain from sale of discontinued contract research operations	—	—	2,236	—	—
Net loss	$ (29,537)	$ (24,320)	$ (16,556)	$ (14,141)	$ (18,761)
Dividends to preferred shareholders	—	—	(74)	(1,497)	
Net loss available to common shareholders	$ (29,537)	$ (24,320)	$ (16,556)	$ (14,215)	$ (20,258)
Net loss available to common shareholders per weighted average number of common shares (basic and diluted):					
From continuing operations	$ (1.00)	$ (0.86)	$ (0.63)	$ (0.49)	$ (0.76)
From discontinued contract research operations	$ —	$ —	$ 0.08	$ (0.01)	$ (0.26)
Net loss	$ (1.00)	$ (0.86)	$ (0.55)	$ (0.50)	$ (1.02)
Weighted average number of shares outstanding (basic and diluted)	29,562,152	28,353,490	29,975,167	28,373,283	19,876,904

	December 28, 2003	December 29, 2002	December 30, 2001	December 31, 2000	January 2, 2000
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 31,091	$ 57,349	$ 90,448	$ 66,532	$ 7,813
Working capital	24,152	47,682	74,458	88,389	16,715
Total assets	71,072	95,373	120,443	134,403	58,518
Long-term liabilities	12,582	12,823	80	294	6,256
Shareholders' equity	48,161	68,772	101,950	114,843	26,206

There were no cash dividends paid to common shareholders for any period presented.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Business Overview

GTC Biotherapeutics, Inc., referred to as GTC or the Company, is a leader in the development, production, and commercialization of human therapeutic proteins in the milk of animals, principally goats and cattle. Using a technology known as transgenics, GTC inserts protein-specific DNA into the animal to enable it to produce that specific protein in its milk. The protein is then purified from the milk under pharmaceutical manufacturing conditions to obtain the therapeutic product, which is typically administered by injection or infusion.

GTC is dependent upon funding from partnering programs, equity financings and proceeds from short and long term debt to finance operations. The Company enters into licensing and development agreements with collaborative partners for the development, production and purification of therapeutic recombinant proteins produced transgenically. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon the achievement of certain milestones and royalties on future product sales, if any.

The key value drivers for the Company include the following:

ATryn®

The Company completed clinical trials for its lead product, ATryn®, a recombinant form of human antithrombin, in the fourth quarter of 2003 for patients with a hereditary antithrombin deficiency that are undergoing high-risk procedures, such as surgery or childbirth. In January 2004, GTC submitted a Market Authorization Application, or MAA, to the European Medicines Evaluation Agency, or EMEA, for approval to market ATryn® in Europe for the hereditary deficiency indication. The application has been accepted for review by the EMEA and the approval process is expected to take approximately twelve months. The Company is also developing plans for expanded clinical trials for use of ATryn® in the treatment of severe burns. The Company believes that this presents a significant opportunity for this product, with a worldwide market that the Company estimates to be between $300 million and $500 million. The Company hopes to commence this development program in 2004, but the timing and execution of these trials is dependent upon the financial resources available to the Company. GTC is also in discussions with the FDA regarding the clinical and regulatory strategy for approval of ATryn® in the U.S. and the FDA's requirement that there be a controlled study of ATryn® for U.S. approval. In 2004, the Company hopes to reach agreement with the FDA and define this strategy for U.S. approval.

rhSA

The Company is developing rhSA, a recombinant form of human serum albumin, for use as an excipient (a non-active component used as a stabilizer in biological formulations). This is being developed in conjunction with its partner, Fresenius AG, under the Taurus Joint Venture. During 2004, GTC intends to initiate the production of qualification batches for evaluation as an excipient by its clients and for development of a Drug Master File. The Company believes that under this timetable for development, GTC has the opportunity to achieve commercial sales of rhSA within two to three years depending primarily on the level of development funding devoted to this program. The Company expects that the timetable of development will be based on the financial resources available to the Company, as well as its ability to attract additional marketing or strategic partners to provide additional funding.

External Portfolio

GTC follows a partnership strategy with its portfolio of external programs, whereby both the Company's unique intellectual property position and molecular biology expertise are used in the transgenic production of an external partner's protein. The advantages of using GTC's production platform include enabling production of proteins that are difficult to express in traditional recombinant production systems, a significantly lower cost of capital investment as compared with conventional production systems, an assured lower cost of goods, and flexibility in capacity expansion. The dynamics surrounding the amount of available production capacity in traditional recombinant manufacturing systems continues to evolve within the industry. However, the production of difficult-to-express products, as well as the reduced cost of capital for production of high volume products, continues to be areas in which the Company enjoys a competitive advantage. In many cases, the Company's technology provides an alternative means of production that the partner may or may not choose to use, even if the Company can produce the partner's protein successfully. The Company's external programs provide GTC with a portfolio of opportunities for a revenue stream through milestone payments and through sales of pre-clinical and clinical product during the development phase. Assuming clinical success, the Company may also achieve revenues from production of product for the partner, and, in some cases, royalties on commercial sales. GTC views this area as an operating business which currently contributes to the support of the production and regulatory infrastructure of the Company and which has the potential to provide positive cash flow for investment in GTC's proprietary programs. The approval of ATryn® may encourage one or more of the Company's external partners to move forward in the clinical development of their external programs with GTC. The Merrimack program represented 54% and 20% of the 2003 and 2002 revenues, respectively, NIH funding for the Company's internal malaria program represented 29% of the 2003 revenue, the program with Elan for an undisclosed protein represented 10% and 22% of the 2003 and 2002 revenues, respectively, and the Bristol Myers Squibb program represented 10% of the revenue in 2003.

Critical Accounting Policies and Estimates

The preparation of consolidated financial statements requires that the Company make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. The Company's critical accounting policies are summarized in Note 2 in the Notes to Consolidated Financial Statements included in Item 8 of this report. On an on-going basis, the Company evaluates its estimates, including those related to revenue recognition, investments, intangible and long-lived assets, income taxes, accrued expenses, financing operations, and contingencies and litigation. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

The Company believes that its application of the following accounting policies involve the most significant judgments and estimates used in the preparation of its consolidated financial statements.

Revenue Recognition

The Company enters into licensing and development agreements with collaborative partners for the development, production and purification of therapeutic recombinant proteins produced in the milk of transgenic animals. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon the achievement of certain milestones, revenues from sales of product to partners and royalties on future product sales, if any. When there are two or more distinct phases or services embedded into one contract, such as development and commercialization or manufacturing services, the contract is considered a multiple element

arrangement. For revenue arrangements entered into in fiscal periods beginning after July 1, 2003, the Company accounts for multiple-element arrangements in accordance with Emerging Issues Task Force (EITF) No. 00-21.

Management has to evaluate whether it can determine the fair value of the different elements if when the delivered services have value to the customer on a stand-alone basis. If so, then the different elements are accounted for separately. For example, if the Company enters into an arrangement to perform development services, but the Company is obligated to perform follow-on manufacturing services, then the Company must determine the fair value of both the development services and the manufacturing services. If the terms of both the development and manufacturing services are at fair value, then the Company will account for the development services separately. If the terms of the development and manufacturing services are not at fair value, but the Company can determine the fair value of each element, then the total amount of the contract is allocated to each element based on their relative fair values. If the Company cannot determine the fair value of the development services, but can determine the fair value of the manufacturing services, then revenue will be allocated to the development phase using the residual method.

Non-refundable license fees, milestones and collaborative research and development revenues under collaborative arrangements, where the Company is also obligated to provide development services and the Company can reasonably estimate the effort required to complete its contractual obligations, are recognized as revenue over the period of continuing involvement, using a model similar to the one prescribed by EITF No. 91-6. Under that model, revenue is recognized for non-refundable license fees, milestones and collaborative research and development using the lesser of non-refundable cash received and milestones met or the result achieved using level-of-efforts accounting. Under the level-of-efforts accounting, revenue is based on the cost of effort since the contract's commencement up to the reporting date, divided by the total expected research and development costs from the contract's commencement to the end of the research and development period, multiplied by the total expected contractual payments under the arrangement. Revisions in cost estimates and expected contractual payments as contracts progress have the effect of increasing or decreasing profits in the current period. For development contracts which the Company can not reasonably estimate the effort to complete its contractual obligations, revenue is limited to the lesser of costs incurred or non-refundable cash received provided the Company can reasonably conclude that the costs of completing the contract will not exceed the revenues under the contract. The Company has a contract under which the revenues are less than the estimated costs to complete, including the full allocation of internal overhead costs. Therefore, the Company delayed the recognition of revenue on this contract until the estimated costs to complete were equal to the contract revenue and, from that point, began recognizing revenue equal to costs incurred under the contract. Payments received in advance of being earned are recorded as deferred revenue.

Profits expected to be realized are based on the total contract sales value and the Company's estimates of costs at completion. The sales value is based on achievable milestones and is revised throughout the contract as the Company demonstrates achievement of milestones. The Company's estimates of costs include all costs expected to be incurred to fulfill performance obligations of the contracts. Estimates of total contract costs are reviewed and revised throughout the lives of the contracts, with adjustments to profits resulting from such revisions being recorded on a cumulative basis in the period in which the revisions are made. All revenue recognition estimates are made based upon the current facts and circumstances and are reassessed on at least a quarterly basis. If changes in these estimates or other immaterial adjustments to revenue are identified, the adjustments will be recorded as they become known.

Unbilled contract revenue represents efforts incurred or milestones achieved which had not been billed at the balance sheet date. Deferred contract revenue represents amounts received from customers that exceeded the amount of revenue recognized to date on the balance sheet date.

Inventory

The Company capitalizes inventory produced for commercial sale. All of the inventory on hand at December 28, 2003 is related to ATryn®, which has not yet been approved for commercial sale. The Company expects that all of the capitalized inventory will be sold commercially in Europe, provided the Company receives marketing approval. If, at any time, the Company believes that marketing approval of ATryn® is no longer probable, the Company will charge the inventory to expense. Such a determination is highly judgmental. Although no specific clinical plans require it to date, it is possible that the Company could use some of the capitalized inventory for additional clinical trials and, if so, the Company would expense the inventory when it was designated for use in the clinical trial.

In addition, the Company analyzes its inventory levels quarterly and will write down inventory in certain circumstances including where it has a cost basis in excess of its expected net realizable value. If actual market conditions are less favorable than those projected by management, additional inventory write downs may be required. During the fourth quarter of 2003, the Company recorded a net realizable value write down of approximately $269,000 for its ATryn® inventory based upon an analysis of the current selling price of plasma-based antithrombin in principal European markets.

Validation Costs

The Company capitalizes those incremental costs that are incurred in obtaining approval from the FDA or EMEA for manufacturing assets and the related processes for bulk drug production. Under Statement of Financial Accounting Standards ("SFAS") No. 34, "Capitalization of Interest Costs," the historical cost of acquiring an asset includes the costs necessarily incurred to bring it to the condition and location necessary for its intended use. The capitalization period shall begin when expenditures for the asset have been made and activities that are necessary to get the asset ready for its intended use are in progress. Pursuant to regulations of the FDA or the EMEA, a facility and its related manufacturing assets must achieve "process qualification" in order for it to be approved, or "validated," for commercial production. Without approval from the FDA or the EMEA, the facility cannot be placed into service for commercial production; accordingly, the incremental validation costs incurred by the Company are an essential part of preparing the related assets for their intended use. Validation by the EMEA will allow the Company to manufacture products for sale in Europe, which the Company expects to be the initial market for ATryn®.

The costs that the Company has capitalized to date are those costs that are related to FDA or EMEA approval of the manufacturing equipment to be used for the bulk production of ATryn®, which are being depreciated over the expected useful life of the facility. They include the costs of employees and third parties directly involved in the process, direct material consumed in the validation process and incremental fixed overhead. Costs that are excluded from capitalization include maintenance costs, process development/improvement and fixed overhead. As of December 28, 2003 and December 29, 2002, the Company had approximately $4.1 million and $2.5 million of capitalized validation costs included in property, plant and equipment, respectively.

Valuation of Intangible and Long Lived Assets

The Company assesses the impairment of identifiable intangibles and long lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. If certain facts and circumstances were to suggest that the carrying value of intangibles and long lived assets may not be recoverable, it would measure any impairment based on a projected discounted cash flow method using a discount rate determined by the Company's management to be commensurate with the risk inherent in its current business model.

During 2002, upon adopting FAS 142, "Intangible Assets," the Company performed a cash flow analysis on the Company's intangible marketing rights (see Note 7), which resulted in the gross future

cash flows being greater than the carrying value of the marketing rights. Judgments used during this analysis included the estimation of the value of revenues to be achieved in the Asian markets which were covered by the marketing rights for both ATryn® and other products produced transgenically.

There were no events in 2003 that triggered an impairment review.

Results of Operations

As the Company generates net losses, the key drivers for the losses are costs of revenue, research and development, and selling, general and administrative. Revenue from licensing and development agreements with collaborative partners is more than offset by the related costs which has further contributed to the Company's net loss in 2003 and 2002.

Years Ended December 28, 2003 as Compared to Year Ended December 29, 2002

	December 28, 2003	December 29, 2002	$ Change	% Change
		($ in thousands)		
Revenue	$ 9,640	$10,379	$ (739)	(7)%
Revenue from joint venture and related party	$ 124	$ —	$ 124	100 %
Total Revenue	$ 9,764	$10,379	$ (615)	(6)%
Cost of revenue	$11,116	$13,100	$(1,984)	(15)%
Research and development	$18,036	$11,869	$ 6,167	52 %
Selling, general and administrative	$10,929	$11,319	$ (390)	(3)%

Revenue. All of the revenues in 2002, and $6.9 million of the revenues in 2003, were derived from external programs, while $2.9 million of the revenues in 2003 were derived from the malaria program. The reduction in revenue year to year was primarily due to the inclusion in 2002 of revenue from Fresenius AG in funding the rhSA development program prior to the formation of the Taurus Joint Venture with GTC. Exclusive of the rhSA revenue, for comparison purposes, operating revenues would have increased approximately 14% in 2003. Due to the nature and timing of the Company's milestone-based research and development revenues, the Company expects to see variation in reported revenues on a year-to-year basis.

Cost of revenues and research and development expense. Of the 2003 expenses, approximately $8.7 million was incurred to support the completion of the efficacy study and preparation for regulatory filing for approval to market ATryn® in Europe to treat hereditary antithrombin deficiency. This compares with approximately $5.1 million expended in the ATryn® development program in 2002. Additionally, the Company incurred expenses of $2.1 million in the development of the rhSA program and $1.9 million in the development of the Malaria program in 2003. The Company also incurred costs in 2003 on technology improvements and internal product development. Research and development expenses going forward are expected to fluctuate based on a number of factors including the timing and status of clinical development activities for ATryn® and other programs. Research and development expenses are expected to decline in 2004 as compared with 2003, primarily as result of the completion of the ATryn® clinical trial as well as the overall implementation of cost reduction measures. If the FDA approves a trial protocol for ATryn®, the Company's research and development spending may increase versus the current planned expenditures. The decrease in cost of revenue is due to the nature and timing of development activities for the Company's external programs. The level of expenses on the Company's external programs will continue to fluctuate depending upon the stage of development of these individual contracts.

During the third quarter of 2003, the Company implemented a restructuring plan including a headcount reduction of 13%. The Company also renegotiated some research agreements with outside contractors. On an annualized basis, these changes are expected to reduce the Company's expense base by approximately $4 million. The Company believes it is on track to achieve these savings in the first year. Through the end of the fourth quarter of 2003, the Company had reduced the run rate of expenses by approximately 71% of these expected reductions on an annual basis.

Additionally, in February 2004, the Company implemented a further restructuring including a headcount reduction of approximately 20%. This will result in a restructuring charge of approximately $950,000 in the first quarter of 2004, and it is anticipated that on an annual basis these changes will result in further savings of approximately $4 million.

Selling, General and Administrative Expense. The decrease of approximately $390,000 in selling, general and administrative expenses is primarily a result of a reduction of approximately $700,000 in legal expenses in 2003 due to lower external patent costs compared to 2002, which were partially offset by increased expenses related to the acquisition of office and laboratory space of approximately $300,000 for the Company's downstream production capabilities.

Years Ended December 29, 2002 as Compared to Year Ended December 30, 2001

	December 29, 2002	December 30, 2001	$ Change	% Change
		($ in thousands)		
Revenue	$10,379	$12,152	$(1,773)	(15)%
Revenue from joint venture and related party	—	$ 1,588	$(1,588)	(100)%
Total Revenue	$10,379	$13,740	$(3,361)	(24)%
Cost of revenue	$13,100	$15,075	$(1,975)	(13)%
Research and development	$11,869	$ 7,353	$ 4,516	61 %
Selling, general and administrative	$11,319	$11,078	$ 241	2 %
Equity in loss of joint venture	$ —	$ 4,078	$(4,078)	(100)%
Realized gain on sale of CRL stock	$ —	$ 2,320	$(2,320)	(100)%
Gain from sale of discontinued contract research organization	$ —	$ 2,236	$(2,236)	(100)%

Revenue. Included in revenues for 2002 and 2001 were $1.8 million and $4.6 million, respectively, from the rhSA program with Fresenius AG, a $2.8 million decrease year over year. Approximately $4.2 million of the revenue recognized from the Fresenius AG program in 2001 related to payments for marketing rights. Approximately $1.6 million of revenue in 2001 related to the ATIII LLC joint venture. The Company reacquired full ownership of the ATIII LLC from Genzyme in July 2001, and subsequent to this point the Company funded all costs associated with developing ATryn®.

Exclusive of the rhSA and ATIII LLC revenues, for comparison purposes, operating revenues were $8.6 million in 2002 compared with $7.5 million in 2001, an increase of 15%. Due to the nature and timing of the Company's milestone-based research and development revenues, the Company expects to see variation in reported revenues on a year-to-year basis. Under a contract signed in the fourth quarter of 2002 with Merrimack Pharmaceuticals, Inc., the Company deferred the recognition of revenue of approximately $1.6 million in 2002 which was recognized as revenue in 2003.

Cost of Revenue. The decrease in cost of revenue is related to $1.8 million of costs associated with the rhSA program with Fresenius AG in the second half of 2002 being classified as research and development expenses. The costs of the rhSA program were classified as cost of revenue in 2001 when they were funded by Fresenius AG. Also included in the cost of research and development revenue during the first seven months of 2001 were expenses related to ATryn®.

Equity in Loss of Joint Venture. In 2001, the Company recognized $4.1 million of equity in net loss of joint venture incurred on ATIII LLC under the 1997 joint venture between the Company and Genzyme. The Company entered into an Interim Funding agreement with Genzyme in January 2001, under which the Company funded all the losses incurred by the joint venture from February 2001 onwards. Prior to this, the Company only funded 50% of the losses. The Interim agreement ceased in July 2001 when the Company reacquired Genzyme's ownership interest in the ATIII LLC in exchange for a royalty payable to Genzyme based on the Company's future sales, if any, of ATryn®, commencing three years after the first commercial sale up to a cumulative maximum royalty of $30 million. Following the reacquisition, the results of ATIII LLC are consolidated with the Company's results as part of research and development expenses.

Research and Development Expenses. Internal research and development expenditures for the ATryn® program decreased approximately $100,000 while the internal research and development expenditures related to other internal development programs increased by approximately $500,000. Overall, the Company spent $5.1 million in 2002 on the ATryn® program, which was $1.4 million less than the amount that was spent on ATryn® development in 2001 when it was partially funded by Genzyme. Of the $6.4 million of expenses for the ATryn® program in 2001, $4.1 million is included in equity in loss of joint venture and approximately $2.3 million is included in cost of revenue, subsequent to the reacquisition of the ATIII LLC by the Company. The ATryn® program expenses were higher in 2001 due to higher regulatory and manufacturing costs incurred with Genzyme while the ATIII LLC joint venture was in place. The reduction in ATryn® expense in 2002 reflects the revised clinical and regulatory strategy for this product in the hereditary deficiency indication, which the Company is pursuing as the lead indication for this protein.

Selling, General and Administrative Expenses. The increase in selling, general and administrative expenses is primarily due to the acquisition of office and laboratory space to consolidate several functions into a single location, additional development of information technology systems and increased expenses in regulatory affairs and corporate development which was partially offset by a decrease of approximately $400,000 resulting from bad debt recoveries. The 2001 results included a charge of approximately $975,000 related to contractual obligations in connection with the resignation of the Company's former President and Chief Executive Officer.

Realized Gain on Sale of CRL Stock. The realized gain on the sale of securities is a result of the sale, in July 2001, of all of the shares of the Charles River common stock the Company had acquired as part of the consideration received when the Company sold Primedica Corporation, its wholly-owned pre-clinical contract research testing subsidiary, in February 2001.

Gain From Sale of Discontinued Contract Research Organization. The gain from the sale of discontinued contract research operations is a result of the sale, in February 2001, of Primedica to Charles River.

Cost of Revenue and Research and Development Expense

Research and development costs are expensed as incurred. During its fiscal years ended December 28, 2003, December 29, 2002 and December 30, 2001, the Company spent in total, $29.2 million, $25 million and $22.4 million, respectively, on cost of revenue and research and development expense of which $11.1 million, $13.1 million and $15.1 million, respectively, was related to external programs. Of the total spent on research and development, $8.7 million, $5.1 million and $2.3 million, was spent on the ATIII LLC in fiscal years 2003, 2002 and 2001, respectively. These costs include labor, materials, supplies and overhead, as well as certain subcontracted research projects. Also included are the costs of operating the transgenic production facility such as feed and bedding, veterinary costs and utilities (see Table in Item 1).

In aggregate, the total cost incurred since inception on external programs was $53.7 million at December 28, 2003. The aggregate estimated costs to complete the external programs through the development, herd scale up and purification phases is expected to be approximately $2.6 million, with anticipated minimum revenues of $5.1 million excluding success-based milestones. Subsequent to the development phase of the programs, the activities to be performed by the Company, if any, are to be determined by its partners, who are outside of the Company's control and, therefore, the related costs are unknown.

In aggregate, the total cost incurred since inception on internal programs was $83.2 million at December 28, 2003, excluding funding from development partners. The Company cannot estimate the costs to complete these programs due to significant variability in clinical trial costs and regulatory approval processes.

Liquidity and Capital Resources

Overview

The Company's objective is to appropriately finance its business through a mix of equity financings, collaboration and grant revenue, debt financings and interest income earned on its cash and cash equivalents. The Company's ability to raise future funds during the year will be affected by the progress of the regulatory review of ATryn®, the ability of the Company to enter into new transgenic research and development collaborations and the terms of such collaborations, the results of research and development and preclinical and clinical testing of the Company's internal products, competitive and technological advances, and regulatory requirements.

Historically, the Company has used its cash for a mix of activities focused on enhancing product development and program execution, and development and expansion of operational capabilities. In 2003, the Company used its cash primarily for the general operation of GTC's business.

The Company had cash, cash equivalents and marketable securities of $31.1 million at December 28, 2003. This amount includes cash and cash equivalents of $6.7 million. The Company had working capital of $24.2 million at December 28, 2003 compared to $47.7 million at December 29, 2002.

2003 Financing Activities

On August 1, 2003, the Company issued and sold 3,626,465 shares of common stock at $2.55 per share in a private placement to institutional investors. The Company also issued to the investors warrants to purchase an aggregate of 906,613 shares of the Company's common stock at an exercise price of $3.30 per share. Proceeds to the Company, net of offering costs of $700,000, were approximately $8.5 million.

In December 2003, the Company filed a shelf registration statement with the Securities and Exchange Commission which became effective on January 9, 2004. The shelf registration statement allows the Company to offer and sell from time to time, up to an aggregate of $40 million of the Company's common stock. The shelf registration is intended to provide flexibility in financing the Company's business needs including funding for its product development and clinical programs as well as for general corporate purposes. The terms and price of any future offerings would be established at the time of any offering.

Credit Facility

Of the Company's $14.8 million of outstanding long-term debt at December 28, 2003, approximately $2.2 million is classified as current. Approximately $9.4 million was related to a term loan and an equipment line of credit with Silicon Valley Bank, or SVB, with monthly payments through 2008, approximately $600,000 was related to capital leases with monthly payments through 2006 and approximately $4.8 million was related to a promissory note payable to Genzyme with two equal payments of $2.4 million each due April 3, 2005 and April 3, 2006. The Company had approximately $745,000 available at December 28, 2003 under a Committed Equipment Line with SVB and $1 million was currently available under a revolving line of credit with SVB (see Note 8).

Other Sources of Funds

Other sources of funds during 2003 included $2.1 million in proceeds from long-term debt, $6 million in net redemptions of marketable securities in the Company's portfolio and $485,000 from the issuance of common stock under various employee stock plans.

Other Uses of Funds

Uses of funds during the period included $31.8 million used in operations, of which $29.5 million was due to the Company's net loss.

Other uses of funds during the period included:

- $1.4 million for the manufacture of ATryn® inventory for commercial sale upon approval. At this time the Company does not have plans to increase inventory levels during 2004.
- $1.1 million increase in other assets and liabilities as a result of the conversion of $1.25 million of accounts receivable from Merrimack on the MM-093 program into Merrimack preferred stock as part of Merrimack's December 2003 equity financing.
- $2.1 million decrease in accounts payable resulting from the deferral of payments per contractual terms for two vendors in 2002 not repeated in 2003.
- $3.5 million for capital equipment and further expansion of the transgenic production facility, of which $1.5 million was for manufacturing qualification runs for ATryn®, which were required as part of the MAA submission in Europe. The qualification runs are complete and the Company does not expect to manufacture additional ATryn® in 2004. GTC anticipates a significantly lower level of capital expenditures Company wide in 2004 as compared to 2003.
- $2 million was used for the repayment of long-term debt and capital leases.

Management believes that existing cash resources and potential future cash compensation from new partnering and licensing programs will be sufficient to fund operations into 2005. If the Company does not substantially achieve its partnering revenues or out-licensing arrangements, the Company could be forced to delay, scale back or eliminate one or more of its research and development programs. In addition, from time to time, the Company may seek to raise additional funds from public or private sales of its securities, including equity securities. Should the Company seek to raise additional financing in this manner, there can be no assurance that additional funding will be available on terms acceptable to the Company, if at all. The Company cannot use all of its cash to fund operations as a result of a condition in the Additional Modification Agreement with SVB (see Note 8 of the "Notes to the Consolidated Financial Statements"). Under this Agreement, if the Company's cash and marketable securities drop below $18.2 million, the Company is required to provide cash collateral for the outstanding obligation to SVB, which was approximately $9.6 million at December 28, 2003. If the Company is unable to raise additional funds through debt or equity, the Company believes it can reduce spending to allow existing available cash to last through the first quarter of 2005.

Contractual Obligations

The following summarizes the Company's contractual obligations at December 28, 2003, and the effect such obligations are expected to have on its liquidity and cash flow in future periods.

	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	Total
Contractual Obligations:					
Long-term debt obligations	$2,021	$8,815	$3,317	$ —	$14,153
Capital lease obligations	197	410	—	—	607
Operating lease obligations	631	695	5	—	1,331
Service and sublease agreement with Genzyme	369	—	—	—	369
Total contractual cash obligations	$3,218	$9,920	$3,322	$ —	$16,460

The Company is party to license agreements for certain technologies (see Note 14 of the "Notes to the Consolidated Financial Statements"). In July 2001, the Company reacquired Genzyme's ownership interest in the ATIII LLC joint venture in exchange for a royalty to Genzyme based on the Company's sales of ATryn®, if any, commencing three years after the first commercial sale, up to a cumulative maximum of $30 million. Certain of these other agreements contain provisions for future royalties to be paid on commercial sales of products developed from the licensed technologies. Currently, the amounts payable under these other agreements and any resulting commitments on the Company's behalf are unknown and are not able to be estimated since the level of future sales, if any, is uncertain. Accordingly, they are not included in the preceding table.

In January 2004, the Company entered into a Loan Modification Agreement with SVB. This Modification Agreement reduced from $25 million to $18.2 million the amount the Company must maintain as unrestricted cash and marketable securities before the Company is required to provide cash collateral for the outstanding obligation to SVB, which was approximately $9.6 million at December 28, 2003. The Company has never paid a cash dividend on its Common Stock and currently expects that future earnings will be retained for use in its business.

The Company has entered into transactions with related parties (see Note 16 of the "Notes to Consolidated Financial Statements") in the normal course of business. The terms of these transactions are considered to be at arms-length.

New Accounting Pronouncements

In January 2003, the FASB issued FASB Interpretation No. 46 or FIN 46, "Consolidation of Variable Interest Entities," to expand upon and strengthen existing accounting guidance that addresses when a company should include in its financial statements the assets, liabilities and activities of another entity. Until now, one company generally has included another entity in its consolidated financial statements only if it controlled the entity through voting interests. FIN 46 changes that by requiring a variable interest entity (VIE), as defined, to be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity's activities or entitled to receive a majority of the entity's residual returns or both. FIN 46 also requires disclosures about variable interest entities that the company is not required to consolidate but in which it has a significant variable interest. In December 2003, the FASB released a revised version of FIN 46 (hereafter referred to as FIN 46R) clarifying certain aspects of FIN 46 and providing certain entities with exemptions from the requirements of FIN 46. The variable interest model of FIN 46R was only slightly modified from that

contained in FIN 46. A VIE would be required to be consolidated if either of the following conditions are met:

1. The total equity investment at risk is not sufficient to permit the entity to finance its activities without additional subordinated financial support provided by any parties, including equity holders.
2. The equity investors lack any one of the following three characteristics of a controlling interest:
   - The direct or indirect ability through voting rights or similar rights to make decisions about an entity's activities that have a significant effect on the success of the entity.
   - The obligation to absorb the expected losses of the entity.
   - The right to receive the expected residual returns of the entity.

FIN 46R requires the application of either FIN 46 or FIN 46R by public entities to all Special Purpose Entities ("SPEs") created prior to February 1, 2003 at the end of the first interim or annual reporting period ending after December 15, 2003. All entities created after January 31, 2003 by Public Entities were already required to be analyzed under FIN 46, and they must continue to do so, unless FIN 46R is adopted early. FIN 46R will be applicable to all non-SPEs created prior to February 1, 2003 by Public Entities that are not small business issuers at the end of the first interim or annual reporting period ending after March 15, 2004. The Company does not expect the provisions of FIN 46 to have a material effect on its results of operations and financial position.

In December 2003, the SEC released Staff Accounting Bulletin No. 104 (SAB 104) entitled, "Revenue Recognition." SAB 104 updates portions of the interpretative guidance included in Topic 13 of the codification of staff accounting bulletins in order to make this interpretive guidance consistent with current authoritative accounting guidance. The principal revisions relate to the deletion of interpretive material no longer necessary because of private sector developments in U.S. generally accepted accounting principles, and the incorporation of certain sections of the staff's "Revenue Recognition in Financial Statements Frequently Asked Questions and Answers" document into Topic 13.

Factors Affecting Future Operations and Results

This Annual Report on Form 10-K contains forward-looking statements, including statements regarding GTC's future revenues, research and development programs, clinical trials and collaborations and the Company's future cash requirements. The words or phrases "will likely result," "are expected to," "will continue," "is anticipated," "estimate," "project," or similar expressions are intended to identify "forward-looking statements" within the meaning of Section 21E of the Exchange Act and Section 27A of the Securities Act of 1933, as amended, as enacted by the Private Securities Litigation Reform Act of 1995. Statements that are not historical facts are based on its current expectations, beliefs, assumptions, estimates, forecasts and projections for GTC's business and the industry and markets related to its business. The statements contained in this report are not guarantees of future performance and involve certain risks, uncertainties and assumptions which are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed in such forward-looking statements. Important factors which may affect future revenues, research and development programs, clinical trials and collaborations and the Company's future cash requirements include, without limitation, regulatory review of the Company's ATryn® product, the ability of the Company to enter into transgenic research and development collaborations in the future and the terms of such collaborations, the results of research and development and preclinical and clinical testing of the Company's internal product, competitive and technological advances and regulatory requirements, and those set forth in Exhibit 99 "Important Factors Regarding Forward-Looking Statements" to this Form 10-K, which is incorporated into this item by this reference.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company has certain financial instruments at December 28, 2003, including a term loan, an equipment line of credit, a revolving line of credit to cover small needs such as letters of credit, a promissory note payable and a standby letter of credit which are sensitive to changes in interest rates. The Company's term loan with a commercial bank has a carrying value of $6.6 million which approximates its fair value. The Company's $6.3 million equipment line of credit with a commercial bank accrues interest at the prime rate. The Company's standby letter of credit of $249,360 is required under a facility lease. The Company's promissory note in the amount of $4.8 million is payable to Genzyme. At December 28, 2003, $5.5 million is outstanding under the equipment line of credit and nothing has been drawn down on the revolving line of credit or standby letter of credit. These instruments are not leveraged and are held for purposes other than trading.

For the term loan, equipment line and promissory note outstanding, the table below presents the principal cash payments that exist by maturity date.

	2004	2005	2006	2007	2008	Thereafter	Total
				($ in 000's)			
Term Loan	$1,320	$1,320	$1,320	$ 330	—	$ —	$ 4,290
Equipment Line	701	701	701	701	2,286	—	5,090
Promissory Note Payable	—	2,386	2,387	—	—	—	4,773
Total	$2,021	$4,407	$4,408	$1,031	$2,286	$ —	$14,153

The interest rates on the term loan, equipment line and promissory note payable were 4%, 4% and 2.17% respectively, at December 28, 2003.

Interest Rate Risk

The Company does not engage in trading market risk sensitive instruments or purchasing hedging instruments or "other than trading" instruments that are likely to expose the Company to market risk, whether interest rate, foreign currency exchange, commodity price or equity price risk. The Company has not purchased options or entered into swaps, or forward or future contracts. The Company's primary market risk is interest rate risk on borrowings under its commercial bank loan, these interest rates are based on the prime rate. The aggregate hypothetical loss in earnings for one year on the borrowing held by the Company at December 28, 2003, assuming a hypothetical 6% percent interest rate is approximately $849,000 after tax. The hypothetical loss was based on financial instruments held by the Company at December 28, 2003. Fixed rate financial instruments were not evaluated.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTAL SCHEDULES

Financial Statements

Response to this item is submitted as a separate section of this report immediately following Item 15.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures.

The Company's management, with the participation of its principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of its disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, the "Exchange Act") as of December 28, 2003. Based on this evaluation, the principal executive officer and the principal financial officer concluded that the Company's disclosure controls and procedures were effective and designed to ensure that the information required to be disclosed in the reports filed or submitted by it under the Exchange Act is recorded, processed, summarized and reported within the requisite time periods.

(b) Changes in Internal Control over Financial Reporting.

There was not change in the Company's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act of 1934, as amended) identified in connection with the evaluation of the Company's internal control that occurred during its last fiscal quarter that has materially affected, or is reasonably likely to materially affect, its internal control over financial reporting.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The requisite information regarding the Company's directors, executive officers and audit committee members is contained in part under the caption "Executive Officers of the Registrant" in Part I, Item 1A hereof and the remainder is incorporated by reference from the discussion responsive thereto under the captions "Election of Directors" and "Section 16(a) Beneficial Ownership Reporting and Compliance" in the Company's Proxy Statement for the 2004 Annual Meeting of Stockholders to be held on May 26, 2004 (the "Proxy Statement"). The Company has adopted a Code of Business Conduct and Ethics that applies to its chief executive officer, chief financial officer, and controllers. A copy of this Code of Business Conduct and Ethics is available without charge upon request from the Chief Financial Officer at GTC Biotherapeutics, Inc., 175 Crossing Boulevard, Framingham, MA 01702. If the Company makes any substantive amendments to this Code of Business Conduct and Ethics or grants any waiver from a provision of it, the Company will disclose the nature of such amendment or waiver on its website at www.gtc-bio.com or in a Current Report on Form 8-K.

ITEM 11. EXECUTIVE COMPENSATION

The information set forth under the captions "Compensation and Other Information Concerning Directors and Officers" in the 2004 Proxy Statement is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information set forth under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance Under Equity Compensation Plans" in the 2004 Proxy Statement is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information set forth under the caption "Transactions with Related Parties" in the 2004 Proxy Statement is incorporated herein by reference. See also Notes 9 and 14 to the Consolidated Financial Statements included herewith.

ITEM 14.

This information set forth under the caption "Auditors" in the 2004 Proxy Statement is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULE AND REPORTS ON FORM 8-K

(a)(1)(2) Financial Statements and Financial Statement Schedule.

All other schedules have been omitted because the required information is not applicable or not present in amounts sufficient to required submission of the schedule, or because the information required is in the consolidated financial statements or the notes thereto.

(3) Exhibits

Exhibit No.	Description
3.1.1	Restated Articles of Organization of GTC, filed with the Secretary of the Commonwealth of Massachusetts on December 27, 1993. Filed as Exhibit 3.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 1993 (File No. 0-21794) and incorporated herein by reference.
3.1.2	Articles of Amendment to the Restated Articles of Organization filed with the Secretary of the Commonwealth of Massachusetts on October 3, 1994. Filed as Exhibit 3.1.2 to GTC's Annual Report on Form 10-K for the year ended December 28, 1997 (File No. 0-21794) and incorporated herein by reference.
3.1.3	Articles of Amendment to the Restated Articles of Organization filed with the Secretary of Commonwealth of Massachusetts on June 26, 1997. Filed as Exhibit 3 to GTC's Quarterly Report on Form 10-Q for the quarter ended June 29, 1997 (File No. 0-21794) and incorporated herein by reference.
3.1.4	Articles of Amendment to the Restated Articles of Organization of the Company filed with the Secretary of the Commonwealth of Massachusetts on June 1, 2000. Filed as Exhibit 4.1.5 to the Company's Registration Statement on Form S-8 filed with the Commission on June 2, 2000 (File No. 333-38490) and incorporated herein by reference.
3.1.5	Certificate of Vote of Directors Establishing a Series of a Class of Stock of GTC and designating the Series C Junior Participating Cumulative Preferred Stock. Filed as Exhibit 3.1 to GTC's Current Report on Form 8-K filed on June 1, 2001 (File No. 0-21794) and incorporated herein by reference.

Exhibit No.	Description
3.1.6	Articles of Amendment to the Restated Articles of Organization of the Company filed with the Secretary of the Commonwealth of Massachusetts on May 31, 2002. Filed as Exhibit 3.1 to the GTC's Current Report on Form 8-K filed on June 3, 2002 (File No. 0-21794) and incorporated herein by reference.
3.2	By-Laws of the Company, as amended. Filed as Exhibit 3.1 to the Company's Form 10-Q for the quarter ended July 4, 1999 (File No. 0-21794) and incorporated herein by reference.
4.1	Specimen Common Stock Certificate. Filed as Exhibit 4.1 to GTC's Registration Statement on Form S-1 (File No. 33-62782) (the "GTC S-1") and incorporated herein by reference.
4.2	Warrant to Purchase Common Stock, dated July 3, 1995, issued to Genzyme Corporation ("Genzyme"). Filed as Exhibit 10.5 to GTC's Quarterly Report on Form 10-Q for the period ended July 2, 1995 (File No. 0-21794) and incorporated herein by reference.
4.3	Warrant to Purchase Common Stock, dated as of June 26, 1997, issued to Government Land Bank d/b/a The MassDevelopment. Filed as Exhibit 4 to GTC's Quarterly Report on Form 10-Q for the period ended June 29, 1997 (File No. 0-21794) and incorporated herein by reference.
4.4	Warrant to Purchase Common Stock, dated as of December 28, 1998, issued to Genzyme. Filed as Exhibit 4.11 to GTC's Annual Report on Form 10-K for the year ended January 3, 1999 (File No. 0-21794) and incorporated herein by reference.
4.5	Warrant to Purchase Common Stock, dated November 12, 1999, issued to Genzyme. Filed as Exhibit 8 to Genzyme's Amendment No. 6 to Schedule 13D (File No. 005-46637) filed with the Commission on November 24, 1999 and incorporated herein by reference.
4.6	Warrant to Purchase Common Stock, dated November 12, 1999, issued to Genzyme. Filed as Exhibit 9 to Genzyme's Amendment No. 6 to Schedule 13D (File No. 005-46637) filed with the Commission on November 24, 1999 and incorporated herein by reference.
4.7	Form of Common Stock Purchase Warrant. Filed as Exhibit 10.2 to GTC's Current Report on Form 8-K filed on August 4, 2003 (File No. 0-21794) and incorporated herein by reference.
4.8	Registration Rights Agreement between GTC and certain Stockholders named therein. Filed as Exhibit 10.53 to GTC's Annual Report on Form 10-K for the year ended December 28, 1997 (File No. 0-21794) and incorporated herein by reference.
4.9	Shareholder Rights Agreement, dated as of May 31, 2001, between GTC and American Stock Transfer and Trust Company, as Rights Agent. Filed as Exhibit 4.1 to GTC's Current Report on Form 8-K filed on June 1, 2001 (File No. 0-21794) and incorporated herein by reference.
4.10	Registration Rights Agreement, dated as of July 30, 2003, between GTC and the Purchasers named therein. Filed as Exhibit 10.3 to GTC's Current Report on Form 8-K filed on August 4, 2003 (File No. 0-21794) and incorporated herein by reference.
10.1*	Technology Transfer Agreement between GTC and Genzyme, dated as of May 1, 1993. Filed as Exhibit 2.1 to the GTC S-1 and incorporated herein by reference.
10.2	Research and Development Agreement between GTC and Genzyme, dated as of May 1, 1993. Filed as Exhibit 10.1 to the GTC S-1 and incorporated herein by reference.
10.3	Services Agreement between GTC and Genzyme, dated as of May 1, 1993. Filed as Exhibit 10.2 to the GTC S-1 and incorporated herein by reference.

Exhibit No.	Description
10.4	Sublease Agreement between GTC and Genzyme, dated as of May 1, 1993. Filed as Exhibit 10.3 to the GTC S-1 and incorporated herein by reference.
10.5	License Agreement between GTC and Genzyme, as successor to IG Laboratories, Inc., dated as of May 1, 1993. Filed as Exhibit 10.4 to the GTC S-1 and incorporated herein by reference.
10.6.1*	Cooperation and Licensing Agreement between GTC and Tufts University, dated September 6, 1988, as amended through May 13, 1993 (the "Cooperation and Licensing Agreement"). Filed as Exhibit 10.18 to GTC's Annual Report on Form 10-K for the year ended December 31, 1994 (File No. 0-21794) and incorporated herein by reference.
10.6.2	Amendment No. 7, dated April 1, 1993, to Cooperation and Licensing Agreement. Filed as Exhibit 10.6 to GTC's Quarterly Report on Form 10-Q for the period ended October 1, 1995 (File No. 0-21794) (the "GTC October 1995 10-Q") and incorporated herein by reference.
10.6.3	Amendment No. 8, dated October 21, 1993, to Cooperation and Licensing Agreement. Filed as Exhibit 10.7 to the GTC October 1995 10-Q and incorporated herein by reference.
10.6.4*	Amendment No. 9, dated December 1, 1993, to Cooperation and Licensing Agreement. Filed as Exhibit 10.8 to the GTC October 1995 10-Q and incorporated herein by reference.
10.6.5	Amendment No. 10, dated November 1, 1993, to Cooperation and Licensing Agreement. Filed as Exhibit 10.9 to the GTC October 1995 10-Q and incorporated herein by reference.
10.6.6	Amendment No. 11, dated May 25, 1995, to Cooperation and Licensing Agreement. Filed as Exhibit 10.10 to the GTC October 1995 10-Q and incorporated herein by reference.
10.6.7*	Amendment No. 14, effective as of September 6, 1997, to Cooperation and Licensing Agreement. Filed as Exhibit 10.6.7 to GTC's Annual Report on Form 10-K for the year ended December 29, 2002 (File No. 0-21794) (the "GTC 2002 10-K") and incorporated herein by reference.
10.6.8*	Amendment No. 16, effective as of September 6, 2000, to Cooperation and Licensing Agreement. Filed as Exhibit 10.6.8 to the GTC 2002 10-K and incorporated herein by reference.
10.6.9*	Amendment No. 18, effective as of September 6, 2001, to Cooperation and Licensing Agreement. Filed as Exhibit 10.6.9 to the GTC 2002 10-K and incorporated herein by reference.
10.7*	United States Patent No. 4,873,191 Sublicense Agreement between Xenogen Corporation (formerly DNX, Inc.) and Genzyme Regarding Transgenic Experimental Animals and Transgenic Mammary Production Systems, dated February 1, 1990; and letter of amendment, dated April 19, 1991. Filed together as Exhibit 10.3 to GTC's Amended Quarterly Report on Form 10-Q for the period ended June 29, 2003 (File No. 0-21794) (the "GTC 2003 June 10-Q/A") and incorporated herein by reference.
10.8	Lease dated March 26, 1999 between GTC and NDNE 9/90 Corporate Center LLC. Filed as Exhibit 10.1 to the GTC July 1999 10-Q and incorporated herein by reference.
10.9	Hazardous Materials Indemnity Agreement, December 28, 1998, between the GTC and Genzyme. Filed as Exhibit 10.28.5 to GTC's Annual Report on Form 10-K for the year ended January 2, 2000 and incorporated herein by reference.

Exhibit No.	Description
10.10*	License Agreement by and among GTC, Pharming Group N.V. and Pharming Intellectual Property B.V., dated June 21, 2002. Filed as Exhibit 10.3.1 to the GTC's Quarterly Report on Form 10-Q for the period ended June 30, 2002 (File No. 0-21794) filed on August 2, 2002 (the "GTC June 2002 10-Q") and incorporated herein by reference.
10.11*	Amended and Restated License Agreement by and among Pharming Group, N.V. and Pharming Intellectual Property B.V. and the Company dated June 21, 2002. Filed as Exhibit 10.3.2 to the GTC June 2002 10-Q and incorporated herein by reference.
10.12*	Exclusive Development and License Agreement, dated as of June 8, 1999, between GTC and Advanced Cell Technology, Inc. Filed as Exhibit 10.21 to GTC's Annual Report on Form 10-K for the year ended December 30, 2001 (File No. 0-21794) and incorporated herein by reference.
10.13.1*	Purchase Agreement between GTC and Genzyme, dated as of July 31, 2001. Filed as Exhibit 10.1 to GTC's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001 (File No. 0-21794) (the "GTC September 2001 10-Q") and incorporated herein by reference.
10.13.2*	Services Agreement between GTC and Genzyme, dated as of July 31, 2001. Filed as Exhibit 10.2 to the GTC September 2001 10-Q and incorporated herein by reference.
10.13.3	Collaboration Agreement among GTC, Genzyme Corporation, and ATIII LLC dated as of January 1, 1998. Filed as Exhibit 10.2 to the GTC 2003 10-Q/A and incorporated herein by reference.
10.13.4	Amended and Restated Collaboration Agreement among GTC, Genzyme and ATIII LLC, dated as of July 31, 2001. Filed as Exhibit 10.2 to the GTC September 2001 10-Q and incorporated herein by reference.
10.14	Letter Agreement by and between GTC and Genzyme, dated as of April 4, 2002. Filed as Exhibit 10.4 to the GTC's Quarterly Report on Form 10-Q for the period ended March 31, 2002 (File No. 0-21794) filed on May 1, 2002 (the "GTC March 2002 10-Q") and incorporated herein by reference.
10.15	Subordinated Secured Promissory Note in the amount of $4,772,850 executed by GTC made to Genzyme, dated as of April 4, 2002. Filed as Exhibit 10.5 to the GTC March 2002 10-Q and incorporated herein by reference.
10.16.1*	Loan and Security Agreement by and between GTC and Silicon Valley Bank, dated as of March 27, 2002. Filed as Exhibit 10.1 to the GTC March 2002 10-Q and incorporated herein by reference.
10.16.2	Pledge Agreement by and between GTC and Silicon Valley Bank, dated as of March 27, 2002. Filed as Exhibit 10.2 to the GTC March 2002 10-Q and incorporated herein by reference.
10.16.3	Negative Pledge Agreement by and between GTC and Silicon Valley Bank, dated as of March 27, 2002. Filed as Exhibit 10.3 to the GTC March 2002 10-Q and incorporated herein by reference.
10.16.4	Loan Modification Agreement between GTC and SVB dated as of January 25, 2004. Filed herewith.

Exhibit No.	Description
10.17*	Sublease Agreement by and between the Company and Antigenics, Inc., dated July 16, 2002. Filed as Exhibit 10.4 to the GTC June 2002 10-Q and incorporated herein by reference.
10.18*	Limited Liability Company Agreement of Taurus hSA LLC dated as of December 20, 2002. Filed as Exhibit 10.20.1 to GTC's 2002 10-K and incorporated herein by reference.
10.19*	Contribution and License Agreement by and between GTC and Taurus hSA LLC dated as of December 20, 2002. Filed as Exhibit 10.20.2 to GTC's 2002 10-K and incorporated herein by reference.
10.20*	Service Agreement by and between GTC and Cambrex Bio Science MA, Inc. dated as of August 20, 2002. Filed as Exhibit 10.21 to GTC's 2002 10-K and incorporated herein by reference.
10.21.1*	Agreement Relating to the Production of Clarified Goat Milk Containing Recombinant Human Alpha Fetoprotein by and between GTC and Merrimack Pharmaceuticals, Inc., dated as of June 27, 2003 (the "Merrimack Agreement"). Filed as exhibit 10 to GTC's 2003 June Form 10-Q/A and incorporated herein by reference.
10.21.2	First Amendment, dated as of December 11, 2003, to the Merrimack Agreement. Filed herewith.
10.22.1**	GTC Amended and Restated 1993 Equity Incentive Plan. Filed as Exhibit 10.7 to GTC's Annual Report on Form 10-K for the year ended December 30, 2001 (File No. 0-21794) and incorporated herein by reference.
10.22.2**	GTC 2002 Equity Incentive Plan. Filed as Exhibit 10.6 to GTC's Amended Quarterly Report on Form 10-Q for the period ended March 31, 2002 (File No. 0-21794) and incorporated herein by reference.
10.23**	GTC 2002 Employee Stock Purchase Plan. Filed as Exhibit 10.7 to the GTC March 2002 10-Q and incorporated herein by reference.
10.24	GTC Form of Confidential and Proprietary Information Agreement signed by GTC employees. Filed as Exhibit 10.9 to the GTC S-1 and incorporated herein by reference.
10.25	GTC Form of Agreement Not to Compete. Filed as Exhibit 10.10 to the GTC S-1 and incorporated herein by reference.
10.26	Form of Indemnification Agreement between GTC and its directors. Filed as Exhibit 10.12 to GTC's Annual Report on Form 10-K for the year ended December 31, 1994 (File No. 0-21794) and incorporated herein by reference. Such agreements are materially different only as to the signing directors and the dates of execution.
10.27**	Employment Agreement, dated as of March 27, 1996, between GTC and Harry Meade. Filed as Exhibit 10.44 to GTC's Quarterly Report on Form 10-Q for the period ended March 31, 1996 and incorporated herein by reference.
10.28.1**	Amended and Restated Employment Agreement, dated as of August 28, 1997, between GTC and John B. Green. Filed as Exhibit 10.2 to the GTC September 1997 10-Q and incorporated herein by reference.
10.28.2**	Amendment No. 1 to Employment Agreement between GTC and John B. Green. Filed as Exhibit 10.3 to GTC's Quarterly Report for the period ended September 27, 1998 (File No. 0-21794) and incorporated herein by reference.

Exhibit No.	Description
10.29**	Executive Employment Agreement, dated as of July 18, 2001, between GTC and Geoffrey F. Cox. Filed as Exhibit 10.2 to the GTC September 2001 10-Q and incorporated herein by reference.
10.30**	Executive Employment Agreement, dated as of February 9, 2002 between GTC and Paul K. Horan. Filed as Exhibit 10.30 to GTC's 2002 10-K and incorporated herein by reference.
10.31**	Management Agreement between GTC and Daniel Woloshen dated as of May 27, 1999. Filed as Exhibit 10.1 to GTC's Quarterly Report on Form 10-Q for the period ended March 30, 2003 (File No. 0-21794) (the "GTC March 2003 10-Q") and incorporated herein by reference.
10.32**	Management Agreement between GTC and Gregory Liposky dated as of June 14, 2000. Filed as Exhibit 10.2 to the GTC March 2003 10-Q and incorporated herein by reference.
21	List of Subsidiaries. Filed herewith.
23	Consent of PricewaterhouseCoopers LLP. Filed herewith.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith.
32	Certifications pursuant to 18 U.S.C. Section 1350. Filed herewith.
99	Important Factors Regarding Forward-Looking Statements. Filed herewith.

* Certain confidential information contained in the document has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended, or Rule 24b-2 promulgated under the Securities and Exchange Act of 1934, as amended.

** Indicates a management contract or compensatory plan.

(b) Reports on Form 8-K

On November 12, 2003, the Company filed with the SEC a Current Report on Form 8-K (Items 9 and 12) reporting the Company's financial results for the third quarter of 2003.*

* Information furnished under Item 9 or Item 12 of Form 8-K is not incorporated by reference, is not deemed filed and is not subject to liability under Section 11 of the Securities Act of 1933 or Section 18 of the Securities Exchange Act of 1934.

Report of Independent Auditors

To the Board of Directors and Shareholders of GTC Biotherapeutics, Inc.:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations and comprehensive loss, of shareholders' equity and of cash flows present fairly, in all material respects, the financial position of GTC Biotherapeutics, Inc. and its subsidiaries at December 28, 2003 and December 29, 2002, and the results of their operations and their cash flows for each of the three years in the period ended December 28, 2003 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which 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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

PricewaterhouseCoopers LLP
Boston, Massachusetts
March 4, 2004

GTC BIOTHERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

(Dollars in thousands except share amounts)

	December 28, 2003	December 29, 2002
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,733	$ 26,911
Marketable securities	24,358	30,438
Accounts receivable and unbilled contract revenue	1,613	2,179
Other current assets	1,777	1,932
Total current assets	34,481	61,460
Net property, plant, and equipment	22,600	21,701
Net intangible assets	11,094	12,128
Inventory	1,574	—
Other assets	1,323	84
Total assets	$ 71,072	$ 95,373
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,340	$ 4,448
Accounts payable—Genzyme	1,924	2,370
Accrued liabilities	3,524	4,442
Deferred contract revenue	323	638
Current portion of long-term debt and capital leases	2,218	1,880
Total current liabilities	10,329	13,778
Long-term debt and capital leases, net of current portion	7,769	8,013
Note payable—Genzyme	4,773	4,773
Deferred lease obligation	40	37
Total liabilities	22,911	26,601
Commitments and contingencies (see Note 6)		
Shareholders' equity:		
Preferred stock, $.01 par value; 5,000,000 shares authorized; no shares were issued and outstanding	—	—
Common stock, $.01 par value; 100,000,000 shares authorized; 34,749,473 and 30,579,064 shares issued and 31,929,473 and 27,759,064 shares outstanding at December 28, 2003 and December 29, 2002, respectively	347	306
Additional paid-in capital	207,535	198,469
Treasury stock, at cost, 2,820,000 shares	(9,545)	(9,545)
Accumulated deficit	(150,179)	(120,642)
Accumulated other comprehensive income	3	184
Total shareholders' equity	48,161	68,772
Total liabilities and shareholders' equity	$ 71,072	$ 95,373

The accompanying notes are an integral part of the consolidated financial statements.

GTC BIOTHERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Dollars in thousands except share and per share amounts)

	For the Fiscal Years Ended		
	December 28, 2003	December 29, 2002	December 30, 2001
Revenues:			
Revenue	$ 9,640	$ 10,379	$ 12,152
Revenue from joint venture and related party	124	—	1,588
	9,764	10,379	13,740
Costs of revenue and operating expenses:			
Cost of revenue	11,116	13,100	15,075
Research and development	18,036	11,869	7,353
Selling, general and administrative	10,929	11,319	11,078
Equity in loss of joint venture	—	—	4,078
	40,081	36,288	37,584
Operating loss from continuing operations	(30,317)	(25,909)	(23,844)
Other income (expense):			
Interest income	1,103	2,028	3,478
Interest expense	(508)	(439)	(746)
Realized gain on sale of CRL stock	—	—	2,320
Other income	185	—	—
Loss from continuing operations	(29,537)	(24,320)	(18,792)
Discontinued operations			
Gain from sale of discontinued contract research operations	—	—	2,236
Net loss	$ (29,537)	$ (24,320)	$ (16,556)
Net loss per common share (basic and diluted):			
From continuing operations	$ (1.00)	$ (0.86)	$ (0.63)
From discontinued contract research operations	$ —	$ —	$ 0.08
Net loss	$ (1.00)	$ (0.86)	$ (0.55)
Weighted average number of common shares outstanding (basic and diluted)	29,562,152	28,353,490	29,975,167
Comprehensive loss:			
Net loss	$ (29,537)	$ (24,320)	$ (16,556)
Other comprehensive income (loss):			
Unrealized holding gains (loss) on available for sale securities	(181)	(44)	171
Total other comprehensive income (loss)	(181)	(44)	171
Comprehensive loss	$ (29,718)	$ (24,364)	$ (16,385)

The accompanying notes are an integral part of the consolidated financial statements.

GTC BIOTHERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

(In Thousands)

	Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Shareholders' Equity
	Shares	Amount	Shares	Amount				
Balance, December 31, 2000	29,697	$297	—	$ —	$194,255	$ (79,766)	$ 57	$ 114,843
Net loss						(16,556)		(16,556)
Common stock sold under Employee Stock Purchase Plan	102				424			424
Common stock issuance to the GTC Savings and Retirement Plan	50	1			724			725
Proceeds from the exercise of stock options	351	4			1,984			1,988
Stock based compensation					355			355
Unrealized gain on investment							171	171
Balance, December 30, 2001	30,200	302	—	—	197,742	(96,322)	228	101,950
Net loss						(24,320)		(24,320)
Common stock sold under Employee Stock Purchase Plan	337	4			450			454
Common stock issuance to the GTC Savings and Retirement Plan	41				234			234
Proceeds from the exercise of stock options	1				3			3
Acquisition of treasury stock from Genzyme			(2,820)	(9,545)				(9,545)
Stock based compensation					40			40
Unrealized loss on investment							(44)	(44)
Balance, December 29, 2002	30,579	306	(2,820)	(9,545)	198,469	(120,642)	184	68,772
Net loss						(29,537)		(29,537)
Common stock sold under Employee Stock Purchase Plan	382	3			472			475
Common stock issuance to the GTC Savings and Retirement Plan	155	2			170			172
Proceeds from the exercise of stock options	7				10			10
Proceeds from the issuance of common stock, net of offering costs	3,626	36			8,414			8,450
Unrealized loss on investment							(181)	(181)
Balance, December 28, 2003	34,749	$347	(2,820)	$(9,545)	$207,535	$(150,179)	$ 3	$ 48,161

The accompanying notes are an integral part of the consolidated financial statements.

GTC BIOTHERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Dollars in thousands)

	For the Fiscal Years Ended		
	December 28, 2003	December 29, 2002	December 30, 2001
Cash flows for operating activities:			
Net loss from continuing operations	$(29,537)	$(24,320)	$(18,792)
Adjustments to reconcile net loss from continuing operations to net cash used in operating activities:			
Depreciation and amortization	3,476	2,416	2,614
Stock based compensation	—	40	355
Non cash interest income (loss) from marketable securities	(135)	759	305
Common stock issuance to GTC savings and retirement plan	172	234	725
Equity in loss of joint venture	—		4,078
Realized gain on sale of CRL stock	—	—	(2,320)
Loss on disposal of fixed assets	—	140	—
Recovery of provision for doubtful accounts	—	(361)	—
Changes in assets and liabilities:			
Inventory	(1,445)	—	—
Accounts receivable and unbilled contract revenue	566	44	891
Other assets and liabilities	(1,081)	(1,452)	236
Accounts payable	(2,108)	2,525	850
Accounts payable—Genzyme Corporation	(446)	518	508
Payable to ATIII LLC	—	—	(1,096)
Other accrued expenses	(918)	(636)	564
Deferred contract revenue	(315)	(2,982)	(902)
Net cash used in operating activities	(31,771)	(23,075)	(11,984)
Cash flows for investing activities:			
Purchase of property, plant and equipment	(3,470)	(6,498)	(3,438)
Intangible assets	—	(1,517)	—
Investment in joint venture	—	—	(4,077)
Purchase of marketable securities	(23,968)	(52,644)	(83,593)
Redemption of marketable securities	30,002	85,001	45,267
Proceeds from the sale of CRL stock	—	—	18,192
Net cash provided by (used in) investing activities	2,564	24,342	(27,649)
Cash flows from financing activities:			
Net proceeds from private placement of common stock	8,450	—	—
Net proceeds from the sale of discontinued operations (net of $2,124 expenses)	—	—	23,876
Net proceeds from employee stock purchase plan	475	454	424
Net proceeds from the exercise of stock options	10	3	1,988
Proceeds from long-term debt	2,090	10,015	—
Acquisition of treasury stock from Genzyme	—	(4,773)	—
Repayment of long-term debt	(1,735)	(6,725)	(974)
Repayment of principal on capital leases	(261)	(180)	—
Net cash provided by (used in) financing activities	9,029	(1,206)	25,314
Net cash (used) provided by discontinued operations	—	—	145
Net increase (decrease) in cash and cash equivalents	(20,178)	61	(14,174)
Cash and cash equivalents at beginning of the period	26,911	26,850	41,024
Cash and cash equivalents at end of the period	$ 6,733	$ 26,911	$ 26,850
Supplemental disclosure of cash flow information: *			
Cash paid during the period for interest	$ 512	$ 423	$ 349

* See Note 4 for supplemental disclosures of non-cash transactions.

The accompanying notes are an integral part of the consolidated financial statements.

Fiscal years ended December 28, 2003, December 29, 2002 and December 30, 2001 (all tabular $ in thousands, except per share data).

NOTE 1. NATURE OF BUSINESS

GTC Biotherapeutics, Inc., referred to as GTC or the Company, is a leader in the development, production, and commercialization of human therapeutic proteins in the milk of animals, principally goats and cattle. Using a technology known as transgenics, GTC inserts protein-specific DNA into the animal to enable it to produce that specific protein in its milk. The protein is then purified from the milk under pharmaceutical manufacturing conditions to obtain the therapeutic product, which is typically administered by injection.

GTC is dependent upon funding from partnering programs, equity financings and proceeds from short and long term debt to finance operations. The Company enters into licensing and development agreements with collaborative partners for the development, production and purification of transgenic versions of therapeutic recombinant proteins. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon the achievement of certain milestones and royalties on future product sales, if any.

The Company has three internal programs in active development. These are the recombinant human antithrombin program, which will be sold under the brand name ATryn® once regulatory approval is obtained, the recombinant human serum albumin program, known as rhSA, and a malaria vaccine program using one of the malaria parasites surface proteins known as MSP-1 as an antigen. All of these programs involve products that are difficult-to-express proteins. The ATryn® and rhSA proteins are also required in large volumes. The ATryn® program has the potential to generate commercial product revenues in the next two to three years The Company seeks partners for its internal programs to provide a source of funding for these programs as well as to augment its clinical and marketing expertise.

GTC's external programs use the Company's intellectual property and technology platform to develop transgenic production of a partner's proprietary protein. External programs generate current revenue through research funding and achievement of milestones. These programs provide GTC the opportunity for long-term product revenues as a result of GTC serving as the clinical and commercial manufacturing partner for the program product. This business has the potential to generate positive cash flow and eventually profits, helping support the continued development of the Company's internal programs and technology platform.

In GTC's portfolio of external programs, the most advanced is the program with Merrimack Pharmaceuticals, Inc. for production and purification of Merrimack's MM-093, a recombinant human alpha-fetoprotein, or rhAFP. GTC has been producing MM-093 transgenically for use in Merrimack's ongoing human clinical studies. The rhAFP protein has been difficult to express in traditional recombinant protein production systems. GTC is also working with Centocor to develop transgenic protein production. This program has begun expansion to provide a supply of product for preclinical evaluation. Four of the other programs in the external portfolio, two with Abbott and two with Bristol-Myers Squibb, have concluded with the successful completion of founder status, but no further work will be undertaken unless the respective partner chooses to pursue transgenic production for preclinical or clinical testing.

NOTE 1. NATURE OF BUSINESS (Continued)

In February 2001, GTC completed the divestiture of its wholly-owned contract research organization subsidiary, Primedica Corporation. Accordingly, Primedica is reported as a discontinued operation in these financial statements (see also Note 17).

Genzyme is the largest single shareholder of the Company, holding 4,924,919 shares of Common Stock as of December 28, 2003, which represents approximately 15% of the outstanding GTC Common Stock. Genzyme also holds four Common Stock purchase warrants exercisable for 145,000, 288,000, 55,833 and 29,491 shares of GTC Common Stock at prices of $2.84, $4.88, $6.30 and $6.30 per share, respectively, which were the market prices of the common stock at the time the respective Genzyme warrants were issued. The expiration dates of these warrants range from July 2005 through November 2009. All of the shares held by Genzyme (including shares issuable on exercise of Genzyme warrants) are entitled to registration rights.

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, the uncertainties of clinical trials and regulatory requirements for approval of therapeutic compounds, the need for additional capital, competitive new technologies, dependence on key personnel, protection of proprietary technology, and compliance with the United States Food and Drug Administration (FDA) and other government regulations. The Company's consolidated financial statements have been presented on the basis that it is a going concern, which contemplates the continuity of business, realization of assets and the satisfaction of liabilities in the ordinary course of business. The Company has incurred losses from operations and negative operating cash flow in each of the fiscal years ended December 28, 2003, December 29, 2002 and December 30, 2001. Management's plans with regard to these matters include continued research and development of the Company's technology, seeking additional corporate partners and raising capital through the sale of equity. If the Company is unable to successfully raise additional capital through sale of equity, management has the ability to implement any cost reductions as necessary to continue operations through December 2004.

NOTE 2. SIGNIFICANT ACCOUNTING POLICIES

Basis of Consolidation

The consolidated financial statements include the results of the Company, its wholly-owned subsidiaries and its joint venture. All significant inter-company transactions have been eliminated and the Company operates in one business segment.

The Company accounted for its 50% investment in the ATIII LLC joint venture under the equity method through February 2001. Between February 2001 and July 2001, the Company fully funded the joint venture costs under an Interim Funding Agreement. In July 2001, the Company completed the reacquisition of Genzyme's ownership interest in the joint venture and the results of the joint venture were thereafter consolidated for financial reporting purposes (see Note 12).

The Company consolidates the Taurus hSA LLC joint venture for financial reporting purposes (see Note 15).

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date

NOTE 2. SIGNIFICANT ACCOUNTING POLICIES (Continued)

of the financial statements and the reported amounts of revenues and expenses during the reporting period. The significant estimates and assumptions in these financial statements include revenue recognition, collectibility of accounts receivable and unbilled revenues, estimates of accrued expenses and tax valuation reserves. Actual results could differ materially from those estimates.

Cash and Cash Equivalents

Cash equivalents, consisting principally of money market funds and municipal notes purchased with initial maturities of three months or less, are valued at market value.

Marketable Securities

Marketable securities have been classified as available for sale and are stated at market value based on quoted market prices. Gains and losses on sales of securities are calculated using the specific identification method. Marketable securities at December 28, 2003 and December 29, 2002 can be summarized as follows:

	2003		2002	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Government backed obligations	$ 2,073	$ 2,063	$12,498	$12,516
Corporate obligations	22,127	22,295	17,756	17,922
Total marketable securities	$24,200	$24,358	$30,254	$30,438

At December 28, 2003, December 29, 2002 and December 30, 2001, the marketable securities had associated unrealized gains of $3,000, $184,000 and $228,000, respectively, included in accumulated other comprehensive income and equity. The Company had a realized gain of $2.3 million on the sale of the Charles River Laboratories stock in 2001. All other realized gains on available for sale securities in 2003, 2002 and, 2001 were immaterial. At December 29, 2002, the contractual maturities of the Company's investments available for sale range from 4 months to 36 months. All of the Company's investments are classified as short-term, which is consistent with their intended use. Unrealized losses on marketable securities were approximately $50,000 and $9,000 at December 28, 2003 and December 29, 2002, respectively.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents, marketable securities and trade accounts receivable. The Company is subject to the concentration of credit risk of its commercial bank that holds the revolving line of credit and term loan. At December 28, 2003 and December 29, 2002, approximately 59% and 97%, respectively, of cash, cash equivalents and marketable securities were held by one United States financial institution. Total credit facilities at one commercial bank are $10.6 million at December 28, 2003 and $11.6 million at December 29, 2002.

The Company performs ongoing credit evaluations of its customers' financial conditions and maintains reserves for potential credit losses. There were no write-offs for fiscal 2003, 2002 and 2001.

NOTE 2. SIGNIFICANT ACCOUNTING POLICIES (Continued)

At December 28, 2003, December 29, 2002 and December 30, 2001, four customers, two customers and five customers, respectively, accounted for 100% of accounts receivable. Four customers accounted for 100% (the largest of which is 54%) of the revenue for the year ended December 28, 2003, five customers accounted for 81% (the largest of which is 23%) of the revenue for the year ended December 29, 2002 and four customers accounted for 72% (the largest of which is 34%) of the revenue for the year ended December 30, 2001. See ITEM 7 for discussion of the significant customers.

Property, Plant and Equipment

Property, plant and equipment are stated at cost and depreciated using the straight-line method over estimated useful lives of three to thirty years. Leasehold improvements are amortized using the straight-line method over the life of the improvement or the remaining term of the lease, whichever is shorter. The direct costs of the New Zealand goats ("Livestock") are capitalized and amortized using the straight-line method over their estimated useful lives of three years prior to 2003 and five years beginning in 2003.

The Company capitalizes those incremental costs that are incurred in obtaining approval from the FDA or the European Medicines Evaluation Agency, or EMEA for manufacturing assets and the related processes for bulk drug production. Under Statement of Financial Accounting Standards (SFAS) No. 34, "Capitalization of Interest Costs," the historical cost of acquiring an asset includes the costs necessarily incurred to bring it to the condition and location necessary for its intended use. The capitalization period shall begin when expenditures for the asset have been made and activities that are necessary to get the asset ready for its intended use are in progress. Pursuant to regulations of the FDA or the EMEA, a facility and its related manufacturing assets must achieve "process qualification" in order for it to be approved, or "validated," for commercial production. Without approval from the FDA or the EMEA, the facility cannot be placed into service for commercial production; accordingly, the incremental validation costs incurred by the Company are an essential part of preparing the related assets for their intended use. Validation by the EMEA will allow the Company to manufacture products for sale in Europe, which the Company expects to be the initial market for ATryn®.

The costs that the Company has capitalized to date are those costs that are related to FDA or EMEA approval of the manufacturing equipment to be used for the bulk production of ATryn® and are being depreciated over the expected life of the facility. They include the costs of employees and third parties directly involved in the process, direct material consumed in the validation process, and incremental fixed overhead. Costs that are excluded from capitalization include costs of maintenance, process development/improvement and fixed overhead. As of December 28, 2003 and December 29, 2002, the Company had approximately $4.1 million and $2.5 million of unamortized capitalized validation costs included in property, plant and equipment.

NOTE 2. SIGNIFICANT ACCOUNTING POLICIES (Continued)

The following is the summary of property, plant and equipment and related accumulated amortization and depreciation as of December 28, 2003 and December 29, 2002.

	Years of Life	December 28, 2003	December 29, 2002
Land	—	$ 1,401	$ 1,401
Buildings	20-30	14,230	14,208
Livestock	3-5	2,842	2,744
Leasehold improvements	lease life	1,500	1,368
Laboratory, manufacturing and office equipment	3-10	11,167	7,949
Laboratory, manufacturing and office equipment—capital lease	3-10	1,960	1,960
		33,100	29,630
Less accumulated amortization and depreciation		(10,500)	(7,929)
Net property, plant and equipment		$ 22,600	$ 21,701

Depreciation and amortization expense was $2,571,000, $1,424,000 and $1,237,000, for the fiscal years ended December 28, 2003, December 29, 2002 and December 30, 2001, respectively. Assets in the amount of $268,000 were disposed of in 2002 with an associated loss of approximately $124,000. Accumulated amortization for equipment under capital lease was $1,093,000, $774,000 and $616,000 at December 28, 2003, December 29, 2002 and December 30, 2001, respectively.

In January 2002, the Company completed a $414,000 purchase of approximately 135 acres of farm land in eastern New York which may be developed as a second production site.

Long-Lived Assets

The Company reviews long-lived assets for impairment by comparing the cumulative undiscounted cash flows from the assets with their carrying amount. Any write-downs are to be treated as permanent reductions in the carrying amount of the assets. Management's policy regarding long-lived assets is to evaluate the recoverability of its assets when the facts and circumstances suggest that these assets may be impaired. This analysis relies on a number of factors, including operating results, business plans, budgets, economic projections and changes in management's strategic direction or market emphasis. The test of such recoverability is a comparison of the asset value to its expected cumulative net operating cash flow over the remaining life of the asset.

Accounting for Employee Equity Plans

In December 2002, the Financial Accounting Standards Board issued FASB No. 148 ("SFAS 148"), Accounting for Stock Based Compensation—Transition and Disclosure. SFAS 148, which was effective for fiscal years ending after December 15, 2002, amends Statement of Accounting Standards No. 123 ("SFAS 123"), Accounting for Stock Based Compensation and provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based compensation. In addition, SFAS 148 amends the disclosure requirements of SFAS 123 regardless of the accounting method used to account for stock-based compensation. The Company continues to apply APB Opinion 25 and related interpretations in accounting for its employee equity plans. Accordingly,

NOTE 2. SIGNIFICANT ACCOUNTING POLICIES (Continued)

no compensation cost has been recognized for options granted to employees with exercise prices equal to or greater than the fair market value at the grant date. The Company applies the disclosure only provisions of SFAS 148. If the compensation cost for the Company's stock-based compensation plans to employees had been determined based on the fair value at the grant dates as calculated in accordance with SFAS 123, the Company's net loss and loss per share for the years ended December 28, 2003, December 29, 2002 and December 30, 2001 would have been increased to the pro forma amounts indicated below:

	December 28, 2003		December 29, 2002		December 30, 2001	
	Net Loss	Net Loss Available Per Common Share (basic and diluted)	Net Loss	Net Loss Available Per Common Share (basic and diluted)	Net Loss	Net Loss Available Per Common Share (basic and diluted)
Net loss reported	$(29,537)	$(1.00)	$(24,320)	$(0.86)	$(16,556)	$(0.55)
Deduct: *	(2,417)	(0.08)	(2,854)	(0.10)	(2,703)	(0.09)
Pro Forma net loss	$(31,954)	$(1.08)	$(27,174)	$(0.96)	$(19,259)	$(0.64)

* Total stock-based employee compensation expense determined under fair value based method for all awards.

The effects of applying SFAS 123 in this pro forma disclosure are not indicative of future amounts. SFAS 123 does not apply to awards prior to 1995, and additional awards in future years are anticipated (see more details in Note 10).

The fair value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumption: an expected life of five years, expected volatility of 100% for fiscal 2003, 95% for fiscal 2002 and 90% for fiscal 2001, a dividend yield of 0% and a risk-free interest rate of 2.96% for fiscal 2003, 4.47% for fiscal 2002 and 4.69% for fiscal 2001. The average fair value of those options granted during fiscal 2003, 2002 and 2001 was $1.22, $2.53 and $4.36, respectively.

The fair value of the employees' purchase rights was estimated using the Black-Scholes model with the following weighted-average assumptions: a dividend yield of 0%, expected volatility of 98% for fiscal 2003, 95% for fiscal 2002 and 90% for fiscal 2001, an expected life of five years for fiscal 2003, 2002 and 2001 and a risk-free interest rate of 0.96% for 2003, 1.61% for 2002 and 4.64% for fiscal 2001. The average fair value of those purchase rights granted during fiscal 2003, 2002 and 2001 was $0.70, $0.95 and $3.30, respectively.

Revenue Recognition and Contract Accounting

The Company enters into licensing and development agreements with collaborative partners for the development of production and purification of therapeutic recombinant proteins produced in the milk of transgenic animals. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon the achievement of certain milestones and royalties on future product sales, if any.

When there are two or more distinct services or deliverables embedded into one contract, such as development and commercialization or manufacturing services, the contract is considered a multiple

NOTE 2. SIGNIFICANT ACCOUNTING POLICIES (Continued)

element arrangement. For revenue arrangements entered into after July 1, 2003, the Company accounts for multiple-element arrangements in accordance with Emerging Issues Task Force (EITF Issue) No. 00-21. When management can determine the fair value of the different elements and the delivered services have value to the customer on a stand-alone basis, then the different elements are accounted for separately. For example, if the Company enters into an arrangement to perform development services, but the Company is obligated to perform follow-on manufacturing services, then the Company must determine the fair value of both the development services and the manufacturing services. If the terms of both the development and manufacturing services are at fair value, then the Company will account for the development services separately. If the terms of the development and manufacturing services are not at fair value, but the Company can determine the fair value of each element, then the total amount of the contract is allocated to each element based on their relative fair values. If the Company cannot determine the fair value of the development services, but can determine the fair value of the manufacturing services, then revenue will be allocated to the development phase using the residual method. If the Company cannot determine the fair value of the undelivered services or if the delivered services do not have value to the customer on a stand alone basis, then the contract is accounted for as a single unit of accounting.

Non-refundable license fees, milestones and collaborative research and development revenues under collaborative arrangements, where the Company is also obligated to provide development services and the Company can reasonably estimate the effort required to complete its contractual obligations, are recognized as revenue over the period of continuing involvement, using a model similar to the one prescribed by EITF No. 91-6. Under that model, revenue is recognized for non-refundable license fees, milestones and collaborative research and development using the lesser of non-refundable cash received and milestones met or the result achieved using level-of-efforts accounting. Under the level-of-efforts accounting, revenue is based on the cost of effort since the contract's commencement up to the reporting date, divided by the total expected research and development costs from the contract's commencement to the end of the research and development period, multiplied by the total expected contractual payments under the arrangement. Revisions in cost estimates and expected contractual payments as contracts progress have the effect of increasing or decreasing profits in the current period. For development contracts which the Company can not reasonably estimate the effort to complete its contractual obligations, revenue is limited to the lesser of costs incurred or non-refundable cash received provided the Company can reasonably conclude that the costs of completing the contract will not exceed the revenues under the contract. Payments received in advance of being earned are recorded as deferred revenue. Revenue under manufacturing service contracts pursuant to which the Company is paid for its costs plus a fixed profit margin is recognized as the Company incurs costs. Any up-front payments are spread over the term of the manufacturing arrangement. Revenue under contracts pursuant to which the Company is paid based on units or volume produced is recognized when title and risk of loss have passed to the customer.

Profits expected to be realized are based on the total contract sales value and the Company's estimates of costs at completion. The sales value is based on achievable milestones and is revised throughout the contract as the Company demonstrates achievement of milestones. The Company's estimates of costs include all costs expected to be incurred to fulfill performance obligations of the contracts. Estimates of total contract costs are reviewed and revised throughout the lives of the contracts, with adjustments to profits resulting from such revisions being recorded on a cumulative basis in the period in which the revisions are made. All revenue recognition estimates are made based upon

NOTE 2. SIGNIFICANT ACCOUNTING POLICIES (Continued)

the current facts and circumstances and are reassessed on at least a quarterly basis. If changes in these estimates or other immaterial adjustments to revenue are identified, the adjustments will be recorded as they become known.

Unbilled contract revenue represents efforts incurred or milestones achieved which had not been billed at the balance sheet date. Deferred contract revenue represents amounts received from customers that exceeded the amount of revenue recognized to date on the balance sheet date. Research and development revenues from the ATIII LLC (see Note 14) consisted of $0, $0 and $973,000 for the fiscal years ended 2003, 2002 and 2001, respectively, after the Company acquired the remainder of the interests in that entity in 2001, and the remainder of the revenue was from commercial clients.

Inventory

The Company carries inventory at the lower of cost or market using the first-in, first-out method. The Company capitalizes inventory produced for commercial sale and all of the inventory on hand at December 28, 2003 is related to ATryn® which has not yet been approved for commercial sale. The Company expects that all of the capitalized inventory will be sold commercially in Europe provided the Company receives marketing approval. If, at any time, the Company believes that marketing approval of ATryn® is no longer probable, the Company will charge the inventory to expense. Although no specific clinical plans require it to date, it is possible that the Company could use some of the capitalized inventory for additional clinical trials and, if so, the Company would expense the inventory when it was designated for use in the clinical trial. The Company determines cost using the first-in, first-out method. The Company analyzes its inventory levels quarterly and will write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements. Expired inventory will be disposed of and the related costs will be written off. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required. In the fourth quarter of 2003, the Company recorded a net realizable value write down of inventory of approximately $269,000 which was recorded to cost of revenue as a result of inventoriable costs incurred in excess of the net realizable value of the related inventory.

Research and Development Costs

All research and development costs are expensed as incurred. During its fiscal years ended December 28, 2003, December 29, 2002 and December 30, 2001, the Company spent, in total, $29.2 million, $25 million and $22.4 million, respectively, on cost of revenue and research and development expense of which $11.1 million, $13.1 million and $15.1 million, respectively, was related to external programs. Of the total spent on research and development, $8.7 million, $5.1million and $2.3 million, was spent on the ATIII LLC in fiscal years 2003, 2002 and 2001, respectively. These costs include labor, materials and supplies and overhead, as well as certain subcontracted research projects. Also included are the costs of operating the transgenic production facility, such as feed and bedding, veterinary costs and utilities.

Net Loss per Common Share

The Company applies Statement of Financial Accounting Standards No. 128 ("SFAS 128"), *Earnings Per Share* in calculating earnings per share. Potential common shares of the Company consist

NOTE 2. SIGNIFICANT ACCOUNTING POLICIES (Continued)

of warrants (see Note 9), stock options (see Note 10), stock to be issued under the defined contribution retirement plan (see Note 10), convertible debt (see Note 8) and convertible preferred stock (see Note 9). The Company was in a net loss position in 2003, 2002 and 2001, and therefore 6.2 million, 5.6 million and 3.1 million potential common shares, respectively, were not used to compute diluted loss per share, as the effect was antidilutive.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial statement and tax bases of assets and liabilities using the expected enacted tax rates for the year in which the differences are expected to reverse. The measurement of deferred tax assets is reduced by a valuation allowance if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

Guarantees

In November 2002, the FASB issued FIN 45, Guarantors Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, an interpretation of FASB Statements No. 5, 57, and 107 and Rescission of FASB Interpretation No. 34. FIN 45 clarifies the requirements of FASB Statement No. 5, Accounting for Contingencies relating to the guarantors accounting for, and disclosure of, the issuance of certain types of guarantees. For guarantees that fall within the scope of FIN 45, the Interpretation requires that guarantors recognize a liability equal to the fair value of the guarantee upon its issuance. The disclosure provisions of the Interpretation are effective for financial statements of interim or annual periods that end after December 15, 2002. However, the provisions for initial recognition and measurement are effective on a prospective basis for guarantees that are issued or modified after December 31, 2002, irrespective of a guarantor's year-end. As permitted under Delaware law, the Company has agreements whereby it indemnifies its officers and directors for certain events or occurrences 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 maximum potential amount of future payments we could be required to make under these indemnification agreements is unlimited; however, we have a Director and Officer insurance policy that limits the Company's exposure and enables us to recover a portion of any future amounts paid. As a result of the Company's insurance policy coverage, GTC believes the estimated fair value of these indemnification agreements is minimal. All of these indemnification agreements were grandfathered under the provisions of FIN No. 45 as they were in effect prior to December 31, 2002. Accordingly, we have no liabilities recorded for these agreements as of December 28, 2003. The Company does not expect the disclosure or measurement provisions of FIN 45 to have a material effect on its results of operations or financial position.

New Accounting Pronouncements

In January 2003, the FASB issued FASB Interpretation No. 46 or FIN 46, "Consolidation of Variable Interest Entities," to expand upon and strengthen existing accounting guidance that addresses when a company should include in its financial statements the assets, liabilities and activities of another entity. Until now, one company generally has included another entity in its consolidated financial statements only if it controlled the entity through voting interests. FIN 46 changes that by requiring a

NOTE 2. SIGNIFICANT ACCOUNTING POLICIES (Continued)

variable interest entity (VIE), as defined, to be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity's activities or entitled to receive a majority of the entity's residual returns or both. FIN 46 also requires disclosures about variable interest entities that the company is not required to consolidate but in which it has a significant variable interest. In December 2003, the FASB released a revised version of FIN 46 (hereafter referred to as FIN 46R) clarifying certain aspects of FIN 46 and providing certain entities with exemptions from the requirements of FIN 46. The variable interest model of FIN 46R was only slightly modified from that contained in FIN 46. A VIE would be required to be consolidated if either of the following conditions are met:

1. The total equity investment at risk is not sufficient to permit the entity to finance its activities without additional subordinated financial support provided by any parties, including equity holders.
2. The equity investors lack any one of the following three characteristics of a controlling interest:
   - The direct or indirect ability through voting rights or similar rights to make decisions about an entity's activities that have a significant effect on the success of the entity.
   - The obligation to absorb the expected losses of the entity.
   - The right to receive the expected residual returns of the entity.

FIN 46R requires the application of either FIN 46 or FIN 46R by public entities to all Special Purpose Entities ("SPEs") created prior to February 1, 2003 at the end of the first interim or annual reporting period ending after December 15, 2003. All entities created after January 31, 2003 by Public Entities were already required to be analyzed under FIN 46, and they must continue to do so, unless FIN 46R is adopted early. FIN 46R will be applicable to all non-SPEs created prior to February 1, 2003 by Public Entities that are not small business issuers at the end of the first interim or annual reporting period ending after March 15, 2004. The Company does not expect the provisions of FIN 46 to have a material effect on its results of operations and financial position.

In December 2003, the SEC released Staff Accounting Bulletin No. 104 (SAB 104) entitled, "Revenue Recognition." SAB 104 updates portions of the interpretative guidance included in Topic 13 of the codification of staff accounting bulletins in order to make this interpretive guidance consistent with current authoritative accounting guidance. The principal revisions relate to the deletion of interpretive material no longer necessary because of private sector developments in U.S. generally accepted accounting principles, and the incorporation of certain sections of the staff's "Revenue Recognition in Financial Statements Frequently Asked Questions and Answers" document into Topic 13.

NOTE 3. SIGNIFICANT AGREEMENTS

Tufts University School of Veterinary Medicine ("Tufts")

GTC and Tufts have agreed to a non-exclusive licensing agreement to a technique for nuclear transfer technology for which Tufts has rights. Tufts also provides animal husbandry, veterinary care and other services to the Company, for which the Company paid Tufts $833,000, $679,000 and $488,000 for the fiscal years ended December 28, 2003, December 29, 2002 and December 30, 2001, respectively. In the fourth quarter of 2003, the Company significantly reduced its activity with Tufts which will result in lower payments to Tufts in 2004. Net sales of products derived from transgenic animals produced by Tufts technology, or from their offspring, are subject to royalties payable to Tufts.

Advanced Cell Technologies, Inc. ("ACT")

In June 1999, GTC signed an exclusive, worldwide licensing agreement with ACT allowing GTC to utilize ACT's patented nuclear transfer technology for the development of biopharmaceuticals in the milk of transgenic mammals. The Company believes ACT's proprietary platform technology, when coupled with GTC's transgenic technology, will provide additional patentable approaches to efficiently develop transgenic animals. GTC paid an upfront license fee of $1,862,000 upon execution of the agreement, which included $1 million of GTC Common Stock, which is classified as an intangible asset (see Note 7). In addition, GTC is required to pay royalties to ACT based upon sales by GTC where ACT's nuclear transfer technology is used. To date, GTC has paid approximately $250,000 of royalties to ACT.

The U.S. Patent and Trademark Office has declared an interference proceeding between ACT and Geron Corporation for one of the patents GTC licenses from ACT. While we have also licensed nuclear transfer technology from Pharming, the Company does not know at this time what impact, if any, this interference proceeding may have on its ability to practice nuclear transfer.

Pharming Group N.V. ("Pharming")

In June 2002, the Company obtained licenses to transgenic cattle technology and nuclear transfer technology from Pharming. The agreement provided for a payment of 1.5 million Euro, or approximately $1.5 million, settlement of which was paid in July of 2002. These licenses relate to technology which is currently being used in the Company's ongoing activities and, therefore, their associated costs are reported as an intangible asset at December 28, 2003 and are being amortized over a 15-year period, the remaining life of the underlying patents.

Merrimack Pharmaceuticals, Inc. ("Merrimack")

In June 2003, the Company and Merrimack executed a definitive agreement for the clinical production and purification of MM-093, a recombinant human alpha-fetoprotein. The terms of the agreement called for deferral of payment of up to $4 million in receivables through the fourth quarter of 2003.

In December 2003, the Company amended the terms of its agreement with Merrimack for the production and purification of MM-093. Under the revised terms, GTC converted $1.25 million of the payments owed by Merrimack to GTC into Merrimack preferred stock. GTC also received an increase in its royalty due from Merrimack on commercial sales of MM-093, if any, as a result of this agreement. This amendment enables GTC, as a holder of preferred stock in Merrimack, to participate

NOTE 3. SIGNIFICANT AGREEMENTS (Continued)

in a larger portion of the potential value of MM-093. GTC is also granting an additional deferment to June 30, 2004 of up to $650,000 in payments owed by Merrimack. The Company had approximately $764,000 of billed receivables from Merrimack at December 28, 2004.

NOTE 4. NON-CASH INVESTING AND FINANCING TRANSACTIONS

During fiscal 2001, as part of the consideration for sale of the Primedica subsidiary, the Company received Charles River Laboratories common stock valued at $15.9 million and, in addition, Charles River assumed all of Primedica's debt of approximately $9 million. The Company also recognized $284,000 of equity compensation expense in connection with pre-existing obligations to certain management employees whose employment with the Company was terminated by the sale of the Primedica subsidiary.

On April 4, 2002, the Company bought back 2.82 million shares of the Company's Common Stock directly from Genzyme (the "Genzyme Stock Buyback") (see Note 9) which was recorded as treasury stock. The Company bought the shares for an aggregate consideration of approximately $9.6 million, consisting of approximately $4.8 million in cash and a promissory note to Genzyme for the remaining $4.8 million. The $4.8 million promissory note bears interest at the London Interbank Offered Rate (LIBOR) plus 1% (LIBOR was at 1.17% at December 28, 2003). The principal is payable in two installments: 50% on April 3, 2005 and the remaining 50% on April 3, 2006.

During 2002, the Company also purchased $818,000 of fixed assets and financed these additions with capital lease obligations.

In December 2003, the Company amended the terms of its agreement with Merrimack Pharmaceuticals for the production and purification of MM-093. Under the revised terms, the Company converted $1.25 million of payments owed by Merrimack into Merrimack preferred stock and agreed to allow Merrimack to defer up to $650,000 of accounts payable to GTC through June 30, 2004. GTC also received an increase in its royalty due from Merrimack on commercial sales of MM-093, if any.

During 2003, the Company also had non cash depreciation related to the ATryn® inventory in the amount of $129,000 (see Note 2).

NOTE 5. ACCRUED LIABILITIES

Accrued liabilities included the following:

	At December 28, 2003	At December 29, 2002
Accrued payroll and benefits	$1,714	$1,627
Accrued bonuses	727	851
Other	1,083	1,964
Total accrued expenses	$3,524	$4,442

In 2003, there were 22 employees terminated as a result of a restructuring during the third quarter. This restructuring included employees from all departments located at both the Company's Framingham and central Massachusetts locations. The Company recorded severance expense in the

NOTE 5. ACCRUED LIABILITIES (Continued)

amount of $236,000 for the year ended December 28, 2003. There were no terminations in 2002 and, therefore, the Company did not record severance expense during 2002. During 2001, the Company recorded severance expense of approximately $975,000 related to the contractual obligations in connection with the resignation of the Company's former President and Chief Executive Officer. The Company incurred a recovery of approximately $61,000 in 2003 upon the final payment related to the Company's former President and Chief Executive Officer. These costs have been included in the Company's selling, general and administrative expenses. During the years ended December 28, 2003, December 29, 2002 and December 30, 2001, approximately $293,000, $424,000 and $315,000, respectively, had been paid out of the severance reserve. At December 28, 2003, $118,000 remained in accrued expenses in relation to unpaid severance costs which will be paid out through the second quarter of 2004.

In February 2004, the Company announced a restructuring of its organization to control costs and to support its focus on clinical development and commercialization of its internal pipeline of proprietary products and its portfolio of external programs. Under the restructuring plan, headcount was reduced by approximately 20% from 159 to 127 full time equivalent employees.

NOTE 6. COMMITMENTS AND CONTINGENCIES

The Company leases equipment and facilities under various operating and capital leases (see Note 8). The deferred lease obligation represents the cumulative difference between actual facility lease payments and lease expense recognized ratably over the lease period. Rent expense for the fiscal years ended December 28, 2003, December 29, 2002 and December 30, 2001 was approximately $1,893,000, $1,310,000 and $1,037,000, respectively.

At December 28, 2003, the Company's future minimum payments required under these leases are as follows:

	Operating	Capital
2004	$ 631	$197
2005	518	202
2006	177	208
2007	4	—
2008	1	—
Thereafter	—	—
Total	$1,331	$607
Less amount representing interest		21
Present value of minimum lease payments (see also Note 8)		$586

The Company is a party to license agreements for certain technologies (see Note 3). Certain of these agreements contain provisions for the future royalties to be paid on commercial sales of products developed from the licensed technologies. Currently the amounts payable under these agreements and any resulting commitments on the Company's behalf are unknown and cannot be practically estimated since the level of future sales, if any, is uncertain.

NOTE 6. COMMITMENTS AND CONTINGENCIES (Continued)

Under a Service Agreement and Sublease Agreement with Genzyme (see Note 14), the Company is committed to make a minimum annual payments of $9,000 and $360,000, respectively, in 2004.

On November 13, 2001, two employees of one of the Company's former subsidiaries filed an action in the Court of Common Pleas for Philadelphia County in Pennsylvania against the Company seeking damages, declaratory relief and certification of a class action relating primarily to their Company stock options. The claims arise as a result of the Company's sale of Primedica Corporation to Charles River Laboratories International, Inc. in February 2001, which the Company believes resulted in the termination of Primedica employees' status as employees of the Company or its affiliates and termination of their options. The plaintiffs contend that the sale of Primedica to Charles River did not constitute a termination of their employment with the Company or its affiliates for purposes of the Company's equity incentive plan and, therefore, that the Company breached its contractual obligations to them and other Primedica employees who had not exercised their stock options. The complaint demands damages in excess of $5 million, plus interest. GTC has filed an answer denying all material allegations in the complaint, and is vigorously defending the case. The Company believes that it has meritorious defenses and that, although the ultimate outcome of the matters cannot be predicted with certainty, the disposition of the matter should not have a material adverse effect on the financial position of the Company.

NOTE 7. INTANGIBLE ASSETS

The Company owned 22% of the SMIG JV joint venture with Sumitomo Metal Industries the purpose of which was to develop proteins transgenically for Asian markets. In September 2000, the Company acquired full ownership of the SMIG JV by issuing shares of GTC's common stock valued at approximately $11.2 million. As a result, the Company holds the marketing rights to transgenic technology in 18 Asian countries, including Japan. Accordingly, the entire purchase price of $11.2 million was allocated to the value of the marketing rights (SMIG marketing rights), the sole assets of SMIG. These costs are being amortized over the estimated 15 year economic useful life of these rights. These rights relate to the Company's current business as they allow the Company to sell transgenic proteins in Asia. Without these rights, the Company would have been severely limited in its penetration of key Asian markets, primarily Japan, and would have had a substantial royalty obligation for any revenues derived from Asia and Europe. The Company is actively pursuing opportunities for its transgenic products in development in these markets.

Intangible assets consist of:

	Amortization Life	December 28, 2003	December 29, 2002
Marketing rights	15 years	$ 11,210	$ 11,210
Accumulated amortization—marketing rights		(2,491)	(1,744)
Net		8,719	9,466
Technology licenses	10 years to 15 years	3,379	3,379
Accumulated amortization—technology licenses		(1,004)	(717)
Net		2,375	2,662
Total intangible assets, net		$ 11,094	$ 12,128

NOTE 7. INTANGIBLE ASSETS (Continued)

Amortization expense was $1,034,000, $984,000 and $934,000 in 2003, 2002 and 2001, respectively.

The estimated aggregate amortization expense for the next five years is $1,038,000 per year from 2004 through 2008 and $5,904,000 for 2009 and thereafter.

NOTE 8. BORROWINGS

In March 2002, the Company entered into a five year Loan and Security Agreement (the "Loan Agreement") with Silicon Valley Bank, or SVB, in the amount of $11.6 million, of which $5.5 million was used to refinance an exiting term loan, $1.1 million refinanced previous capital asset acquisitions, all of which was drawn during 2002, and $4 million was available to finance future capital requirements, of which $3.4 million was drawn during 2002 and $585,000 was drawn during 2003, and $1 million is available under a revolving line of credit at December 28, 2003. As a requirement under a facility lease, the Company also has a standby letter of credit in the amount of $249,360 with SVB. Interest on the SVB debt instruments accrues at the prime rate, which was 4% at December 28, 2003.

In June 2003, the Company entered into a Loan Modification Agreement (the "Modification Agreement") with Silicon Valley Bank. The Modification Agreement established a "2003 Committed Equipment Line" which made an additional $2,250,000 available to the Company for the financing of capital asset acquisitions. During 2003, $1,505,000 was drawn down and $745,000 remained available for future capital asset acquisitions at December 28, 2003. All other terms and conditions remain unchanged from the original agreement entered into in March 2002.

Under the Loan Agreement with SVB, the Company was required to maintain unrestricted cash and marketable securities, net of outstanding obligations under the revolving credit line, if any, of at least $25 million. If at any time, the Company failed to satisfy these terms, the Company was required to deposit with SVB an amount of unrestricted cash equal to the outstanding obligations under the Loan Agreement. In connection with the financing, the Company granted SVB a first lien on all assets of the Company except intellectual property.

In January 2004, the Company entered into a Loan Modification Agreement (the "Additional Modification Agreement") with SVB. This Additional Modification Agreement amended the terms of the 2003 Committed Equipment Line established under the Modification Agreement to extend the availability of the unused portion of the 2003 Committed Equipment Line to June 30, 2004 from December 31, 2003. The Additional Modification Agreement also reduced from $25 million to $18.2 million the amount the Company must maintain as unrestricted cash and marketable securities before the Company is required to provide cash collateral for the outstanding obligation to SVB, which was approximately $9.6 million at December 28, 2003. In addition, the Additional Modification Agreement requires the Company to provide SVB with evidence that the Company has submitted to the EMEA a market approval application for ATryn® which was submitted by the Company on January 26, 2004. All other terms and conditions remain unchanged from the original agreement entered into in March 2002.

On April 4, 2002, the Company repurchased 2.82 million shares of the Company's common stock, par value $0.01 per share (the "Common Stock") from Genzyme, which was recorded as treasury stock. The Company purchased the shares for an aggregate consideration of approximately $9.6 million, consisting of approximately $4.8 million in cash and a promissory note to Genzyme for the remaining $4.8 million. The $4.8 million promissory note bears interest at the LIBOR plus 1% (LIBOR was at

NOTE 8. BORROWINGS (Continued)

1.17% at December 28, 2003). The principal is payable in two installments: 50% on April 3, 2005 and the remaining 50% on April 3, 2006. This note is collateralized by a subordinated lien on all the assets of the Company except intellectual property.

The Company's long-term debt consisted of the following:

	December 28, 2003	December 29, 2002
Bank term loan, with monthly payments through March 2008 ($168 in 2004 and $145 in 2003) interest varies as described above, collateralized by real estate	$ 9,380	$ 9,026
Promissory note to Genzyme, with principal payments of $2,386 in April 2005 and April 2006, interest varies as described above, collateralized by a subordinated lien on all assets except intellectual property	4,773	4,773
Capital lease obligations, with monthly payments of $19 through September 2003 and December 2006, interest at 3.50%, collateralized by property (see also Note 4)	607	867
	14,760	14,666
Less current portion	2,218	1,880
	$12,542	$12,786

Maturities of long-term debt are as follows:

2004	$ 2,218
2005	4,610
2006	4,615
2007	1,031
2008	2,286
2009 and thereafter	—
	$14,760

Based on the borrowing rates currently available to the Company for loans with similar terms and average maturities, the value of the notes payable approximates fair value. Cash paid for interest for the fiscal years ended December 28, 2003, December 29, 2002, and December 30, 2001 was $512,000, $423,000 and $349,000, respectively. There was no interest expense capitalized to construction in progress in 2003, 2002 and 2001.

NOTE 9. STOCKHOLDERS' EQUITY

Authorized Shares

The Company's authorized capital stock consists of 100,000,000 shares of common stock, par value $0.01 per share, and 5,000,000 shares of preferred stock, par value $0.01 per share. In March 2001, the Company's Board of Directors restored all unissued or reacquired shares of the Company's Series A Preferred Stock and Series B Preferred Stock to the status of authorized but undesignated and unissued shares of preferred stock.

NOTE 9. STOCKHOLDERS' EQUITY (Continued)

Genzyme Stock Buyback

On April 4, 2002, the Company repurchased 2.82 million shares of the Company's Common Stock from Genzyme, which was recorded as treasury stock. The Company purchased the shares for an aggregate consideration of approximately $9.6 million, consisting of approximately $4.8 million in cash and a promissory note to Genzyme for the remaining $4.8 million. The Company's Common Stock was valued at $3.385 per share in this transaction, using the simple average of the high and low transaction prices quoted on the NASDAQ National Market on the previous trading day. Genzyme has committed to a 24-month lock-up provision on their remaining 4.92 million shares of the Company's Common Stock, which represented approximately 15% of the Company's outstanding shares. The lock-up provision will be released before April 2004 if the simple average of the prices of the Company's daily high and low stock trades, as reported on the NASDAQ National Market, exceeds $12.00 per share for 20 consecutive trading days.

The $4.8 million promissory note bears interest at the LIBOR plus 1% (LIBOR was at 1.17% at December 28, 2003). The principal is payable in two installments: 50% on April 3, 2005 and the remaining 50% on April 3, 2006. This note is collateralized by a subordinated lien on all the assets of the Company except intellectual property.

Shareholder Rights Plan

On May 31, 2001, the Board of Directors adopted a Shareholder Rights Plan (the "Plan") as set forth in the Shareholder Rights Agreement, dated May 31, 2001, between the Company and American Stock Transfer and Trust Company, as Rights Agent (the "Rights Agreement"). A series of preferred stock of the Company designated as Series C Junior Participating Cumulative Preferred Stock, par value $.01 per share (the "Series C Preferred Stock"), has been created in accordance with the Rights Agreement. The Plan is designed to deter coercive takeover tactics, including the accumulation of shares in the open market or through private transactions, and to prevent an acquirer from gaining control of the Company without offering a fair and adequate price and terms to all of the Company's shareholders. As such, the Plan enhances the Board of Directors' ability to protect shareholder interests and ensure that shareholders receive fair and equal treatment in the event any proposed takeover of the Company is made in the future. Pursuant to the Rights Agreement, the Board of Directors declared a dividend distribution of one preferred stock purchase right for each outstanding share of the Company's Common Stock to shareholders of record as of June 1, 2001. The preferred stock purchase rights are attached to, and will trade with, the Company's Common Stock. The purchase rights are currently exercisable upon the occurrence of certain triggering events described in the Rights Agreement.

Common Stock Placements

In August 2003, the Company issued and sold 3,626,465 shares of its Common Stock at $2.55 per share in a private placement to institutional investors. The Company also issued warrants to investors to purchase an aggregate of 906,613 shares of the Company's Common Stock at an exercise price of $3.30 per share. The Company paid SG Cowen a placement agent fee plus warrants to purchase 54,396 shares of the Company's Common Stock on the same terms as the placement warrants. Proceeds to the Company, net of offering costs of $700,000, were approximately $8.5 million.

NOTE 9. STOCKHOLDERS' EQUITY (Continued)

In December 2003, the Company filed a shelf-registration statement with the Securities and Exchange Commission which became effective on January 9, 2004. The shelf registration statement allows the Company to offer and sell from time to time, up to an aggregate of $40 million of Common Stock. The terms and price of any future offerings would be established at the time of the offering.

A summary of the outstanding GTC warrants as of December 28, 2003, of which 1,499,333 are currently exercisable, is as follows:

Common Shares Issuable for	Exercise Price Per Share	Warrant Expiration Date
145,000	$2.84	July 3, 2005
20,000	$8.75	June 26, 2007
288,000	$4.88	December 28, 2008
55,833	$6.30	November 12, 2009
29,491	$6.30	November 22, 2009
961,009	$3.30	August 1, 2008
1,499,333		

As of December 28, 2003, the Company has reserved 7,289,494 shares of Common Stock, subject to adjustment, for future issuance under the various classes of warrants, the Equity Plans and Employee Stock Purchase Plans (see 97).

NOTE 10. EMPLOYEE BENEFIT PLANS

Stock Options and Purchase Plan

In May 1993, the Board of Directors adopted and the shareholders approved the 1993 Equity Incentive Plan (the "Equity Plan"), the 1993 Director Stock Option Plan (the "Director Plan") and the 1993 Employee Stock Purchase Plan (the "Purchase Plan"). In March 2001, the Board of Directors voted to terminate the Director Plan and amend the Equity Plan.

Under the Equity Plan, 2,015,000 shares of common stock were issued or reserved for issuance pursuant to incentive stock options, non-statutory stock options, restricted stock awards, stock appreciation rights or stock units in accordance with specific provisions to be established by a committee of the Board of Directors at the time of grant. To date, all options have been issued at 85% or greater of the fair value at the grant date. The Equity Plan also permits the Company to assume outstanding options in an acquisition without using shares reserved under the Plan. The number of shares reserved for future issuance under this plan was increased several times over the ensuing years to 5,540,000 at December 30, 2001, which amount includes 200,000 shares transferred from the Director Plan upon its termination.

In May 2002, the shareholders approved the 2002 Equity Incentive Plan (the "2002 Equity Plan"), authorizing a total of 2,500,000 shares for future issuance to the employees, consultants and directors of the Company and its affiliates. The terms of the 2002 Equity Plan are similar to the terms of the Equity Plan.

The 2002 Equity Plan provides (i) that non-employee directors are eligible for grants under the 2002 Equity Plan, (ii) that automatic grants of options to non-employee directors (other than a

NOTE 10. EMPLOYEE BENEFIT PLANS (Continued)

Chairman of the Board) be made on his or her election or re-election to the Board of Directors, such options to be exercisable for 7,500 shares of each year in the term of office to which such director is elected or re-elected, and having an exercise price equal to the opening price on the date of grant, commencing with the first election or re-election of a non-employee director in 2001 and (iii) that automatic grants of options be made to a non-employee Chairman of the Board on election or re-election to the Board of Directors, such options to be exercisable for 15,000 shares for each year in term of office to which such director is elected or re-elected, and having an exercise price equal to the opening price on the date of grant.

Under both the Equity Plan and the 2002 Equity Plan, an option's maximum term is ten years and it vests ratably 20% on the date of issuance and 20% thereafter on the anniversary of the grant.

A summary of the status of the Company's stock option plans as of December 28, 2003, December 29, 2002 and December 30, 2001 and changes during the years ending on those dates is presented below:

	Shares	Weighted Average Exercise Price
Balance at December 31, 2000	2,454,905	$10.35
Granted at Fair Value	1,124,333	$ 6.46
Exercised	(347,554)	$ 5.73
Cancelled	(1,078,240)	$11.16
Balance at December 30, 2001	2,153,444	$ 8.68
Granted at Fair Value	1,068,320	$ 3.38
Exercised	(750)	$ 4.56
Cancelled	(42,795)	$11.68
Balance at December 29, 2002	3,178,219	$ 6.95
Granted at Fair Value	896,575	$ 1.66
Exercised	(8,020)	$ 1.35
Cancelled	(284,566)	$ 6.47
Balance at December 28, 2003	3,782,208	$ 5.73

At December 28, 2003, December 29, 2002 and December 30, 2001, there were 2,230,035, 1,804,885 and 1,298,463 shares exercisable at a weighted average exercise price of $7.1611, $7.9062 and $8.2781, respectively.

NOTE 10. EMPLOYEE BENEFIT PLANS (Continued)

The following table summarizes information about stock options outstanding at December 28, 2003:

Range of Exercise Prices	Number Outstanding	Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
$ 0.81 - $1.21	88,500	8.71	$ 0.96	46,100	$ 0.98
$ 1.25 - $1.45	758,775	9.13	$ 1.45	155,755	$ 1.45
$ 1.50 - $3.57	265,680	7.07	$ 2.70	151,420	$ 2.69
$ 3.62 - $3.80	814,190	8.14	$ 3.79	322,516	$ 3.79
$ 3.82 - $5.03	499,380	6.80	$ 4.78	374,596	$ 4.74
$ 5.25 - $8.00	694,253	4.78	$ 7.23	571,693	$ 7.09
$ 8.09 - $17.31	558,980	5.42	$11.54	522,395	$11.24
$17.75 - $37.75	102,450	6.57	$27.69	85,560	$27.68
$ 0.81 - $37.75	3,782,208	7.04	$ 5.73	2,230,035	$ 7.16

At December 28, 2003, 949,915 shares were available for grant.

Under the Purchase Plan, 1,300,000 shares of common stock were reserved for the grant of purchase rights to employees in one or more offerings in accordance with provisions to be established by a committee of the Board of Directors prior to commencement of any offering period. Participants may purchase shares of common stock at not less than 85% of the lower of the market value at the beginning of each offering or on the purchase date. Purchase dates occur every three months for a period of two years from the offering date. Participants may not carry over balances from one purchase date to the next. Offering dates occur every six months.

The Company, in December 2001, issued 22,500 shares to a Director for consulting services considered to be outside the scope of his customary services as a member of the Company's Board of Directors. The valuation of these options was determined to be $71,000 using the Black-Scholes option pricing model. Since the options were fully vested on the date of grant, the compensation expense of $71,000 for these Director options was recognized in full during 2001.

During 2002, the Company issued a total of 18,000 options to four outside consultants. The valuation of these options was determined to be $40,000 using the Black-Scholes option pricing model. Since the options were fully vested on the date of grant, the compensation expense of $40,000 for these options was recognized in full during 2002.

In May 2002, the shareholders voted to amend, restate and rename the Purchase Plan as the 2002 Employee Stock Purchase Plan (as amended and restated the "2002 Purchase Plan"). Under the 2002 Purchase Plan, 600,000 additional shares were authorized for future issuance. The amended terms of the 2002 Purchase Plan are substantially similar to the terms of the Purchase Plan. No shares of common stock remained available for issuance under the 2002 Purchase Plan as of December 28, 2003. The purchases of common stock under the 2002 Purchase Plan during fiscal 2003 totaled 381,429 shares at an aggregate purchase price of approximately $475,000 and during fiscal 2002 totaled 337,392 shares at an aggregate purchase price of approximately $454,000. No compensation expense has been recorded related to the 2002 Purchase Plan. In December 2002, the Company suspended all new offerings pending the shareholder approval for additional shares in 2003. The ongoing offering from July 1, 2002 continued until there were no shares remaining to cover the purchases.

NOTE 10. EMPLOYEE BENEFIT PLANS (Continued)

In May 2003, the shareholders approved the 2003 Employee Stock Purchase Plan (the "2003 Purchase Plan"). Under the 2003 Purchase Plan, 750,000 additional shares were authorized for future issuance. A total of 735,564 shares of common stock remained available for issuance under the 2003 Plan as of December 28, 2003. Under the 2003 Purchase Plan, the Compensation Committee has established separate six-month offerings every six months, with purchase dates every three months.

401(k) Plan

All employees of the Company, subject to certain eligibility requirements, can participate in the Company's defined contribution plan. Currently, the Company may match up to 50% of each participating employee's contributions to the plan to a maximum of 3% of salary. The Company may also contribute an additional 2% of each employee's salary as a retirement contribution. All contributions are at the discretion of the Board of Directors. Expense recognized under this plan was approximately $228,000, $349,000 and $243,000 for the fiscal years ended December 28, 2003, December 29, 2002 and December 30, 2001, respectively.

NOTE 11. INCOME TAXES

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using future expected enacted rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized.

The income tax (benefit) provision from continuing operations consisted of the following:

	2003	2002	2001
Deferred:			
Federal	$(9,666)	$(9,177)	$(6,783)
State	(1,079)	(1,587)	(641)
Foreign	(81)		
Change in Valuation Allowance	10,826	10,764	7,424
Total Deferred	$ —	$ —	$ —

A reconciliation of the U.S. federal statutory tax rate to the effective tax rate is as follows:

	Fiscal Years Ended		
	December 28, 2003	December 29, 2002	December 30, 2001
Federal tax expense (benefit)	(34.0)%	(34.0)%	(34.0)%
State taxes—net	(4.3)	(7.7)	(3.5)
Research and development tax credits	(1.3)	(3.6)	(4.9)
Other	2.9	1.6	1.6
Change in valuation allowance	36.7	43.7	40.8
Effective tax rate	0%	0%	0%

The components of the deferred tax assets and liabilities at December 28, 2003 and December 29, 2002, respectively, are as follows (dollars in thousands):

	December 28, 2003	December 29, 2002
Deferred Tax Assets/(Liabilities):		
Advance payments	$ 130	$ 257
Accrued compensation	472	476
Other accruals	194	293
Tax credits	4,548	4,434
Net operating loss carryforwards	60,476	49,800
Capitalized research and development expenses	7,873	7,169
Depreciation	(1,239)	(801)
Total deferred tax asset	72,454	61,628
Valuation allowance	(72,454)	(61,628)
	$ —	$ —

As of December 28, 2003, the Company had federal net operating loss and research and experimentation credit carryforwards of approximately $162 million and $3.1 million, respectively, which may be available to offset future federal income tax liabilities. These carryforwards expire at various dates starting in 2004 and going through 2023. As of December 28, 2003, GTC's foreign subsidiaries had NOL carryforward of $241,000, which does not expire. The Company has recorded a deferred tax

asset of approximately $4.8illion reflecting the benefit of deductions from the exercise of stock options. This deferred asset has been fully reserved until it is more likely than not that the benefit from the exercise of stock options will be realized. The benefit from this $4.8 million deferred tax asset will be recorded as a credit to additional paid-in capital if and when realized. As required by Statement of Financial Accounting Standards No. 109, management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating loss and research and experimentation credit carryforwards. Management has determined that it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets and, as a result, a valuation allowance of approximately $72.5 million has been established at December 28, 2003.

Ownership changes, as defined in the Internal Revenue Code, may have limited the amount of net operating loss carryforwards that can be utilized annually to offset future taxable income. Subsequent ownership changes could further affect the limitation in future years.

NOTE 12. GEOGRAPHICAL INFORMATION

Net revenues from external customers are based on the location of the customer.

Geographic information for net revenues from external customers, by fiscal year, is presented in the table below:

	United States	Japan	Europe	Total
2003	$9,759	$ 5	$ —	$ 9,764
2002	8,447	6	1,926	10,379
2001	8,913	31	4,796	13,740

Of the Company's long-lived assets, $8.7 million of intangible assets are located in an offshore subsidiary and the remaining $2.4 million are located in the United States.

Geographic information for long lived assets, by fiscal year, is presented in the table below:

	United States	United Kingdom	New Zealand	Total
2003	$19,065	$5,638	$794	$25,497
2002	19,231	2,554	—	21,785

NOTE 13. UNAUDITED RESULTS OF QUARTERLY OPERATIONS

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2003				
Revenue	$ 1,744	$ 4,111	$ 2,164	$ 1,745
Operating profit (loss)	(7,393)	(6,008)	(7,606)	(8,530)
Net loss	(7,393)	(6,008)	(7,606)	(8,530)
Net loss per share—basic and diluted	(0.27)	(0.21)	(0.25)	(0.27)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2002				
Revenue	$ 3,845	$ 3,167	$ 1,827	$ 1,540
Operating loss	(4,566)	(6,493)	(6,970)	(6,291)
Net loss	(4,566)	(6,493)	(6,970)	(6,291)
Net loss per share—basic and diluted	(0.15)	(0.23)	(0.25)	(0.23)

NOTE 14. ARRANGEMENTS WITH GENZYME CORPORATION

From the Company's inception, certain facilities and support services, including both research and administrative support, have been provided by Genzyme. For these services, the Company was charged $3,514,851, $3,338,598 and $2,478,000 for the fiscal years ended December 28, 2003, December 29, 2002 and December 30, 2001, respectively. These charges, which are set by Genzyme, represent an allocation of the Company's proportionate share of Genzyme's overhead costs using formulae which the Company's management believes are reasonable based upon the Company's use of the facilities and services. Also included in this amount are other costs for all periods presented, including payroll costs that are directly attributable to the Company and have been paid by Genzyme and charged to the Company.

Equity Position

Genzyme is the largest single shareholder of the Company, holding 4,924,919 shares of Common Stock as of December 28, 2003, which represents approximately 15% of the outstanding Common Stock. Genzyme also holds four common stock purchase warrants exercisable for 145,000, 288,000, 55,833 and 29,491 shares of GTC Common stock at prices of $2.84, $4.88, $6.30 and $6.30 per share, respectively, which were the market prices of the Common Stock at the time the respective Genzyme warrants were issued. The expiration dates of these warrants range from July 2005 through November 2009. All of the shares held by Genzyme (including shares issuable on exercise of Genzyme warrants) are entitled to registration rights. Genzyme owns approximately 17% of the Company's Common Stock on a fully diluted basis.

On April 4, 2002, the Company bought back 2.82 million shares of the Company's Common Stock from Genzyme which was recorded as treasury stock. The Company purchased the shares for an aggregate consideration of approximately $9.6 million, consisting of approximately $4.8 million in cash and a promissory note to Genzyme for the remaining $4.8 million, as described in Note 8. The Company's Common Stock was valued at $3.385 per share in this transaction, using the simple average of the high and low transaction prices quoted on the NASDAQ National Market on the previous trading day. Genzyme agreed to a 24-month lock-up provision on their remaining 4.92 million shares of the Company's Common Stock, which represented approximately 15% of the Company's outstanding shares. The lock-up provision will be released before April 2004 if the simple average of the prices of the Company's daily high and low stock trades, as reported on the NASDAQ National Market, exceeds $12.00 per share for 20 consecutive trading days.

The $4.8 million promissory note bears interest at the LIBOR plus 1% (LIBOR was at 1.17% at December 28, 2003). The principal is payable in two installments: 50% on April 3, 2005 and the remaining 50% on April 3, 2006. This note is collateralized by a subordinated lien on all the assets of the Company except intellectual property.

In April 1993, the Company entered into several agreements under which Genzyme has agreed to provide various services, facilities and funding to the Company. Those still in effect are described below:

Services Agreement

Under the Services Agreement, the Company receives certain basic laboratory and administrative support services in exchange for a fixed monthly payment ($12,000 per month from January through July 2003 and $3,000 per month from August through December 2003). The monthly fee is adjusted annually based on the services to be provided and changes in Genzyme's cost of providing the services. If the Company requests additional services from Genzyme, the Company has agreed to pay Genzyme fully allocated costs of those services. The Services Agreement is automatically renewed each year thereafter unless terminated by either party not less than 90 days prior to the end of any annual period.

Under the Services Agreement, the Company made payments of $101,000, $1,012,000 and $905,000 for the fiscal years ended December 28, 2003, December 29, 2002 and December 30, 2001, respectively, and is committed to make a minimum annual payment of approximately $9,000 in 2004.

Sublease Agreement

Under the Sublease Agreement, the Company has leased certain laboratory, research and office space from Genzyme in exchange for fixed monthly rent payments which approximate the estimated current rental value for such space. In addition, the Company reimburses Genzyme for its pro rata share of appropriate facilities' operating costs such as maintenance, cleaning, utilities and real estate taxes. The sublease is automatically renewed each year and renewals are subject to earlier termination of the sublease by either party after the initial five-year term. Under the Sublease Agreement, the Company made payments for the fiscal years ended December 28, 2003, December 29, 2002 and December 30, 2001, of $356,000, $281,000 and $368,000, respectively, and is committed to make a minimum annual rental payment of approximately $360,000 in 2004.

Technology Transfer Agreement

Under the Technology Transfer Agreement dated May 1, 1993, Genzyme transferred substantially all of its transgenic assets and liabilities to the Company, assigned its relevant contracts and licensed to the Company technology owned or controlled by it and relating to the production of recombinant proteins in the milk of transgenic animals (the "Field") and the purification of proteins produced in that manner. The license is worldwide and royalty free as to Genzyme, although the Company is obligated to Genzyme's licensors for any royalties due them. As long as Genzyme owns less than 50% of the Company, Genzyme may use the transferred technology, or any other technology it subsequently acquires relating to the Field, for internal purposes only without any royalty obligation to the Company.

Research and Development Agreement

Pursuant to a Research and Development Agreement dated May 1, 1993, Genzyme and the Company each agreed to provide to the other research and development services relating, in the case of the Company, to transgenic production of recombinant proteins and, in the case of Genzyme, to the purification of such proteins. Each company receives payments from the other equal to the performing party's fully allocated cost of such services, which can be no less than 80% of the annual budgets established by the parties under the agreement on a month to month basis, plus, in most cases, a fee equal to 10% of such costs. The Company also receives research and development services from Genzyme, for which it incurred costs of $0, $17,000 and $43,000 in 2003, 2002 and 2001, respectively. The agreement expired on December 31, 1998 and the parties are continuing under this agreement on a month-to-month basis.

In addition, on July 31, 2001, the Company and Genzyme entered in to a services agreement pursuant to which Genzyme may perform manufacturing, research and development and regulatory services for the ATryn® program. Payments by the Company to Genzyme are on a cost plus 5% basis. Related costs of $2,934,000, $2,090,000 and $1,162,000 were incurred in 2003, 2002 and 2001, respectively. These costs included amounts for clinical and regulatory support provided by Genzyme BV to GTC for the filing of the MAA for submission to market ATryn® in Europe.

In June of 2003, the Company and Genzyme entered into a Services Agreement under which the Company shall provide certain services to Genzyme for which Genzyme shall pay the Company monthly based on a rate agreed upon by both the Company and Genzyme. Services to be performed under this agreement will continue until December 31, 2004, unless earlier terminated per the terms of the agreement. Any additional one year terms shall be only upon mutual written agreement by the Company and Genzyme, to be agreed upon at least three months prior to expiration. Included in the

Company's accounts receivable balance at December 28, 2003 was approximately $117,000 due from Genzyme related to services provided under this agreement.

ATIII LLC Re-Acquisition

In 1997, the Company and Genzyme Corporation established the ATIII LLC joint venture for the marketing and distribution rights of ATryn® in all territories other than Asia. In July 2001, the Company reacquired Genzyme's ownership interest in the joint venture in exchange for a royalty to Genzyme based on the Company's sales of ATryn®, if any, commencing three years after the first commercial sale, up to a cumulative maximum of $30 million.

Cambrex Bio Science MA, Inc. ("Cambrex")

In August 2002, the Company and Cambrex entered into a service agreement for Cambrex to provide certain Technology Services relating to biopharmaceutical drug product process transfer, process validation, purification, quality control and quality assurance. As of December 28, 2003, the Company had paid approximately $4.4 million to Cambrex and had accrued approximately $62,000 for services rendered under the contract. The amount paid to Cambrex has either been capitalized as part of the Company's fixed assets or capitalized as part of the Company's inventory (see Note 2).

Malaria Vaccine Contract

The NIAID has funded a contract for the development and production of clinical grade production of MSP-1, as a malaria vaccine. The development work is being performed under the existing NIAID Contract No. NO1-A1-05421 managed by Science Applications International Corporation. The scope of work includes developing founder goats that express the MSP-1 antigen in their milk as well as the downstream purification process and final product formulation. The approved scope of work also includes the submittal of an Investigational New Drug application to the FDA. GTC's portion of this project will be supported completely with Federal funds amounting to at least $4.9 million to be paid through September 2007, of which $2.9 million was paid during 2003 and a majority of the remainder is expected to be paid during 2004.

NOTE 15. JOINT VENTURES

Taurus hSA LLC

In late 2002, Fresenius AG and GTC restructured their relationship for the therapeutic blood expander market into a joint venture, called Taurus hSA LLC or the Taurus Joint Venture, to include the development of rhSA program as an excipient. The Taurus Joint Venture will manage development of GTC's rhSA for both the excipient and blood expander markets. GTC currently has a 55% interest in the joint venture. Each party has the right, but not the obligation, to make future contributions to the Taurus Joint Venture. The joint venture structure allows the development of the excipient market with the potential to attract additional marketing or strategic partners that may also assist with the financing of the joint venture. Ownership interests will be adjusted based on future levels of financial participation from existing and new partners. The Company is engaged in ongoing discussions with third parties to obtain further financing for the Taurus Joint Venture and the Company has also developed alternative plans to advance the joint venture using its existing resources with limited external financing. GTC and Fresenius made available all relevant commercial licenses, manufacturing and marketing rights, and intellectual property to enable the joint venture to operate worldwide in both the excipient and blood expander markets. The existence of the Taurus Joint Venture is perpetual unless terminated or dissolved earlier in accordance with the terms of the agreement. Upon any liquidation, sale or other disposition of all, or substantially all of the assets of the Taurus Joint Venture, and after the payment of debts and liabilities, expenses of liquidation and any reserves for unforeseen

liabilities or in-kind distributions, the net proceeds would be applied and distributed first to Fresenius and then to the Company, each according to its percentage interest. Each member would also have reversion rights to any intellectual property it contributes to the Taurus Joint Venture. The Company consolidates the Taurus Joint Venture on GTC's financial statements for financial reporting purposes.

NOTE 16. OTHER RELATED PARTY TRANSACTIONS

Consulting Agreement

In July 2002, the Company entered into a consulting agreement in the amount of $25,000 with a spouse of a Senior Vice President of the Company. The scope of work related to the evaluation of potential market opportunities for rhSA in several areas. As of December 28, 2003, the Company had paid $25,000 to the consultant for services rendered and the contract has been completed. Management believes this was an arm's-length transaction and the Board of Directors is aware of the agreement.

Board of Directors

Other than the Chairman of the Board, all Directors who are not employees of the Company receive an annual retainer of $12,000, payable quarterly. Members of the standing committees also receive an annual retainer of $2,000, payable quarterly and the Chairman of each standing committee receives an additional annual retainer of $3,000, payable quarterly. Members of the Board receive a per meeting fee of $500 and an additional $500 per standing committee meeting that is not in conjunction with the Board meeting. These fees are reduced to $250 for participation via conference call. One Director, who also served as Chairman of the Board, received $43,200 in 2001 as compensation for consulting services. The Company, in December 2001, issued 22,500 shares to a Director for services considered to be outside the customary scope of his services as a member of the Company's Board of Directors. Executive Officers of the Company who are also Directors do not receive additional compensation for their service as Directors.

NOTE 17. DISCONTINUED OPERATIONS

In February 2001, the Company completed the sale of Primedica to Charles River. Accordingly, Primedica is reported herein as a discontinued operation.

	December 31, 2000	January 2, 2000
Revenues from discontinued operations before taxes	$71,986	$54,959
Provision for state taxes	247	320
Revenues from discontinued operations, net of taxes	$71,739	$54,639

NOTE 18. SUBSEQUENT EVENT

Restructuring

In February 2004, the Company announced a restructuring of its organization to control costs and to support its focus on clinical development and commercialization of its internal pipeline of proprietary products and its portfolio of external programs. Under the restructuring plan, headcount was reduced by approximately 20% from 159 to 127 full time equivalent employees. A restructuring charge of approximately $950,000 will be recorded in the first quarter of 2004.

REPORT OF INDEPENDENT AUDITORS ON FINANCIAL STATEMENT SCHEDULE

To the Board of Directors
of GTC Biotherapeutics, Inc.:

Our audits of the consolidated financial statements referred to in our report dated March 4, 2004 appearing in the 2003 Annual Report to Shareholders of GTC Biotherapeutics, Inc. (which report and consolidated financial statements are incorporated by reference in this Annual Report on Form 10-K) also included an audit of the financial statement schedule listed in Item 15(a)(2) of this Form 10-K. In our opinion, this financial statement schedule presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements.

PricewaterhouseCoopers LLP
Boston, Massachusetts
March 4, 2004

Schedule II—Supplemental Valuation and Qualifying Accounts

Years ended December 28, 2003, December 29, 2002 and December 30, 2001:

Deferred tax asset valuation allowance

	Balance at Beginning of Period	Charges/(Benefits) to Costs and Expenses	Balance at End of Period
December 28, 2003	$61,628	10,826	$72,454
December 29, 2002	$50,864	10,764	$61,628
December 30, 2001	$52,384	(1,520)	$50,864

Allowance for unbilled receivable and doubtful accounts

	Balance at Beginning of Period	Charges/(Recoveries) to Costs and Expenses	Write-offs	Balance at End of Period
December 28, 2003	$ —	—	—	$ —
December 29, 2002	$316	(316)	—	$ —
December 30, 2001	$316	—	—	$316

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities and Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in Framingham, Massachusetts on the 8th day of March 2004.

GTC BIOTHERAPEUTICS, INC.

By: /s/ GEOFFREY F. COX

Geoffrey F. Cox
Chairman of the Board, President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934 this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the date indicated.

Signature	Title	Date
/s/ GEOFFREY F. COX Geoffrey F. Cox	Chairman of the Board, President and Chief Executive Officer (Principal Executive Officer)	March 8, 2004
/s/ JOHN B. GREEN John B. Green	Chief Financial and Accounting Officer (Principal Financial and Accounting Officer)	March 8, 2004
/s/ JAMES A. GERAGHTY James A. Geraghty	Director	March 8, 2004
/s/ ROBERT W. BALDRIDGE Robert W. Baldridge	Director	March 8, 2004
/s/ ALAN W. TUCK Alan W. Tuck	Director	March 8, 2004
/s/ FRANCIS J. BULLOCK Francis J. Bullock	Director	March 8, 2004
/s/ PAMELA W. MCNAMARA Pamela W. McNamara	Director	March 8, 2004
/s/ MARVIN L. MILLER Marvin L. Miller	Director	March 8, 2004

EXHIBIT INDEX
to Form 10-K for the Year Ended December 28, 2003

Exhibit No.	Description
10.16.4	Loan Modification Agreement between GTC and SVB dated as of January 25, 2004. Filed herewith.
10.21.2*	First Amendment, dated as of December 11, 2002, to the Agreement Relating to the Production of Clarified Goat Milk Containing Recombinant Human Alpha Fetoprotein by and between GTC and Merrimack, Inc., dated as of June 27, 2002. Filed herewith.
21	List of Subsidiaries. Filed herewith.
23	Consent of PricewaterhouseCoopers LLP. Filed herewith.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith.
32	Certifications pursuant to 18 U.S.C. Section 1350. Filed herewith.
99	Important Factors Regarding Forward-Looking Statements. Filed herewith.

The following exhibits are incorporated herein by reference.

Exhibit No.	Description
3.1.1	Restated Articles of Organization of GTC, filed with the Secretary of the Commonwealth of Massachusetts on December 27, 1993. Filed as Exhibit 3.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 1993 (File No. 0-21794).
3.1.2	Articles of Amendment to the Restated Articles of Organization filed with the Secretary of the Commonwealth of Massachusetts on October 3, 1994. Filed as Exhibit 3.1.2 to GTC's Annual Report on Form 10-K for the year ended December 28, 1997 (File No. 0-21794).
3.1.3	Articles of Amendment to the Restated Articles of Organization filed with the Secretary of Commonwealth of Massachusetts on June 26, 1997. Filed as Exhibit 3 to GTC's Quarterly Report on Form 10-Q for the quarter ended June 29, 1997 (File No. 0-21794).
3.1.4	Articles of Amendment to the Restated Articles of Organization of the Company filed with the Secretary of the Commonwealth of Massachusetts on June 1, 2000. Filed as Exhibit 4.1.5 to the Company's Registration Statement on Form S-8 filed with the Commission on June 2, 2000 (File No. 333-38490).
3.1.5	Certificate of Vote of Directors Establishing a Series of a Class of Stock of GTC and designating the Series C Junior Participating Cumulative Preferred Stock. Filed as Exhibit 3.1 to GTC's Current Report on Form 8-K filed on June 1, 2001 (File No. 0-21794).

Exhibit No.	Description
3.1.6	Articles of Amendment to the Restated Articles of Organization of the Company filed with the Secretary of the Commonwealth of Massachusetts on May 31, 2002. Filed as Exhibit 3.1 to the GTC's Current Report on Form 8-K filed on June 3, 2002 (File No. 0-21794).
3.2	By-Laws of the Company, as amended. Filed as Exhibit 3.1 to the Company's Form 10-Q for the quarter ended July 4, 1999 (File No. 0-21794).
4.1	Specimen Common Stock Certificate. Filed as Exhibit 4.1 to GTC's Registration Statement on Form S-1 (File No. 33-62782) (the "GTC S-1").
4.2	Warrant to Purchase Common Stock, dated July 3, 1995, issued to Genzyme Corporation ("Genzyme"). Filed as Exhibit 10.5 to GTC's Quarterly Report on Form 10-Q for the period ended July 2, 1995 (File No. 0-21794).
4.3	Warrant to Purchase Common Stock, dated as of June 26, 1997, issued to Government Land Bank d/b/a The MassDevelopment. Filed as Exhibit 4 to GTC's Quarterly Report on Form 10-Q for the period ended June 29, 1997 (File No. 0-21794).
4.4	Warrant to Purchase Common Stock, dated as of December 28, 1998, issued to Genzyme. Filed as Exhibit 4.11 to GTC's Annual Report on Form 10-K for the year ended January 3, 1999 (File No. 0-21794) and incorporated herein by reference.
4.5	Warrant to Purchase Common Stock, dated November 12, 1999, issued to Genzyme. Filed as Exhibit 8 to Genzyme's Amendment No. 6 to Schedule 13D (File No. 005-46637) filed with the Commission on November 24, 1999.
4.6	Warrant to Purchase Common Stock, dated November 12, 1999, issued to Genzyme. Filed as Exhibit 9 to Genzyme's Amendment No. 6 to Schedule 13D (File No. 005-46637) filed with the Commission on November 24, 1999.
4.7	Form of Common Stock Purchase Warrant. Filed as Exhibit 10.2 to GTC's Current Report on Form 8-K filed on August 4, 2003 (File No. 0-21794).
4.8	Registration Rights Agreement between GTC and certain Stockholders named therein. Filed as Exhibit 10.53 to GTC's Annual Report on Form 10-K for the year ended December 28, 1997 (File No. 0-21794).
4.9	Shareholder Rights Agreement, dated as of May 31, 2001, between GTC and American Stock Transfer and Trust Company, as Rights Agent. Filed as Exhibit 4.1 to GTC's Current Report on Form 8-K filed on June 1, 2001 (File No. 0-21794).
4.10	Registration Rights Agreement, dated as of July 30, 2003, between GTC and the Purchasers named therein. Filed as Exhibit 10.3 to GTC's Current Report on Form 8-K filed on August 4, 2003 (File No. 0-21794).
10.1*	Technology Transfer Agreement between GTC and Genzyme, dated as of May 1, 1993. Filed as Exhibit 2.1 to the GTC S-1.
10.2	Research and Development Agreement between GTC and Genzyme, dated as of May 1, 1993. Filed as Exhibit 10.1 to the GTC S-1.
10.3	Services Agreement between GTC and Genzyme, dated as of May 1, 1993. Filed as Exhibit 10.2 to the GTC S-1 and incorporated herein by reference.
10.4	Sublease Agreement between GTC and Genzyme, dated as of May 1, 1993. Filed as Exhibit 10.3 to the GTC S-1.

Exhibit No.	Description
10.5	License Agreement between GTC and Genzyme, as successor to IG Laboratories, Inc., dated as of May 1, 1993. Filed as Exhibit 10.4 to the GTC S-1.
10.6.1*	Cooperation and Licensing Agreement between GTC and Tufts University, dated September 6, 1988, as amended through May 13, 1993 (the "Cooperation and Licensing Agreement"). Filed as Exhibit 10.18 to GTC's Annual Report on Form 10-K for the year ended December 31, 1994 (File No. 0-21794).
10.6.2	Amendment No. 7, dated April 1, 1993, to Cooperation and Licensing Agreement. Filed as Exhibit 10.6 to GTC's Quarterly Report on Form 10-Q for the period ended October 1, 1995 (File No. 0-21794) (the "GTC October 1995 10-Q").
10.6.3	Amendment No. 8, dated October 21, 1993, to Cooperation and Licensing Agreement. Filed as Exhibit 10.7 to the GTC October 1995 10-Q.
10.6.4*	Amendment No. 9, dated December 1, 1993, to Cooperation and Licensing Agreement. Filed as Exhibit 10.8 to the GTC October 1995 10-Q.
10.6.5	Amendment No. 10, dated November 1, 1993, to Cooperation and Licensing Agreement. Filed as Exhibit 10.9 to the GTC October 1995 10-Q.
10.6.6	Amendment No. 11, dated May 25, 1995, to Cooperation and Licensing Agreement. Filed as Exhibit 10.10 to the GTC October 1995 10-Q.
10.6.7*	Amendment No. 14, effective as of September 6, 1997, to Cooperation and Licensing Agreement. Filed as Exhibit 10.6.7 to GTC's Annual Report on Form 10-K for the year ended December 29, 2002 (File No. 0-21794) (the "GTC 2002 10-K").
10.6.8*	Amendment No. 16, effective as of September 6, 2000, to Cooperation and Licensing Agreement. Filed as Exhibit 10.6.8 to the GTC 2002 10-K.
10.6.9*	Amendment No. 18, effective as of September 6, 2001, to Cooperation and Licensing Agreement. Filed as Exhibit 10.6.9 to the GTC 2002 10-K.
10.7*	United States Patent No. 4,873,191 Sublicense Agreement between Xenogen Corporation (formerly DNX, Inc.) and Genzyme Regarding Transgenic Experimental Animals and Transgenic Mammary Production Systems, dated February 1, 1990; and letter of amendment, dated April 19, 1991. Filed together as Exhibit 10.3 to GTC's Amended Quarterly Report on Form 10-Q for the period ended June 29, 2003 (File No. 0-21794) (the "GTC 2003 June 10-Q/A").
10.8	Lease dated March 26, 1999 between GTC and NDNE 9/90 Corporate Center LLC. Filed as Exhibit 10.1 to the GTC July 1999 10-Q.
10.9	Hazardous Materials Indemnity Agreement, December 28, 1998, between the GTC and Genzyme. Filed as Exhibit 10.28.5 to GTC's Annual Report on Form 10-K for the year ended January 2, 2000.
10.10*	License Agreement by and among GTC, Pharming Group N.V. and Pharming Intellectual Property B.V., dated June 21, 2002. Filed as Exhibit 10.3.1 to the GTC's Quarterly Report on Form 10-Q for the period ended June 30, 2002 (File No. 0-21794) filed on August 2, 2002 (the "GTC June 2002 10-Q").
10.11*	Amended and Restated License Agreement by and among Pharming Group, N.V. and Pharming Intellectual Property B.V. and the Company dated June 21, 2002. Filed as Exhibit 10.3.2 to the GTC June 2002 10-Q.

Exhibit No.	Description
10.12*	Exclusive Development and License Agreement, dated as of June 8, 1999, between GTC and Advanced Cell Technology, Inc. Filed as Exhibit 10.21 to GTC's Annual Report on Form 10-K for the year ended December 30, 2001 (File No. 0-21794).
10.13.1*	Purchase Agreement between GTC and Genzyme, dated as of July 31, 2001. Filed as Exhibit 10.1 to GTC's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001 (File No. 0-21794) (the "GTC September 2001 10-Q").
10.13.2*	Services Agreement between GTC and Genzyme, dated as of July 31, 2001. Filed as Exhibit 10.2 to the GTC September 2001 10-Q.
10.13.3	Collaboration Agreement among the Company, Genzyme Corporation, and ATIII LLC dated as of January 1, 1998. Filed as Exhibit 10.2 to the GTC 2003 10-Q/A.
10.13.4	Amended and Restated Collaboration Agreement among GTC, Genzyme and ATIII LLC, dated as of July 31, 2001. Filed as Exhibit 10.2 to the GTC September 2001 10-Q.
10.14	Letter Agreement by and between GTC and Genzyme, dated as of April 4, 2002. Filed as Exhibit 10.4 to the GTC's Quarterly Report on Form 10-Q for the period ended March 31, 2002 (File No. 0-21794) filed on May 1, 2002 (the "GTC March 2002 10-Q").
10.15	Subordinated Secured Promissory Note in the amount of $4,772,850 executed by GTC made to Genzyme, dated as of April 4, 2002. Filed as Exhibit 10.5 to the GTC March 2002 10-Q.
10.16.1*	Loan and Security Agreement by and between GTC and Silicon Valley Bank, dated as of March 27, 2002. Filed as Exhibit 10.1 to the GTC March 2002 10-Q.
10.16.2	Pledge Agreement by and between GTC and Silicon Valley Bank, dated as of March 27, 2002. Filed as Exhibit 10.2 to the GTC March 2002 10-Q.
10.16.3	Negative Pledge Agreement by and between GTC and Silicon Valley Bank, dated as of March 27, 2002. Filed as Exhibit 10.3 to the GTC March 2002 10-Q.
10.17*	Sublease Agreement by and between the Company and Antigenics, Inc., dated July 16, 2002. Filed as Exhibit 10.4 to the GTC June 2002 10-Q.
10.18*	Limited Liability Company Agreement of Taurus hSA LLC dated as of December 20, 2002. Filed as Exhibit 10.20.1 to GTC's 2002 10-K.
10.19*	Contribution and License Agreement by and between GTC and Taurus hSA LLC dated as of December 20, 2002. Filed as Exhibit 10.20.2 to GTC's 2002 10-K.
10.20*	Service Agreement by and between GTC and Cambrex Bio Science MA, Inc. dated as of August 20, 2002. Filed as Exhibit 10.21 to GTC's 2002 10-K and incorporated herein by reference.
10.21.1*	Agreement Relating to the Production of Clarified Goat Milk Containing Recombinant Human Alpha Fetoprotein by and between GTC and Merrimack Pharmaceuticals, Inc., dated as of June 27, 2003 (the "Merrimack Agreement"). Filed as exhibit 10 to GTC's 2003 June Form 10-Q/A and incorporated herein by reference.
10.22.1**	GTC Amended and Restated 1993 Equity Incentive Plan. Filed as Exhibit 10.7 to GTC's Annual Report on Form 10-K for the year ended December 30, 2001 (File No. 0-21794).
10.22.2**	GTC 2002 Equity Incentive Plan. Filed as Exhibit 10.6 to GTC's Amended Quarterly Report on Form 10-Q for the period ended March 31, 2002 (File No. 0-21794)

Exhibit No.	Description
10.23**	GTC 2002 Employee Stock Purchase Plan. Filed as Exhibit 10.7 to the GTC March 2002 10-Q.
10.24	GTC Form of Confidential and Proprietary Information Agreement signed by GTC employees. Filed as Exhibit 10.9 to the GTC S-1.
10.25	GTC Form of Agreement Not to Compete. Filed as Exhibit 10.10 to the GTC S-1.
10.26	Form of Indemnification Agreement between GTC and its directors. Filed as Exhibit 10.12 to GTC's Annual Report on Form 10-K for the year ended December 31, 1994 (File No. 0-21794). Such agreements are materially different only as to the signing directors and the dates of execution.
10.27**	Employment Agreement, dated as of March 27, 1996, between GTC and Harry Meade. Filed as Exhibit 10.44 to GTC's Quarterly Report on Form 10-Q for the period ended March 31, 1996.
10.28.1**	Amended and Restated Employment Agreement, dated as of August 28, 1997, between GTC and John B. Green. Filed as Exhibit 10.2 to the GTC September 1997 10-Q.
10.28.2**	Amendment No. 1 to Employment Agreement between GTC and John B. Green. Filed as Exhibit 10.3 to GTC's Quarterly Report for the period ended September 27, 1998 (File No. 0-21794).
10.29**	Executive Employment Agreement, dated as of July 18, 2001, between GTC and Geoffrey F. Cox. Filed as Exhibit 10.2 to the GTC September 2001 10-Q.
10.30**	Executive Employment Agreement, dated as of February 9, 2002 between GTC and Paul K. Horan. Filed as Exhibit 10.30 to GTC's 2002 10-K.
10.31**	Management Agreement between GTC and Daniel Woloshen dated as of May 27, 1999. Filed as Exhibit 10.1 to GTC's Quarterly Report on Form 10-Q for the period ended March 30, 2003 (File No. 0-21794) (the "GTC March 2003 10-Q").
10.32**	Management Agreement between GTC and Gregory Liposky dated as of June 14, 2000. Filed as Exhibit 10.2 to the GTC Marc h2003 10-Q.

* Certain confidential information contained in the document has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended, or Rule 24b-2 promulgated under the Securities and Exchange Act of 1934, as amended.

** Indicates a management contract or compensatory plan.

Corporate Information

BOARD OF DIRECTORS

Geoffrey F. Cox, Ph.D.
Chairman of the Board
President and Chief Executive Officer
GTC Biotherapeutics, Inc.

Robert W. Baldridge
Independent Business Consultant
Former CEO and Director of
TSI Corporation

Francis J. Bullock, Ph.D.
Independent Consultant
Former Sr. Vice President of
Research Operations
Schering-Plough Pharmaceutical
Research Division

James A. Geraghty
Senior Vice President
Genzyme Corporation

Pamela W. McNamara
Chief Executive Officer
CRF, Inc.
Former CEO, Arthur D. Little

Marvin L. Miller
Executive Chairman
Onconova Therapeutics, Inc.
Former President and CEO
Nextran, an affiliate of
Baxter Healthcare Corporation

Alan W. Tuck
Partner
Bridgespan Group, a nonprofit
consulting organization

EXECUTIVE OFFICERS

Geoffrey F. Cox, Ph.D.
Chairman of the Board
President and Chief Executive Officer
GTC Biotherapeutics, Inc.

John B. Green, C.P.A.
Senior Vice President
Chief Financial Officer and Treasurer
GTC Biotherapeutics, Inc.

Gregory F. Liposky
Senior Vice President Operations
GTC Biotherapeutics, Inc.

Harry M. Meade, Ph.D.
Senior Vice President Research
and Development
GTC Biotherapeutics, Inc.

Daniel S. Woloshen
Senior Vice President and General
Counsel
GTC Biotherapeutics, Inc.

CORPORATE OFFICES

GTC Biotherapeutics, Inc.
175 Crossing Boulevard
Framingham, MA 01702
(508) 620-9700

TRANSFER AGENT

American Stock Transfer & Trust
Company
59 Maiden Lane
New York, NY 10038
(800) 937-5449
www.amstock.com

The transfer agent is responsible for handling shareholder questions regarding lost stock certificates, address changes and changes of ownership or name in which shares are held.

INDEPENDENT ACCOUNTANTS

PricewaterhouseCoopers LLP
Boston, MA

EXTERNAL LEGAL COUNSEL

Palmer & Dodge LLP
Boston, MA

MARKET FOR COMMON STOCK

Nasdaq National Market System
Trading Symbol: GTCB

SEC FORM 10-K

Copies of the Company's 2003 Annual Report and Form 10-K as filed with the Securities and Exchange Commission may be obtained free of charge by writing to the Company at 175 Crossing Boulevard, Framingham, MA 01702, or by calling (508) 620-9700 x5374.

ANNUAL MEETING

The Annual Meeting of Shareholders will be held on Wednesday, May 26, 2004 at 2:00 p.m. in the Board Room, 33rd floor of the State Street Bank, 225 Franklin Street, Boston, Massachusetts 02110.

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GTC Biotherapeutics