GTC BIOTHERAPEUTICS



## OUR LEADERSHIP POSITION IN TRANSGENIC TECHNOLOGY IS SUSTAINED BY:

- 1 THE MOST ADVANCED PRODUCT IN THE CLINIC
- 3 INTERNAL PRODUCTS IN DEVELOPMENT
- 12 EXTERNAL PARTNERED PROGRAMS

# PRODUCT PORTFOLIO

## Internal Programs

Development Stages

| PRODUCT NAME | PRODUCT TYPE | INDICATION | CELL CULTURE/ PLASMA PRODUCT | TRANSGENIC PRODUCT | PARTNER |
|---|---|---|---|---|---|
| rhATIII | Plasma Protein | Hereditary Deficiency | Marketed | Phase III | In discussions |
| rhATIII | Plasma Protein | Burns | Pilot Study | Development Founder status | In discussions |
| rhSA | Plasma Protein | Excipient | Marketed | Development Founder status | Joint venture |
| rhSA | Plasma Protein | Blood Expander | Marketed | Preclinical Founder status | Joint venture |
| MSP-1 | Vaccine Antigen | Malaria | Not feasible | Transgenic development | NIH - NIAID |

## External Partnerships

| | | | | | |
|---|---|---|---|---|---|
| Remicade® | Monoclonal antibody | Rheumatoid Arthritis<br>Crohn's Disease | Marketed | Preclinical<br>Founder status | Centocor |
| Undisclosed | Monoclonal antibody | Undisclosed | Undisclosed | Undisclosed | Centocor |
| Antegren® | Monoclonal antibody | Neurological<br>Disorders | Phase III<br>clinicals | Preclinical<br>Founder status | Elan<br>Pharmaceuticals |
| Undisclosed | Monoclonal antibody | Undisclosed | Undisclosed | Preclinical<br>Transgenic evaluation | Elan<br>Pharmaceuticals |
| D2E7 | Monoclonal antibody | Rheumatoid Arthritis | Marketed as<br>Humira® | Preclinical<br>Founder status | Abbott<br>Laboratories |
| Undisclosed | Monoclonal antibody | Undisclosed | Undisclosed | Preclinical<br>Founder status | Abbott<br>Laboratories |
| MM1-093<br>(formally ABI.001) | Recombinant protein | Myasthenia Gravis<br>Multiple Sclerosis<br>Rheumatoid Arthritis | Not feasible | Preclinical<br>Founder status entering<br>production for clinical<br>material | Merrimack<br>Pharmaceuticals |
| PRO 542 | Immunoglobulin<br>fusion protein | HIV AIDS | Phase II clinicals | Preclinical<br>Founder status | Progenics<br>Pharmaceuticals |
| 5G1.1 | Monoclonal antibody | Rheumatoid Arthritis<br>& Nephritis | Phase II clinicals | Preclinical<br>Transgenic evaluation | Alexion<br>Pharmaceuticals |
| huN901 | Monoclonal antibody | Small-cell<br>lung cancer | Phase II clinicals | Preclinical<br>Transgenic evaluation | Immunogen |
| CTLA4Ig | Immunoglobulin fusion<br>protein | Rheumatoid<br>Arthritis | Phase II clinicals | Preclinical<br>Founder status | Bristol-Myers<br>Squibb |
| Undisclosed | Immunoglobulin<br>fusion protein | Organ transplant<br>rejection<br>Autoimmune disorders | Phase II clinicals | Preclinical<br>Founder status | Bristol-Myers<br>Squibb |

# TO OUR VALUED SHAREHOLDERS:



The biotechnology industry is going through one of the most difficult periods in its young history as I write this letter. GTC has several strengths in this difficult environment. We have been fortunate to be able to weather these conditions with significant financial resources on our balance sheet. Careful use of resources, in combination with using our operating platform in a service business to support external programs, has enabled us to fund our internal development program while building the infrastructure of the Company.

GTC has two sectors to its core business that we believe bring us some financial advantages while giving us many opportunities to advance programs into commercial products. The first sector is the production, development and commercialization of our own proprietary proteins and the second is a group of external partnerships with pharmaceutical and biotechnology companies who recognize the potential of this technology for the production of their own proprietary proteins. This latter sector of our business offers the potential of establishing both revenue and positive cash flow through milestones and commercial partnerships for therapeutic protein production which can be invested in the development of our own proprietary product portfolio and corporate infrastructure.

**Internal Programs** Our lead product in this group of programs is recombinant human antithrombin III (rhATIII). Antithrombin is an important blood protein that helps manage coagulation and inflammation. Last year we committed to the initiation of a pharmacokinetic study for rhATIII in hereditary deficient (HD) patients and publishing the results before the end of September 2002. I am very pleased to say that GTC accomplished this successfully and on time, enabling the dosing regimen for the efficacy study to be established. GTC began the efficacy study, as promised, before the end of 2002. We anticipate the study being the final clinical trial required before filing for market approval in Europe for rhATIII in HD patients. This trial will include a minimum of 12 patients with hereditary deficiency of antithrombin that are undergoing surgery or childbirth. The endpoint of this study is the prevention of deep vein thrombosis in this challenged group of patients. We plan to complete this study in the second half of 2003 in readiness to submit for marketing approval in Europe in the first half of 2004. We believe that rhATIII presents a major opportunity for GTC when supported by a broad based clinical development program in additional indications.

Our second internal program, recombinant human serum albumin (rhSA) has also made significant progress. We have now established the purification procedures for producing this high quality product from the milk of transgenic cows. In 2002, we renegotiated our agreement with Fresenius AG to establish a joint venture (JV). GTC has a majority ownership in this JV. The JV embraces the concept of initially developing rhSA for the excipient market and then developing the much larger blood expander therapeutic market. Albumin, when used as an excipient, is currently sourced from the human blood supply in significant quantities to formulate and stabilize a range of protein based drugs. The excipient market for rhSA provides an opportunity for the JV to develop commercial sales and revenues over the next two to three years, much sooner than we would otherwise anticipate from pursuing only the blood expander indication, which originally was the primary focus of Fresenius' partnership with GTC. The JV structure also enables us to seek further sources of financing from strategic and financial partners to advance development of the rhSA program.

We will continue to seek further opportunities for expanding our range of proprietary proteins, exploiting the enabling characteristics of our transgenic technology. We expect our malaria vaccine, using the MSP-1 protein as an antigen, will be the next internal program to move into commercial development. This protein has not been able to be expressed in commercially viable quantities in cell culture. However, GTC has been able to achieve significant production of this protein using its transgenic animal technology. This program has been through preclinical studies in a cooperative research arrangement with the National Institute of Allergy and Infectious Diseases (NIAID), which is part of the National Institutes of Health. Recently, the NIAID approved a proposal to fund the development and production of clinical-grade MSP-1. This proposal includes developing founder goats that express the MSP-1 antigen in their milk, downstream purification and final product formulation as well as the submittal of an Investigational New Drug (IND) application to the Food and Drug Administration (FDA). GTC's portion of this project will be supported completely with Federal funds amounting to at least $4.9 million.

**External Partnerships** This sector of our business provides current revenue from the achievement of certain development milestones as well as offering the potential for commercial partnering as these programs progress through clinical trials and into commercial product sales. GTC has the potential to receive revenues both for the production of bulk product using our transgenic technology as well as revenues associated with the downstream purification of product suitable for clinical use and later for commercial production.



In 2002 we made significant progress in our external program portfolio. Towards the end of 2002, GTC entered into a relationship with Merrimack Pharmaceuticals for the production and purification of recombinant human alpha-fetoprotein (rhAFP) using our transgenic platform. This contract is an important demonstration of the enabling value of the transgenic technology in difficult-to-express proteins. Merrimack expects to enter clinical trials with this product, initially for Myasthenia Gravis, in the second half of 2003. GTC's goal in 2003 is to bring at least one additional external program into production for clinical studies as well as initiate new contracts for additional external programs.

**Technology Enhancement** GTC's technology brings the strength of both enabling the commercial development of many proteins that are difficult to express at commercial scale in classic bioreactor based technologies and also provides economic advantages for proteins that require large production volumes. Among examples of difficult-to-express proteins are certain fusion proteins and some blood plasma based proteins, such as in our rhATIII and rhSA programs.

During 2002, we continued to enhance and broaden GTC's technology and capabilities. In particular, we successfully implemented and expanded our capabilities in the use of nuclear transfer technology for the production of transgenic animals. This technology allows GTC to develop productive animals more quickly and reliably. During the year, we also established our downstream protein purification capabilities at clinical scale in accordance with the good manufacturing practices (GMP) expected by regulatory agencies for early stage clinical studies. GMP purification is an important element in broadening GTC's production capabilities for both our own internal proprietary programs as well as for our external partner programs.

**Corporate Developments** On the financial side, we are continuing to operate GTC in a prudent fashion while recognizing that the greatest value we can bring to our Company is successfully advancing our lead programs in a timely fashion. We will continue to carefully balance these objectives. We ended the year with about $57 million in cash and marketable securities, which together with revenue opportunities, we believe will provide the necessary financial resources to support the Company's operation into 2005. Our cash burn in 2003 is projected to be between $20 and $25 million, a significant part of which supports our preparations for filing rhATIII for marketing authorization in Europe.

During 2002, we negotiated the buy back of 2.8 million shares of our common stock from Genzyme Corporation, bringing Genzyme's ownership in GTC to 18%. While Genzyme proposed this transaction to GTC, we felt that this was in the best interests of our shareholders when put together with the lock-up and loan arrangements negotiated with Genzyme. With this reduced ownership interest, our Board determined that we change our corporate name to GTC Biotherapeutics. The new GTC name has successfully demonstrated our independent strategy and position in the marketplace. On the other hand, one outcome resulting from Genzyme's reduced ownership was the resignation of Henri Termeer and Henry Blair from our Board. I want to take this opportunity to thank both of these Directors for their extraordinary contribution to GTC since the company was first established. Both will be greatly missed. On the positive side, we have been very happy to welcome two new Directors to our Board. Pamela McNamara joins us following an impressive career in healthcare and biotechnology consulting, principally with Arthur D. Little; also joining us is Marvin Miller, recently CEO of Nextran, a Baxter subsidiary, and previously holding senior sales, marketing and business development positions in major pharmaceutical and diagnostic companies, including Johnson & Johnson and Roche.

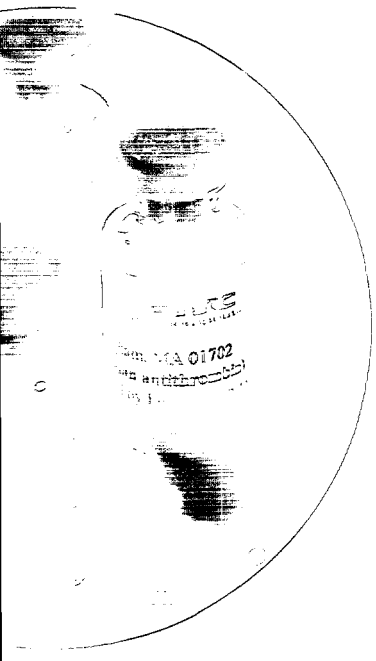
Our Company has an exciting twelve months ahead of it, and we face our challenges with confidence and enthusiasm. The opportunities for GTC are very significant. Effective execution of our strategies is crucial to our success. I thank all our shareholders for their continuing support, and you have our assurance of the enthusiastic commitment of the management of GTC to the future success of our Company. I look forward to telling you of our progress next year.

Geoffrey F. Cox.

# INTERNAL PROGRAMS - PRODUCT LEADERSHIP IN THE CLINIC



GTC HAS THREE INTERNAL PROGRAMS IN ACTIVE DEVELOPMENT. THESE ARE RECOMBINANT HUMAN ANTITHROMBIN III (rhATIII), RECOMBINANT HUMAN SERUM ALBUMIN (rhSA) AND A MALARIA VACCINE CANDIDATE, MSP-1, WHICH IS A MEROZOITE SURFACE PROTEIN.



## Recombinant Human Antithrombin III (rhATIII)

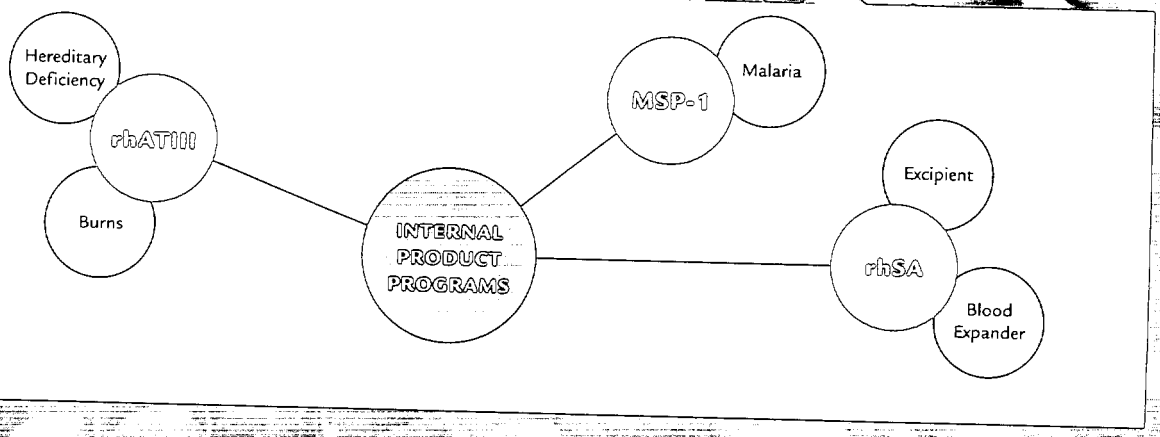
Antithrombin is a protein with anti-coagulant and anti-inflammatory properties that is normally found in human blood serum. Individuals who inherently have an insufficient level of antithrombin (typically 25 - 60% of normal) have a hereditary deficiency (HD) for this blood protein. There are about 1 in 5,000 people with this condition. These patients are at risk for developing deep vein thromboses during trauma such as surgery and childbirth.

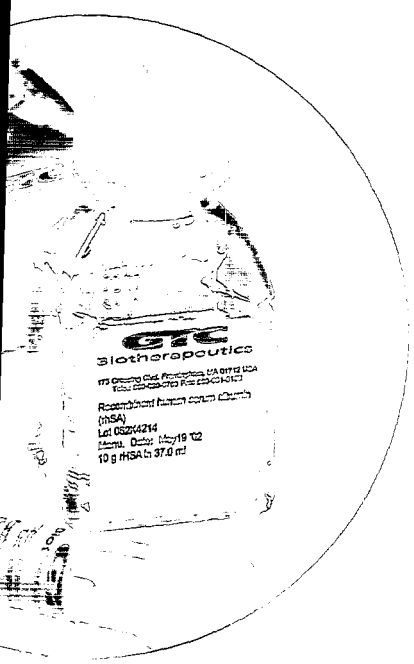
GTC's lead product, rhATIII, is at the forefront of transgenic platform technology. It was the first transgenically produced product to enter human clinical trials - including efficacy studies - and remains the most advanced in the clinic of any product produced using this technology. It is poised to be the first transgenically produced product to be filed for approval by regulatory authorities. In September of 2002, GTC completed and published the results of a pharmacokinetic study in Europe utilizing rhATIII in HD patients. This study established the appropriate dosing regimen to be utilized in the subsequent efficacy study which commenced before the end of 2002. GTC continues to enroll and treat HD patients who are undergoing surgery or delivery of a baby. GTC plans to complete this study before the end of 2003 and then file for European regulatory approval in the first half of 2004. In parallel, in 2003, GTC also plans to define its regulatory strategy and clinical approach for obtaining regulatory approval in the United States.

Currently, the antithrombin that is approved for therapeutic use is fractionated from whole blood plasma. Plasma derived antithrombin is currently marketed in Europe, Japan and the United States with annual worldwide sales of $250M. Overall sales of this product have been limited in various markets and is highly dependent on the available supply. For example, the United States market represents only $10M of the total sales worldwide, partially due to the intermittent availability of plasma-derived antithrombin. GTC's rhATIII can address the worldwide supply issue, as well as provide a well characterized product. GTC plans to expand and develop the market potential for rhATIII through a series of well designed clinical studies in additional indications leveraging ATIII's anti-coagulant and anti-inflammatory properties as well as penetrating the existing plasma based market. Negotiations are underway with a number of potential partners for this product in the United States, Europe and Asia. GTC is looking for partners that can provide both financial

RECOMBINANT HUMAN ANTITHROMBIN III (rhATIII) PRODUCT IS INSPECTED PRIOR TO SHIPMENT FOR USE IN HUMAN CLINICAL STUDIES.








**In the United States, there are 75,000 new burn cases per year with approximately 20% of those patients being severely burned. This market figure is similar for Europe. The incidence of burns in Asia however is much higher. In Japan, government figures report that 500,000 people are treated for burns each year.**

support for clinical studies in additional indications as well as provide marketing capability for rhATIII.

Acquired ATIII deficiency occurs in a number of conditions, and may result from a decrease in the amount of ATIII produced, an increase in the rate of ATIII consumption, or an abnormal loss of ATIII from circulation. Examples of conditions in which acquired ATIII deficiency may occur are burns, prevention of neurocognitive deficiency in patients undergoing cardio pulmonary bypass, heparin resistance, bowel perforation, acute liver failure, disseminated intravascular coagulation, sepsis and septic shock, multiple organ failure, pre-eclampsia, and bone marrow or organ transplantation. GTC is currently focusing on the larger market opportunities in discussions with potential collaborators, such as developing the use of rhATIII to treat burns. ATIII levels may be dramatically reduced in burn patients 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 burn patients as well as helping to reduce the scarring that often results. GTC believes that the worldwide market for the burns indication is significant.

### Recombinant Human Serum Albumin (rhSA)

Human serum albumin (hSA) is a blood protein which is responsible for maintaining the physiology of the blood. Albumin is used both therapeutically as a blood volume expander in critical care or surgical patients and as an excipient where it helps stabilize biologic drug formulations under a wide range of storage conditions. GTC estimates the total production volume needed for the excipient market is in the range of one to two metric tons per year.

Strategically, the excipient business will provide the opportunity for commercial product sales much sooner than would be practical for the therapeutics market with a significantly lower capital investment. The recombinant nature of GTC's product provides a well characterized protein with a stable single source of supply. This will help drug formulators settle on a single specification for worldwide sales of their products and avoid adding plasma derived materials to their recombinant products.

Due to the large volume requirements for this protein, GTC has developed the rhSA product using transgenic cows to take advantage of their large milk production volumes. GTC continues to expand this herd to meet production requirements. Bench scale purification of product has been achieved and the purifica-

tion process is being scaled up for production level quantities. This work was financed by Fresenius. This relationship was recently changed with the formation of a joint venture in order to expand the commercial development opportunities of this product. This structure, in which GTC holds a majority interest, allows for the option to attract additional marketing or strategic partners who may also assist with the financing and expansion of this endeavor. Initially, the joint venture will focus on developing rhSA for the pharmaceutical excipient market with the potential for commercial sales within the next few years and then address the much larger blood expander market.

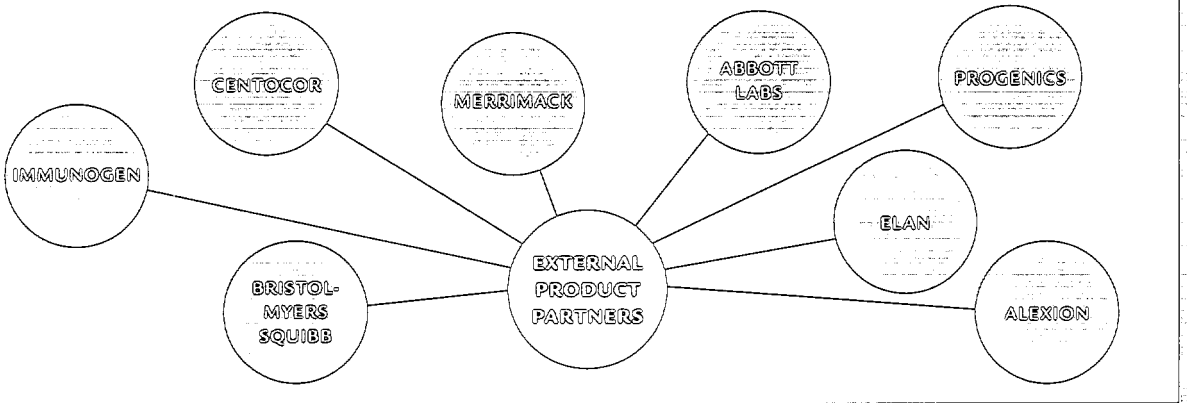
rhSA is another example of a difficult-to-express plasma protein under development by GTC, that is also required in large volumes. Albumin is currently produced by human plasma fractionation. Worldwide sales for hSA that is produced from human blood are approximately between $1 billion to $1.5 billion requiring roughly 400 metric tons per year.

### Malaria Vaccine

Merozoite Surface Protein 1 (MSP-1) is a protein being developed for use in a malaria vaccine. This vaccine is being developed to protect individuals against one of the growth stages of the malaria parasite, therefore halting progression of the disease. Malaria affects over 300 million people worldwide and results in several million deaths each year, mostly among infants and children. GTC has been developing this product in collaboration with the National Institutes of Health (NIH) and the Federal Malaria Vaccine Coordinating Committee. MSP-1 had not been successfully expressed in traditional cell culture systems at reasonable quantities. Through innovative molecular biology by GTC's scientists, expression of active MSP-1 has been achieved at commercially viable levels. A study using GTC's MSP-1 expressed in mouse milk showed effective protection in monkeys when challenged with the malaria parasite. This study was published in conjunction with the National Institute of Allergy and Infectious Diseases (NIAID) in the Proceedings of the *National Academy of Sciences* in December of 2001. Recently, the NIAID approved a proposal to fund the development and production of clinical-grade MSP-1. The scope of work includes developing founder transgenic goats that express the MSP-1 antigen in their milk, downstream purification and final product formulation as well as the submittal of an 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.

AT GTC, MILK POOLING IS A STEP IN TRANSGENIC MANUFACTURING.

PURIFICATION PROCESS DEVELOPMENT AT GTC SUPPORTS RESEARCH, PRE-CLINICAL AND CLINICAL SCALE PRODUCTION.

# EXTERNAL PARTNERSHIPS – GTC'S SERVICE BUSINESS GENERATING REVENUES



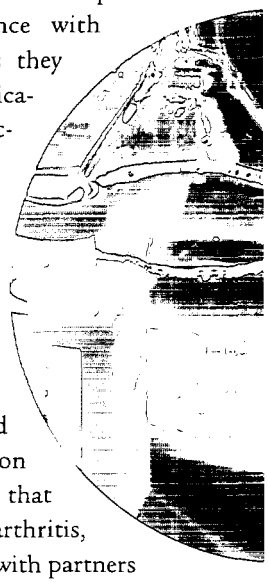
GTC'S EXTERNAL PROGRAM BUSINESS UTILIZES THE COMPANY'S INTELLECTUAL PROPERTY AND TECHNOLOGY TO DEVELOP TRANSGENIC PRODUCTION FOR CLIENT COMPANIES' PROPRIETARY PRODUCTS. THESE PROGRAMS INITIALLY GENERATE REVENUES FOR GTC BASED ON DEVELOPMENT FEES, ACHIEVEMENT OF SPECIFIC MILESTONES AND TRANSFER PAYMENTS FOR MANUFACTURING. FURTHER DEVELOPMENT FOLLOWING CHARACTERIZATION OF THE PRODUCT IN PRECLINICAL TESTING AND PHARMACOKINETIC STUDIES MAY LEAD TO THE NEGOTIATION OF A COMMERCIAL SUPPLY AGREEMENT WHICH WOULD ALLOW GTC TO PARTICIPATE IN THE SUCCESS OF THE PRODUCT THROUGH ROYALTIES AND SUPPLY COMMITMENTS. CONTINUED GENERATION AND PROGRESSION OF THESE PROGRAMS INTO THE CLINIC AND ON TO COMMERCIALIZATION WOULD HELP SUPPORT THE CONTINUED DEVELOPMENT OF GTC'S INTERNAL PROGRAMS AND TECHNOLOGY PLATFORM, AND ESTABLISH AN IMPORTANT SOURCE OF LONG TERM REVENUES.

THROUGH EXTERNAL PROGRAM PARTNERSHIPS, GTC PROVIDES PHARMACEUTICAL AND BIOTECHNOLOGY COMPANIES WITH UNIQUE BENEFITS.

One advantage is the enablement that the power of the technology itself can provide – expression of those proteins that cannot be produced efficiently using traditional methods. The second is the economic benefit that GTC can provide. External partners are often interested in the favorable economics of GTC's operating platform which include a very significant reduction in capital investment in comparison with traditional cell-culture based bioreactor technology coupled with the assurance of lower unit production costs. For example, many antibodies are under development for the treatment of a large array of chronic diseases such as inflammatory and autoimmune conditions, including rheumatoid arthritis. This dictates large production volumes where GTC's economic advantages and flexibility in scaling up production become compelling features of this technology and operating platform.

### GTC's external product portfolio

There are currently 12 products in GTC's external product portfolio. The formation of each of these partnerships has been driven by technical or economic enablement, or possibly both. The most advanced program is a partnership with Merrimack Pharmaceuticals. This multi-million dollar agreement provides for the production and purification of material for use in human clinical trials in Myasthenia Gravis to begin in 2003. This product, MM-093, formerly known as ABI.001, is a recombinant human alpha-fetoprotein (rhAFP) and is an example of a product which has been difficult to express using traditional cell culture. GTC has developed goats that produce MM-093 in their milk and has established the purification regime for the delivery of clinical-grade product. rhAFP may have the potential to treat a wide range of autoimmune conditions in addition to Myasthenia Gravis. GTC will be able to expand capacity in accordance with Merrimack's needs as they examine further indications, scaling production through breeding and herd expansion.



The remaining external programs are for the development of transgenic versions of products such as monoclonal antibodies and immunoglobulin fusion proteins for conditions that include rheumatoid arthritis, HIV/AIDS and cancer, with partners such as Abbott, Centocor, and Elan. Many of these programs have now advanced to the stage of having founder animals, which are the potential start of a commercial production herd. (See chart on page 1.)

GTC continues to search for new external program partnership opportunities. The commitment of GTC's management, the timely execution of current programs and the innovation of our scientists continue to foster these relationships.

# ENHANCING THE TECHNOLOGY PLATFORM



GTC CONTINUOUSLY INVESTIGATES METHODS TO ENHANCE ITS TECHNOLOGY PLATFORM. IMPROVEMENTS HAVE BEEN MADE THROUGHOUT THE PROCESS, FROM THE LEVEL OF DNA THROUGH PRODUCTION AND PURIFICATION OF CLINICAL-GRADE PRODUCT.

### Starting with DNA

GTC's molecular biologists engineer the DNA which has been either developed internally or supplied by the partner in order to optimize and target expression of the desired protein in milk. In the case of proteins that are difficult to express using traditional cell culture, enhancements may be made to the DNA to enable their expression transgenically.

### Nuclear Transfer

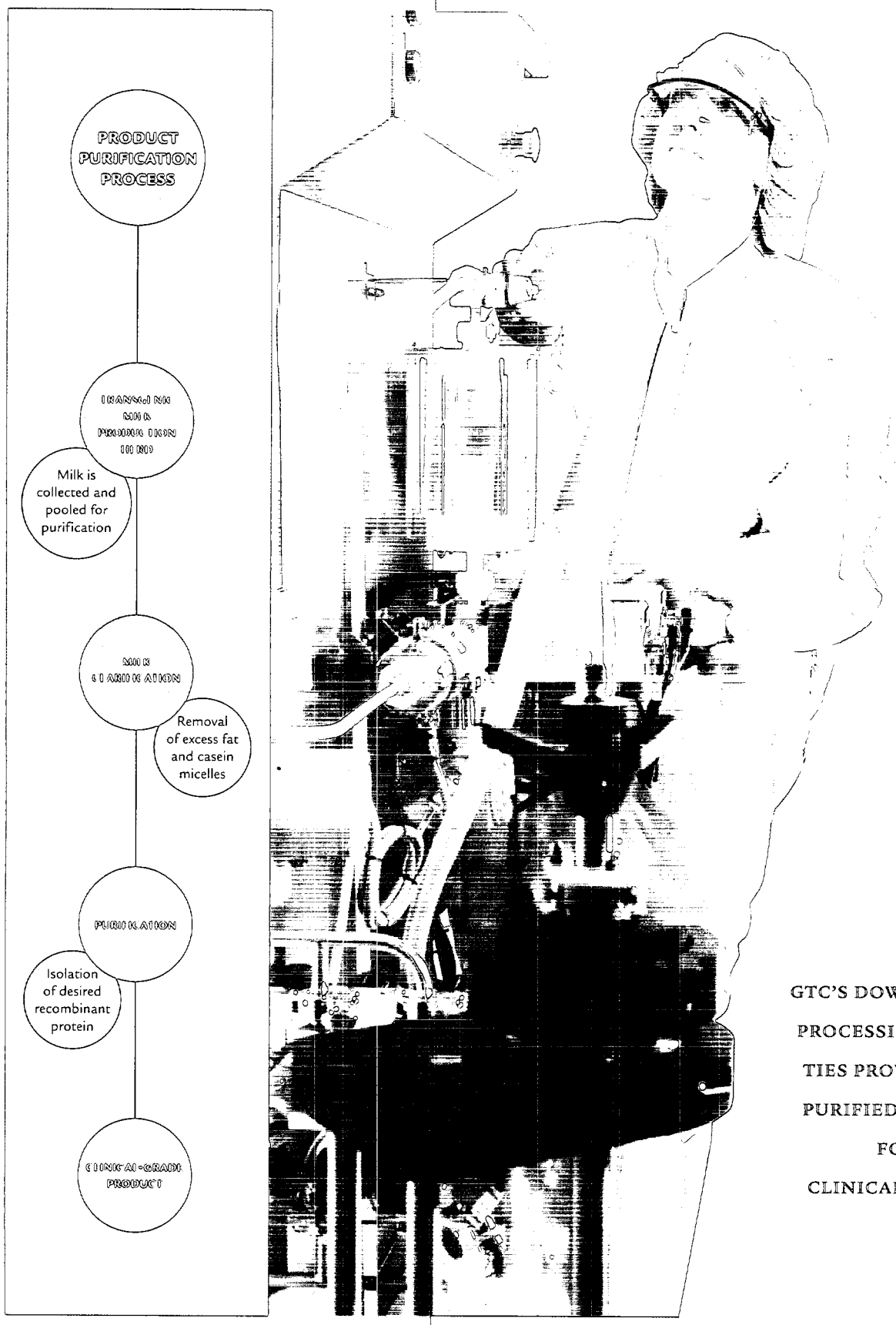
GTC is now using nuclear transfer technology to develop transgenic goats and cows. The first step in this technology involves the generation of a characterized cell line which has incorporated the specific DNA for expression of the target protein in milk. Individual cells from the cell line(s) are then 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 offspring born using this method are transgenic, providing for a more predictive and reliable way of generating the appropriate animals.

Transgenic offspring are bred upon maturity, and upon lactation are analyzed for optimal genetic and protein expression characteristics. This process leads to the selection of a founder line for expansion of the production herd. During these first lactations, milk is collected for initial purification runs to produce early clinical-grade product. Breeding the first transgenic animals can also begin the process of expanding to a production herd.

### Purification Capability

Milk is initially clarified using tangential flow filtration. This process removes excess fats and casein micelles resulting in a clear, amber colored fluid which is the starting material for further purification to clinical-grade quality using traditional purification processes. GTC has made extensive progress in expanding its purification capability at its facilities in central Massachusetts. Processing laboratories for bench scale purification and extensive analytical methodology for purified product have been established. More recently, clinical purification capability has been added to GTC's technology platform. GTC now has the ability to purify clinical-grade product to the GMP standards expected by regulatory agencies.

GTC will continue to develop and expand the technology surrounding its operating platform, which is essential to the future of the Company's business.




GTC'S DOWNSTREAM PROCESSING FACILITIES PROVIDE BULK PURIFIED PRODUCT FOR HUMAN CLINICAL STUDIES.

# SELECTED FINANCIAL DATA

**(DOLLARS IN THOUSANDS EXCEPT PER SHARE DATA)**



| | For the Fiscal Years Ended | | | | |
|---|---|---|---|---|---|
| | December 29, 2002 | December 30, 2001 | December 31, 2000 | January 2, 2000 | January 3, 1999 |
| **Statement of Operations Data (1)** | | | | | |
| Net Revenues | $ 10,379 | $ 13,740 | $ 16,163 | $ 13,825 | $ 11,596 |
| Operating costs and expenses | 36,288 | 37,584 | 32,749 | 26,764 | 26,968 |
| Operating loss from continuing operations | (25,909) | (23,844) | (16,586) | (12,939) | (15,372) |
| Loss from continuing operations | (24,320) | (18,792) | (13,817) | (13,622) | (15,243) |
| Loss from discontinued operations | - | - | (324) | (5,139) | (4,347) |
| Gain from sale of discontinued operations | - | 2,236 | | - | - |
| Net loss available to common shareholders | (24,320) | (16,556) | (14,215) | (20,258) | (20,746) |
| Net loss available per common share (basic and diluted) | (0.86) | (0.55) | (0.50) | (1.02) | (1.15) |
| Weighted average number of shares outstanding (basic and diluted) | 28,353,490 | 29,975,167 | 28,373,283 | 19,876,904 | 17,978,677 |
| **Balance Sheet Data (1)** | | | | | |
| Cash and cash equivalents | $ 26,911 | $ 26,850 | $ 41,024 | $ 7,813 | $ 12,097 |
| Marketable securities | 30,438 | 63,598 | 25,508 | | |
| Working capital | 47,682 | 74,458 | 88,389 | 16,715 | 26,905 |
| Net assets of discontinued contract research operations held for sale | - | - | 37,272 | 33,155 | 32,039 |
| Total assets | 95,373 | 120,443 | 134,403 | 58,518 | 60,052 |
| Long-term liabilities | 12,823 | 80 | 294 | 6,256 | 3,063 |
| Shareholders' equity | 68,772 | 101,950 | 114,843 | 26,206 | 36,220 |

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 29, 2002

# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# FORM 10-K

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

(Mark One)

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

**For the fiscal year ended December 29, 2002**

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 28, 2002, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $34,548,868, 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 13, 2003: 27,758,709.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's Proxy Statement for the Annual Meeting of Stockholders to be held May 21, 2003 are incorporated by reference into Part III of this Form 10-K.

PART I

## ITEM 1. BUSINESS

### Overview

GTC Biotherapeutics, Inc. ("GTC" or the "Company") is the leader in the development, production, and commercialization of therapeutic proteins in the milk of transgenic animals. The genetic material expressing the therapeutic protein is introduced into the genome of an embryo to produce the desired transgenic animal. GTC focuses on using transgenic technology to establish commercial production systems for products that are anticipated to require large production volume or are difficult to express in traditional bioreactor based recombinant production systems. The Company's technology platform is being used to create internal and external product programs. Internal programs exploit GTC's own proprietary proteins and provide leadership in obtaining regulatory and market approval for products produced transgenically as well as providing future opportunities for high margin commercial sales. GTC's external program business area uses 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 and provide GTC the opportunity for long-term product revenues as the commercial manufacturing partner. This operating 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. The Company also 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 has the opportunity to participate in many more potential therapeutic development programs than would be practical independently.

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 for these products for use in clinical trials. This technology platform is supported by the quality systems, regulatory, clinical development, and information technology infrastructure necessary to bring therapeutic protein products 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 (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. An Ig fusion protein consists of a monoclonal antibody (MAB) fragment linked to a second protein fragment. A MAB is a protein that binds specifically to a target molecule.

The Company has three internal programs in active development. These are the recombinant human antithrombin III (rhATIII) program, the recombinant human serum albumin (rhSA) program, and a malaria vaccine program using merozoite surface protein 1 (MSP-1) as an antigen. All of these programs involve products that are difficult-to-express proteins. The rhATIII and rhSA proteins are also required in large volumes. The rhATIII and rhSA programs have the potential to generate commercial product revenues in the next two to three years.

There are currently 12 potential products in GTC's external programs business. The most advanced of these is the program with Merrimack Pharmaceuticals, Inc. ("Merrimack") for production and purification of Merrimack's MM-093 (formerly named ABI.001), a recombinant human alpha-fetoprotein (rhAFP), for use in human clinical studies. This protein has been difficult-to-express in traditional recombinant

production systems. GTC's other corporate partners in the external programs include Abbott, Alexion, Bristol-Myers Squibb, Centocor, Elan, ImmunoGen, and Progenics. These agreements generally provide for transgenic production of targeted proteins in exchange for development fees and milestone payments, transfer payments for manufacturing and, in some cases, the payment of royalties on product sales upon commercialization. Following characterization of the transgenic product in preclinical testing and clinical studies, GTC expects to negotiate commercial partnership agreements for supply of product, which may include royalty arrangements.

**Internal Programs**

***Recombinant Human Antithrombin III (rhATIII)***

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 Medicinal Evaluation Agency (EMEA) to conduct clinical studies of rhATIII in those people that express a low level of antithrombin in their blood as a result of an hereditary antithrombin deficiency (HD). There are approximately 1 in 5,000 people with an antithrombin HD. In December 2001, GTC began dosing HD patients in a pharmacokinetic study to establish an appropriate dosing regimen for an efficacy study. GTC successfully completed this 15 patient pharmacokinetic study and began an efficacy study in HD patients in 2002, primarily based in Europe. The efficacy study is assessing the prevention of deep vein thromboses among HD patients that undergo surgery or childbirth. At least 12 patients must be included in the efficacy study. Assuming that the efficacy study progresses as planned, a regulatory filing for approval in Europe is possible in the first half of 2004. GTC believes that this would make rhATIII 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 (FDA) regarding its clinical and regulatory strategy and expects to file an Investigational New Drug (IND) application in 2003 for rhATIII in HD. The objective of this strategy is to be able to file a Biologics License Application (BLA) with the FDA on rhATIII for HD in 2004.

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. Only about $10 million of these sales were in the US where the plasma based antithrombin product is available intermittently.

GTC is in discussions with potential partners for the rhATIII program to provide marketing and financial support for the rhATIII program. In collaboration with these partners, the Company's plan is to expand the market opportunity for this product through further clinical studies to develop additional potential indications. Acquired ATIII deficiency occurs in a number of conditions, and may result from a decrease in the amount of ATIII produced, an increase in the rate of ATIII consumption, or an abnormal loss of ATIII from the circulation. Examples of conditions in which acquired ATIII deficiency may occur are burns, prevention of neurocognitive deficiency in patients undergoing cardio pulmonary bypass, heparin resistance, bowel perforation, acute liver failure, disseminated intravascular coagulation, sepsis and septic shock, multiple organ failure, pre-eclampsia, and bone marrow or organ transplantation. GTC is currently focusing on the larger market potential indications in discussions with potential collaborators, such as developing the use of rhATIII to treat burns. For example, ATIII 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 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 both therapeutically and as a non-active component of a finished biopharmaceutical product (excipient). The therapeutic use of albumin is indicated 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). 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.

GTC has a strategic interest in developing recombinant human serum albumin, or rhSA, in the excipient market with 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. The recombinant nature of this product is expected to lead to a well characterized protein and a stable single source of supply. This will provide drug manufacturers the opportunity to avoid plasma derived hSA 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.

In 2002, Fresenius AG and GTC restructured their relationship for the therapeutic blood expander market into a joint venture, called Taurus rhSA LLC (the "Taurus Joint Venture"), to include the development of rhSA as an excipient under an agreement that became effective January 1, 2003. The Taurus Joint Venture will manage development of rhSA for both the excipient and blood expander markets. GTC has a majority interest in the joint venture. GTC and Fresenius are making available all relevant commercial licenses, manufacturing rights, and intellectual property to enable the joint venture to operate worldwide in both the excipient and blood expander markets. During 2001 and 2002, Fresenius had added to its marketing rights for rhSA in Europe by exercising its option to the marketing rights in North America and Asia, including Japan. These marketing rights are now part of the joint venture. The excipient market is part of an integrated development plan that can also provide entry to the blood expander market. 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. GTC is seeking additional outside funding for the Taurus Joint Venture in order to advance the rhSA development program. Ownership interests will be adjusted based on future levels of financial participation from existing and new partners.

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 to $1.5 billion. Since this 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 with 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.

*Malaria Vaccine*

GTC is developing a merozoite surface protein (MSP-1) for use 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 (NIH) and the Federal Malaria Vaccine Coordinating Committee to transgenically develop this malaria protein as 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 its gene sequence while conserving the overall amino acid sequence of the protein. A US 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 (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.* Although MSP-1 can be produced in other recombinant systems, those other systems produce 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 approved a proposal to fund development of clinical grade production of MSP-1. The development work will be performed under the existing NIAID Contract No. NO1-A1-05421 managed by Science Applications International Corporation (SAIC). 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 (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 Programs**

GTC follows a partnership strategy in the 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. External programs also provide GTC the opportunity for a revenue stream through milestone payments during the development phase and subsequently, assuming continuing clinical and development success, the opportunity for long term product revenues as the commercial manufacturing partner. GTC views this business segment 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 of the external programs is with Merrimack, formerly known as Atlantic BioPharmaceuticals. The Merrimack program is for MM-093 (formerly ABI.001), a recombinant human alpha-fetoprotein (rhAFP). The rhAFP protein has been difficult to express in traditional recombinant systems. GTC has developed goats that express this protein in their milk and is currently expanding the production herd. In 2002, GTC and Merrimack agreed to expand their relationship to include production and purification of MM-093. GTC expects to deliver purified MM-093 during 2003 for use in human clinical studies by Merrimack. Merrimack expects to initiate the first human clinical studies of MM-093 later in 2003. Merrimack intends to undertake clinical studies initially in myasthenia gravis. Potential additional indications include multiple sclerosis and rheumatoid arthritis. Myasthenia gravis, Merrimack's lead indication, is an autoimmune disease of the voluntary muscles which affects more than 84,000 patients in the United States and Europe. Merrimack has received Orphan Drug status for MM-093 in myasthenia gravis from the FDA. 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 and additional revenues for eventual commercial production. Payment to GTC on this program is dependent upon Merrimack completing a further equity financing.

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

GTC is actively participating in the field of monoclonal antibodies through seven collaborations. The Company has been granted several patents covering the production of monoclonal antibodies in the milk of transgenic mammals, along with other transgenic process patents, which it believes establish a strong proprietary position in the field. GTC is developing transgenic versions of Remicade® and a second undisclosed MAB for Centocor, Antegren® and an undisclosed MAB for Elan, D2E7, and a second undisclosed protein for Abbott, 5G1.1 for Alexion, and huN901 for ImmunoGen. The indications for these products include arthritis, Crohn's disease, neurological disorders, nephritis, psoriasis and cancer. Abgenix discontinued clinical studies using bioreactor produced material for an eighth MAB program, ABX-IL8.

GTC is actively participating in the transgenic development of three immunoglobulin fusion proteins. The Company has two programs with Bristol-Myers Squibb, one for CTLA4Ig and another undisclosed Ig fusion protein, and the PRO542 program with Progenics. The indications for these products are arthritis, organ transplant rejection, autoimmune disorders and HIV/AIDS.

GTC is continuing active discussions with a number of the companies with a view to moving their programs into the clinical production phase of development.

*Summary Chart of External Programs*

The following chart contains a summary of the Company's active external program partnerships:

| Product Name | Product Type | Indication | Development Stage of Cell Culture Product | Development Stage of Transgenic Product | Partner |
|---|---|---|---|---|---|
| Remicade® | Monoclonal antibody | Crohn's Disease; Rheumatoid Arthritis | Marketed | Preclinical; Founder | Centocor |
| Undisclosed | Monoclonal antibody | Undisclosed | Undisclosed | Undisclosed | Centocor |
| D2E7 | Monoclonal antibody | Rheumatoid Arthritis | Marketed as Humira® | Preclinical; Founder | Abbott Laboratories |
| Undisclosed | Monoclonal antibody | Undisclosed | Undisclosed | Preclinical; Founder | Abbott Laboratories |
| Antegren | Monoclonal antibody | Neurological Disorders | Phase III clinicals | Preclinical; Founder | Elan Pharmaceuticals |
| Undisclosed | Monoclonal antibody | Undisclosed | Undisclosed | Preclinical; Transgenic goats in evaluation | Elan Pharmaceuticals |
| CTLA4Ig | Immunoglobulin fusion protein | Rheumatoid Arthritis | Phase II clinicals | Preclinical; Founder | Bristol-Myers Squibb |
| Undisclosed | Immunoglobulin fusion protein | Organ Transplant Rejection; Autoimmune Disorders | Phase II clinicals | Preclinical; Founder | Bristol-Myers Squibb |
| 5G1.1 | Monoclonal antibody | Rheumatoid Arthritis; Nephritis | Phase II clinicals | Preclinical; Transgenic goats in evaluation | Alexion Pharmaceuticals |
| PRO542 | Immunoglobulin fusion protein | HIV/AIDS | Phase II clinicals | Preclinical; Founder | Progenics Pharmaceuticals |
| huN901 | Monoclonal antibody | Small Cell Lung Cancer | Phase II clinicals | Preclinical; Transgenic goats in evaluation | ImmunoGen |
| MM-093 | Recombinant protein | Myasthenia Gravis Multiple Sclerosis Rheumatoid Arthritis | Not feasible | Preclinical; Founder | Merrimack Pharmaceuticals |
| ABX-IL8 | Monoclonal antibody | Rheumatoid Arthritis | Clinical trials discontinued by Abgenix | Preclinical: Founder | Abgenix Inc. |

## Transgenic Technology Platform

*Overview*

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 over 2,000 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 controlled 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 standard of good manufacturing practice occurs either in GTC's facilities, the facilities of GTC's partners or in contracted facilities. In January 2002, GTC

completed the purchase of approximately 135 acres of land in eastern New York State which the Company may develop over the next several years to provide for herd duplication and additional capacity. Also during 2002, GTC established capacity for the purification of recombinant proteins suitable for clinical studies.

The Company uses goats and cattle in its commercial development programs. A goat gestates in approximately five months and reaches sexual maturity in about another seven months. A typical goat will produce about 2 liters of milk per day during most of its natural lactation cycle. A cow gestates in about nine months and reaches sexual maturity in about another nine months. A typical cow will produce about 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. ("Pharming"), which was negotiated 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 (PTO) has declared an interference proceeding between Advanced Cell Technologies, Inc. (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 less cost than building a cell culture bioreactor facility.
- *Lower Cost of Goods.* Economic factors unique to transgenic production 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.

**Other Corporate Information**

**Patents and Proprietary Rights**

Currently, GTC holds 11 issued U.S. patents and 42 corresponding foreign patents. In accordance with ongoing research and development efforts, GTC has 3 pending U.S. patent applications and 205 corresponding foreign applications covering relevant and newly developed portions of its transgenic technology. Several of these pending applications are included in cross-licensing arrangements with other companies that in turn provide access to their proprietary technologies. 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 ATIII 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, ACT and others 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 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 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 ability 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. In addition there are many companies that are building their own cell culture based production systems or other traditional protein production methods, as well as contract manufacturers who are producing proteins for others.

Two other companies known to GTC are extensively engaged in the application of transgenic technology in mammals for the production of proteins for therapeutic use in humans: Pharming and PPL Therapeutics. Pharming, based in the Netherlands, is primarily engaged in the development of recombinant proteins in the milk of transgenic cows and rabbits. PPL, based in Scotland, utilizes primarily sheep for transgenic protein production. There are also other companies seeking to develop transgenic technology in animals and in plants.

For rhATIII, Bayer in the U.S. and a number of companies internationally, produce and market antithrombin from the fractionation of human plasma. Similarly, there are a number of companies worldwide that produce and market human serum albumin from the fractionation of human plasma. There are 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.

To GTC's knowledge, no therapeutic protein produced in the milk of a transgenic animal has been submitted 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.

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 (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. If a manufacturer successfully demonstrates that the 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, the manufacturer will receive a biological license to market the product in interstate commerce.

GTC is also required to comply with the relevant regulations to support development and commercialization of products produced under contract with external partners.

### Research and Development Costs

During its fiscal years ended December 29, 2002, December 30, 2001 and December 31, 2000, GTC spent in total, $25 million, $22.4 million and $19 million, respectively, on cost of revenue and research and development expense of which $13.1 million, $15.1 million and $15.6 million, respectively, was related to external programs. Of the total spent on research and development, $5 million, $2.3 million and $3.3 million, was spent on the ATIII program in fiscal years 2002, 2001 and 2000, 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 29, 2002, GTC employed 182 people, including 6 part time and temporary employees. Of GTC's total employees, 113 were engaged in farm operations, clarification processes, quality assurance and control, 27 were engaged in research and development and 42 were engaged in administration, business development and marketing. Of GTC's employees, approximately 20 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.

### Available Information

Our internet website is www.gtc-bio.com and through the Investor Information portion of our website, you may access, free of charge, our annual reports on Form 10-K, annual reports on Form 10-Q and proxy statements on Schedule 14A, and amendments to such 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 we electronically file such material with, or furnish 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, 2003 are as follows:

| Name | Age | Position |
|---|---|---|
| Geoffrey F. Cox, Ph.D. | 59 | Chairman of the Board, President and Chief Executive Officer |
| John B. Green | 48 | Senior Vice President, Chief Financial Officer and Treasurer |
| Paul K. Horan, Ph.D. | 60 | Senior Vice President, Corporate Development |
| Gregory F. Liposky | 48 | Senior Vice President, Operations |
| Harry M. Meade, Ph.D. | 56 | Senior Vice President, Research and Development |
| Daniel S. Woloshen | 55 | 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.

Mr. Green was appointed Senior Vice President of GTC in May 2002, having had previously served as Vice President since 1994. Mr. Green also serves 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.

Dr. Horan was appointed Senior Vice President, Corporate Development in March 2002. Prior to joining GTC, Dr. Horan was a founding partner of QED Technologies, Inc. and served as Managing Partner from 1993 to March 2002, and held Chief Executive Officer and Board positions at ChemCore Corporation from 1994 to 1996 and held a Board position at Caliper Technologies Corp. from 1996 to 1997 as part of QED's consulting operations.

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 beginning in August 1994. Prior to that, Dr. Meade served as Research Director from 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, before he joined Genzyme, 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 2,000 goats. GTC believes its owned and leased facilities are adequate for significant further development of commercial transgenic products. GTC also currently leases animal housing, care, treatment and research facilities operated by Tufts University School of Veterinary Medicine in Massachusetts (see Item 1). In January 2002, the Company completed the purchase of approximately 135 acres of farm land in eastern New York State which the Company may choose to develop as a second production site.

## 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 2002, 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 |
|---|---|---|
| 2001: | | |
| 1st Quarter | $15.50 | $3.88 |
| 2nd Quarter | 10.23 | 4.75 |
| 3rd Quarter | 9.75 | 3.25 |
| 4th Quarter | 6.18 | 3.05 |
| 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 |

The records held by the transfer agent indicate that on March 13, 2003 there were approximately 972 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 29, 2002 and December 30, 2001 and for each of the three fiscal years in the period ended December 29, 2002 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 31, 2000, January 2, 2000 and January 3, 1999, and for the years ended January 2, 2000 and January 3, 1999 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 29, 2002 | December 30, 2001 | December 31, 2000 | January 2, 2000 | January 3, 1999 |
| **Statement of Operations Data:** | | | | | |
| Revenues: | | | | | |
| Revenue | $ 10,379 | $ 12,152 | $ 12,880 | $ 9,334 | $ 8,278 |
| Revenue from joint venture | — | 1,588 | 3,283 | 4,491 | 3,318 |
| | 10,379 | 13,740 | 16,163 | 13,825 | 11,596 |
| Costs of revenue and operating expenses: | | | | | |
| Cost of revenue | 13,100 | 15,075 | 15,619 | 11,402 | 10,486 |
| Research and development | 11,869 | 7,353 | 3,357 | 3,690 | 6,155 |
| Selling, general and administrative | 11,319 | 11,078 | 9,148 | 7,875 | 6,042 |
| Equity in loss of joint venture | — | 4,078 | 4,625 | 3,797 | 4,285 |
| | 36,288 | 37,584 | 32,749 | 26,764 | 26,968 |
| Loss from continuing operations | (25,909) | (23,844) | (16,586) | (12,939) | (15,372) |
| Other income and (expenses): | | | | | |
| Interest income | 2,028 | 3,478 | 3,770 | 65 | 280 |
| Interest expense | (439) | (746) | (1,001) | (1,232) | (251) |
| Realized gain on sale of CRL stock | — | 2,320 | — | — | — |
| Other income | — | — | — | 484 | 100 |
| Loss from continuing operations | $ (24,320) | $ (18,792) | $ (13,817) | $ (13,622) | $ (15,243) |
| Discontinued operations | | | | | |
| Income (loss) from discontinued contract research operations, net of taxes | — | — | (324) | (5,139) | (4,347) |
| Gain from sale of discontinued contract research operations | — | 2,236 | — | — | — |
| Net loss | $ (24,320) | $ (16,556) | $ (14,141) | $ (18,761) | $ (19,590) |
| Dividends to preferred shareholders | — | — | (74) | (1,497) | (1,156) |
| Net loss available to common shareholders | $ (24,320) | $ (16,556) | $ (14,215) | $ (20,258) | $ (20,746) |
| Net loss available to common shareholders per weighted average number of common shares (basic and diluted): | | | | | |
| From continuing operations | $ (0.86) | $ (0.63) | $ (0.49) | $ (0.76) | $ (0.91) |
| From discontinued contract research operations | $ — | $ 0.08 | $ (0.01) | $ (0.26) | $ (0.24) |
| Net loss | $ (0.86) | $ (0.55) | $ (0.50) | $ (1.02) | $ (1.15) |
| Weighted average number of shares outstanding (basic and diluted) | 28,353,490 | 29,975,167 | 28,373,283 | 19,876,904 | 17,978,677 |

| | December 29, 2002 | December 30, 2001 | December 31, 2000 | January 2, 2000 | January 3, 1999 |
|---|---|---|---|---|---|
| **Balance Sheet Data:** | | | | | |
| Cash, cash equivalents and marketable securities | $57,349 | $90,448 | $66,532 | $7,813 | $12,097 |
| Working capital | 47,682 | 74,458 | 88,389 | 16,715 | 26,903 |
| Total assets | 95,373 | 120,443 | 134,403 | 58,518 | 60,052 |
| Long-term liabilities | 12,823 | 80 | 294 | 6,256 | 3,063 |
| Shareholders' equity | 68,772 | 101,950 | 114,843 | 26,206 | 36,220 |

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

*SUMMARY BUSINESS DESCRIPTION*

Overview

GTC Biotherapeutics, Inc. ("GTC" or the "Company") is the leader in the development, production, and commercialization of therapeutic proteins in the milk of transgenic animals. The genetic material expressing the therapeutic protein is introduced into the genome of an embryo to produce the desired transgenic animal. GTC focuses on using transgenic technology to establish commercial production systems for products that are anticipated to require large production volume or are difficult to express in traditional bioreactor based recombinant production systems. The Company's technology platform is being used to create internal and external product programs. Internal programs exploit GTC's own proprietary proteins and provide leadership in obtaining regulatory and market approval for products produced transgenically as well as providing future opportunities for high margin commercial sales. GTC's external program business area uses 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 and provide GTC the opportunity for long-term product revenues as the commercial manufacturing partner. This operating 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. The Company also 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 has the opportunity to participate in many more potential therapeutic development programs than would be practical independently.

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 for these products for use in clinical trials. This technology platform is supported by the quality systems, regulatory, clinical development, and information technology infrastructure necessary to bring therapeutic protein products 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 (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. An Ig fusion protein consists of a monoclonal antibody (MAB) fragment linked to a second protein fragment. A MAB is a protein that binds specifically to a target molecule.

The Company has three internal programs in active development. These are the recombinant human antithrombin III (rhATIII) program, the recombinant human serum albumin (rhSA) program, and a malaria vaccine program using merozoite surface protein 1 (MSP-1) as an antigen. All of these programs involve products that are difficult-to-express proteins. The rhATIII and rhSA proteins are also required in large volumes. The rhATIII and rhSA programs have the potential to generate commercial product revenues in the next two to three years.

There are currently 12 potential products in GTC's external programs business. The most advanced of these 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 (rhAFP), for use in human

clinical studies. This protein has been difficult-to-express in traditional recombinant production systems. GTC's other corporate partners in the external programs include Abbott, Alexion, Bristol-Myers Squibb, Centocor, Elan, ImmunoGen, and Progenics. These agreements generally provide for transgenic production of targeted proteins in exchange for development fees and milestone payments, transfer payments for manufacturing and, in some cases, the payment of royalties on product sales upon commercialization. Following characterization of the transgenic product in preclinical testing and clinical studies, GTC expects to negotiate commercial partnership agreements for supply of product, which may include royalty arrangements.

**Genzyme Stock Buyback**

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. 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 represents approximately 18% of the Company's outstanding shares. The lock-up provision will be released 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 London Interbank Offered Rate (LIBOR) plus 1% (LIBOR was at 1.40% at December 29, 2002). 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.

**Taurus rhSA LLC**

In 2002, Fresenius AG and GTC restructured their relationship for the therapeutic blood expander market into a joint venture, called Taurus rhSA LLC (the "Taurus Joint Venture"), to include the development of rhSA as an excipient under an agreement that became effective January 1, 2003. The Taurus Joint Venture will manage development of rhSA for both the excipient and blood expander markets. GTC has a majority interest in the joint venture. GTC and Fresenius are making available all relevant commercial licenses, manufacturing rights, and intellectual property to enable the joint venture to operate worldwide in both the excipient and blood expander markets. During 2001 and 2002, Fresenius had added to its marketing rights for rhSA in Europe by exercising its option to the marketing rights in North America and Asia, including Japan. These marketing rights are now part of the joint venture. The excipient market is part of an integrated development plan that can also provide entry to the blood expander market. 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. GTC is seeking additional outside funding for the Taurus Joint Venture in order to advance the rhSA development program. Ownership interests will be adjusted based on future levels of financial participation from existing and new partners.

**Discontinued Operations**

In February 2001, the Company completed the sale of Primedica Corporation to Charles River Laboratories, Inc. The Company received $26 million in cash, 658,945 shares of Charles River common stock valued at $15.9 million and Charles River assumed all of Primedica's approximately $9 million of capital leases and long-term debt (see Note 2 of the "Notes to the Consolidated Financial Statements"). Primedica is reported as a discontinued operation in these financial statements. Accordingly, the results of operations and the balance sheet data exclude the results of operations and assets and liabilities of

Primedica and its subsidiaries. In July 2001, the Company sold all of the Charles River common stock for net proceeds of $18.2 million.

ATIII LLC

In 1997, the Company and Genzyme Corporation established the ATIII LLC joint venture for the marketing and distribution rights of rhATIII 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 rhATIII, if any, commencing three years after the first commercial sale, up to a cumulative maximum of $30 million.

The ATIII LLC formed a collaboration with Genzyme Molecular Oncology, a division of Genzyme, to jointly develop a form of transgenic ATIII for potential application as an angiogenesis inhibitor in the field of oncology. This research stage collaboration is based on a discovery by Dr. Judah Folkman from Children's Hospital, Boston, Massachusetts that certain conformations of ATIII, referred to as anti-angiogenic ATIII, inhibit angiogenesis *in vitro* and inhibit tumor growth in mice. Potential anti-angiogenic applications of rhATIII, outside the field of oncology, may be developed.

*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. 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 the following critical accounting policies affect its more 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 transgenic development in milk of recombinant proteins for therapeutic uses. 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.

Non-refundable license fees, milestones and collaborative research and development revenues under collaborative agreements, where the Company has continuing involvement, are recognized as revenue over the period of continuing involvement, using the model similar to the one prescribed by Emerging Issues Task Force Issue No. 91-6 (EITF 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. Payments received in advance of being earned are recorded as deferred revenue. When there are two or more distinct phases embedded into one contract, such as development and commercialization, the contract is considered a multiple element arrangement. When management can conclude as to the fair

value of the related items, up front license fees and milestone payments are recognized over the initial phase of the contract only.

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 decisions are made based upon the current facts and circumstances and are reassessed on at least a quarterly basis.

### 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. Factors the Company considers important which could trigger an impairment review include the following:

- Significant underperformance relative to expected historical or projected future operating results;
- Significant changes in the manner of the Company's use of the acquired assets or the strategy for the Company's overall business; and
- Significant negative industry or economic trends.

If the Company were to determine that the carrying value of intangibles and long lived assets may not be recoverable based upon the existence of one or more of the above indicators of impairment, 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. Net intangible assets amounted to $12.1 million as of December 29, 2002.

### Validation Costs

The Company capitalizes validation costs, including both external and internal direct costs incurred in preparing a facility for its intended use. These costs are included in property, plant and equipment. As of December 29, 2002, the Company has approximately $2.5 million of capitalized validation costs included in property, plant and equipment.

### Accounting for Income Taxes

As part of the process of preparing the Company's consolidated financial statements, the Company is required to estimate its income taxes in each of the jurisdictions in which the Company operates. This process involves the Company estimating its actual current tax exposure together with assessing temporary differences resulting from differing treatment of items, such as deferred revenue, for tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included within its consolidated balance sheet. The Company must then assess the likelihood that its deferred tax assets will be recovered from future taxable income and to the extent the Company believes that recovery is not likely, it must establish a valuation allowance. To the extent it establishes a valuation allowance or increases this allowance in a period, it must include an expense within the tax provision in the statement of operations. The Company records a valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realized. While the Company has considered future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for the valuation allowance, in the event the Company were to determine that it would be able to realize its deferred tax assets in the future in excess of its net recorded amount, an adjustment to the deferred tax asset would increase income in the period such determination was made. Likewise, should the Company determine that it would not be

able to realize all or part of its net deferred tax asset in the future, an adjustment to the deferred tax asset would be charged to income in the period such determination was made.

Management judgment is required in determining the Company's provision for income taxes, its deferred tax assets and liabilities and any valuation allowance recorded against its net deferred tax assets. The Company has recorded a valuation allowance of $61.6 million as of December 29, 2002, due to uncertainties regarding its ability to utilize its deferred tax assets, primarily consisting of certain net operating losses carried forward. As a result, a full valuation allowance has been established at December 29, 2002. The valuation allowance is based on its estimates of taxable income by jurisdiction in which it operates and the period over which its deferred tax assets will be recoverable. If results of operations in the future indicate that some or all of the deferred tax assets will be recovered, the reduction of the valuation allowance will be recorded as a tax benefit during one period or over many periods.

*YEAR ENDED DECEMBER 29, 2002 AS COMPARED TO YEAR ENDED DECEMBER 30, 2001*

Total revenues for 2002 were $10.4 million compared with $13.7 million in 2001, a decrease of $3.4 million or 24%. 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 joint venture. The Company reacquired full ownership of the ATIII joint venture from Genzyme in July 2001, and subsequent to this point the Company funded all costs associated with ATIII.

Exclusive of the rhSA and ATIII revenues, operating revenues were $8.6 million in 2002 compared with $7.5 million in 2001, an increase of 14.7%. 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 with Merrimack Pharmaceuticals, Inc., the Company deferred the recognition of revenue of approximately $1.6 million in 2002 which is expected to be recognized in 2003. Payment to the Company on this program is dependent upon Merrimack completing a further equity financing.

Cost of revenue decreased to $13.1 million in 2002 from $15.1 million in 2001, a decrease of $2 million or 13%. This decrease 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 recombinant human antithrombin III ("rhATIII").

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 rhATIII, 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, including expenses related to rhATIII and the equity in loss of joint venture, increased to $11.9 million in 2002 from $11.4 million in 2001, an increase of $400,000 or 4%. Internal research and development expenditures for the rhATIII 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 million in 2002 on the rhATIII program, which was $1.4 million less than the amount that was spent on rhATIII development in

2001 when it was partially funded by Genzyme. Of the $6.4 million of expenses for the rhATIII 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 rhATIII program expenses were higher in 2001 due to higher regulatory and manufacturing costs incurred with Genzyme while the ATIII joint venture was in place. The reduction in rhATIII 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 increased to $11.3 million in 2002 from $11.1 million in 2001, an increase of $200,000 or 2%. The increase 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 substantial charge related to contractual obligations in connection with the resignation of the Company's former President and Chief Executive Officer.

Interest income decreased to $2 million in 2002, from $3.5 million in 2001, due to the impact of lower interest rates and a lower cash balance in 2002.

Interest expense decreased to $439,000 in 2002, from $746,000 in 2001 due to lower interest rates in 2002.

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 in February 2001.

The gain from the sale of discontinued contract research operations is a result of the sale, in February 2001, of Primedica to Charles River.

*YEAR ENDED DECEMBER 30, 2001 AS COMPARED TO YEAR ENDED DECEMBER 31, 2000*

Total revenues for 2001 were $13.7 million, compared with $16.2 million in 2000, a decrease of $2.4 million or 15%. The decrease in revenues was primarily due to cessation of partial funding from Genzyme for the rhATIII program of the ATIII LLC joint venture.

Cost of revenue decreased to $15.1 million in 2001 from $15.6 million in 2000, a decrease of $500,000 or 3%. Research and development program expenses increased to $7.4 million in 2001 from $3.4 million in 2000, an increase of $4 million or 119%. The increase is primarily due to a higher investment in the research and development programs, reflecting continued investment in the Company's technology platform including the areas of molecular biology, protein chemistry and downstream product purification. As a result of the reacquisition of the ATIII LLC joint venture, $2.3 million of rhATIII related costs subsequent to July 31, 2001 are included in the Company's research and development expenses in 2001.

Selling, general and administrative expenses increased to $11.1 million in 2001 from $9.1 million in 2000, an increase of $1.9 million or 21%. The increase is due primarily to a charge related to contractual obligations in connection with the resignation of the Company's former President and Chief Executive Officer, as well as to an increased investment in information technology personnel-related expenses, higher professional fees and recruiting costs.

The Company recognized $4.1 million of joint venture losses incurred on the rhATIII joint venture in 2001 as compared to $4.6 million in 2000. The decrease represents a change in the funding arrangement during 2001. 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. 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 rhATIII, 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 were consolidated into the Company's results, in particular research and development expenses.

Interest income decreased to $3.5 million in 2001, from $3.8 million in 2000. The decrease is due to the impact of lower interest rates in 2001.

Interest expense decreased to $746,000 in 2001, from $1 million in 2000 due to lower outstanding borrowings, as well as lower interest rates in 2001.

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 February 2001.

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*

All research and development costs are expensed as incurred. During its fiscal years ended December 29, 2002, December 30, 2001 and December 31, 2000, the Company spent in total, $25 million, $22.4 million and $19 million, respectively, on cost of revenue and research and development expense of which $13.1 million, $15.1 million and $15.6 million, respectively, was related to external programs. Of the total spent on research and development, $5 million, $2.3 million and $3.3 million, was spent on the ATIII LLC in fiscal years 2002, 2001 and 2000, 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 $42.6 million at December 29, 2002. The aggregate estimated costs to complete the external programs through the development, herd scale up and purification phases is expected to be approximately $5.3 million, with anticipated minimum revenues of $7.1 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 our partners which are, thereby, 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 $65.2 million at December 29, 2002, excluding funding from development partners. The Company cannot estimate the costs to complete these programs due to significant variability in clinical trial costs and FDA regulatory processes.

NEW ACCOUNTING PRONOUNCEMENTS

In April 2002, the Financial Accounting Standards Board ("FASB") issued FASB Statement No. 145 ("SFAS No. 145"), *Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections as of April 2002.* SFAS No. 145 eliminates SFAS No. 4, *Reporting Gains and Losses from Extinguishment of Debt"* which required companies to classify gains or losses from the extinguishment of debt as extraordinary items, net of tax. As a result of this new SFAS, gains and losses from extinguishment of debt should be classified as extraordinary items only if they meet the criteria in APB Opinion No. 30, *Reporting the Results of Operations—Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions.* The adoption of SFAS No. 145 is not anticipated to have a significant effect on the Company's financial position and results of operations.

In July 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* which nullifies EITF Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)*. SFAS No. 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred, whereas EITF No. 94-3 had allowed the liability to be recorded at the commitment date of an exit plan. The Company is required to adopt the provisions of SFAS No. 146 effective for exit or disposal activities initiated after December 31, 2002. The Company does not expect the adoption of SFAS No. 146 to have a significant impact on the Company's financial position or results of operations.

In December 2002, the FASB issued FASB No.148 ("SFAS No. 148"), Accounting for Stock-Based Compensation—Transition and Disclosure. This Statement, which is effective for fiscal years ending after December 15, 2002, amends Statement No. 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, Statement No. 148 amends the disclosure requirements of Statement No. 123 regardless of the accounting method used to account for stock-based compensation. We have chosen to continue to account for stock-based compensation of employees using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations. The enhanced disclosure provisions as required by SFAS No. 148 have been included in the Company's notes to the financial statements for the year ended December 29, 2002.

In November 2002, the FASB Emerging Issues Task Force reached consensus on EITF No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables. EITF No. 00-21 addresses the accounting treatment for arrangements that provide the delivery or performance of multiple products or services where the delivery of a product, system or performance of services may occur at different points in time or over different periods of time. EITF No. 00-21 requires the separation of the multiple deliverables that meet certain requirements into individual units of accounting that are accounted for separately under the appropriate authoritative accounting literature. EITF No. 00-21 is applicable to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The Company does not expect the provisions of EITF 00-21 to have a material effect on its results of operations and financial position.

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, we have agreements whereby we indemnify our officers and directors for certain events or occurrences while the officer or director is, or was serving, at our 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 our exposure and enables us to recover a portion of any future amounts paid. As a result of our insurance policy coverage, we believe 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 January 31, 2003. The Company does not expect the disclosure or measurement provisions of FIN 45 to have a material effect on its results of operations and financial position.

In January 2003, the FASB issued FASB Interpretation No. 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 No. 46 changes that by requiring a variable interest entity, 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 No. 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. The consolidation requirements of FIN No. 46 apply immediately to variable interest entities created after January 31, 2003 and to older entities in the first fiscal year or interim period beginning after June 15, 2003. Certain of the disclosure requirements apply in all financial statements issued after January 31, 2003, regardless of when the variable interest entity was established. The Company does not expect the provisions of FIN 46 to have a material effect on its results of operations and financial position.

*LIQUIDITY AND CAPITAL RESOURCES*

The Company had cash, cash equivalents and marketable securities of $57.3 million at December 29, 2002. This amount includes cash and cash equivalents of $26.9 million.

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. 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. The $4.8 million promissory note bears interest at the LIBOR plus 1% (LIBOR was at 1.40% at December 29, 2002). 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 June 2002, Company obtained licenses to transgenic cattle technology and nuclear transfer technology from Pharming Group N.V. in exchange for a payment of approximately $1.5 million to Pharming. 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 29, 2002 and are being amortized over a 15-year period.

The Company used $28.3 million of cash and marketable securities in 2002 for operating, investing and capital purposes, including the $1.5 million used in the Pharming transaction. The Company also used an additional $4.8 million for the Genzyme Stock Buyback, bringing the total use of cash and marketable securities to approximately $33.1 million for 2002.

The principal sources of funds during the period included $3.3 million in net proceeds from long-term debt, $32.4 million in net redemptions of marketable securities and $457,000 from the issuance of Common Stock under various employee stock plans. Uses of funds during the period included $23.1 million used in operations, $1.5 million used in acquiring the Pharming licenses and $6.5 million invested in capital equipment and further expansion of the transgenic production facility. An additional $4.8 million was used to buy back Common Stock from Genzyme.

The Company had working capital of $47.7 million at December 29, 2002 compared to $74.5 million at December 30, 2001.

In March 2002, the Company entered into a five year Loan and Security Agreement (the "Loan Agreement") with Silicon Valley Bank ("SVB") in the amount of $11.6 million, of which $5.5 million refinanced a prior loan from another bank, $1.1 million financed previous capital asset acquisitions,

$4 million was for future capital requirements (of which $3.4 million was drawn during 2002), and $1 million is available under a revolving line of credit. The principal amounts outstanding under the Loan Agreement accrue interest at a per annum rate equal to the prime rate at the time of draw down (4.75% at December 29, 2002). Under the Loan Agreement, if the Company does not maintain unrestricted cash and marketable securities, net of outstanding obligations under the revolving line of credit, if any, totaling at least $25 million, then the Company has to immediately deposit cash with SVB equal to the amount of the outstanding obligations due to SVB. Principal payments under the Loan Agreement are estimated to be approximately $1.6 million during 2003, $1.7 million during 2004 and $1.7 million during 2005, with a balloon payment in 2008. In addition, the Company has a standby letter of credit in the amount of $249,360 in support of a facility lease, none of which had been drawn down at December 29, 2002.

As programs progress from the development stage to the commercialization stage, the Company expects to incur additional capital expenditures. The Company anticipates investing between $5 million and $8 million in capital expenditures over the next 12 months to facilitate commercialization of rhATIII and other ongoing transgenic development programs. The Company is seeking funding from partners to offset some of this capital requirement.

Management expects current cash resources and partnering revenue opportunities will be sufficient to fund operations into 2005. Revenue in 2003 is anticipated to be between $15 million and $20 million and the Company expects it will use between $20 and $25 million in cash. The Company's projected revenue and cash use for 2003 is dependent upon attracting additional partnering revenues from existing and additional collaborations. In addition, the Company and Merrimack have signed an agreement to begin clinical production of Merrimack's MM-093 (formerly named ABI.001), a recombinant human alpha-fetoprotein (rhAFP). Payment to the Company on this program is dependent upon Merrimack completing a further equity financing. If the Company does not substantially achieve its revenue projections, 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 need to raise additional financing in this manner to fund operations, there can be no assurance that additional funding will be available on terms acceptable to the Company, if at all.

The following summarizes the Company's contractual obligations at December 29, 2002, and the effect such obligations are expected to have on its liquidity and cash flow in future periods.

| | ($ in 000's) | | | | |
|---|---|---|---|---|---|
| | Less than 1 Year | 1 to 3 Years | 3 to 5 Years | More than 5 Years | Total |
| Contractual Obligations: | | | | | |
| Long-term debt obligations | $1,620 | $5,826 | $4,837 | $1,516 | $13,799 |
| Capital lease obligations | 260 | 399 | 208 | — | 867 |
| Operating lease obligations | 657 | 1,004 | 161 | — | 1,822 |
| Service agreement with Genzyme (see Note 11 of the "Notes to the Consolidated Financial Statements") | 112 | — | — | — | 112 |
| Total contractual cash obligations | $2,649 | $7,229 | $5,206 | $1,516 | $16,600 |

The Company is party to license agreements for certain technologies (see Note 12 of the "Notes to the Consolidated Financial Statements"). Certain of these 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 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.

Management's current expectations regarding the sufficiency of the Company's cash resources are forward-looking statements, and the Company's cash requirements may vary materially from such expectations. Such forward-looking statements are dependent on several factors, including 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, competitive and technological advances and regulatory requirements.

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 14 of the "Notes to Consolidated Financial Statements") in the normal course of business. These transactions are considered to be at arms-length.

*FACTORS AFFECTING FUTURE OPERATIONS AND RESULTS*

This Annual Report on Form 10-K contains forward-looking statements, including statements regarding our results of operations, research and development programs, clinical trials and collaborations. 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 our current expectations, beliefs, assumptions, estimates, forecasts and projections for our business and the industry and markets related to our 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 operating results, research and development programs, clinical trials and collaborations include, without limitation, 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 29, 2002, including a term loan, an equipment line of credit, a revolving line of credit, a promissory note payable and a standby letter of credit which are sensitive to changes in interest rates. The Company has a term loan with a commercial bank, with a carrying value of $6.6 million which approximates its fair value. Also, the Company has an equipment line of credit with a commercial bank for $4 million, which accrues interest at the prime rate and a standby letter of credit of $249,360 in support of a facility lease. Finally, the Company has a promissory note to Genzyme in the amount of $4.8 million. At December 29, 2002, $3.4 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 flows that exist by maturity date and the related average interest rate.

| | ($ in 000's) | | | | | | |
|---|---|---|---|---|---|---|---|
| | 2003 | 2004 | 2005 | 2006 | 2007 | Thereafter | Total |
| Term Loan | $1,320 | $1,320 | $1,320 | $1, 320 | $330 | $ — | $ 5,610 |
| Equipment Line | 300 | 400 | 400 | 400 | 400 | 1,516 | 3,416 |
| Promissory Note Payable | — | — | 2,386 | 2,387 | — | — | 4,773 |
| Total | $1,620 | $1,720 | $4,106 | $ 4,107 | $730 | $1,516 | $13,799 |

The interest rates on the term loan, equipment line and promissory note payable were 4.75%, 4.75% and 2.40% respectively, at December 29, 2002.

**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 29, 2002, assuming a hypothetical 6 percent interest rate is approximately $828,000 after tax. The hypothetical loss was based on financial instruments held by the Company at December 29, 2002. 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.

# PART III

## ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

This information is set forth in part under the captions "Election of Directors" and "Section 16(a) Beneficial Reporting Compliance" in the Company's Proxy Statement for the 2003 Annual Meeting of Shareholders to be held on May 21, 2003 (the "2003 Proxy Statement"), which are incorporated herein by reference, and the remainder of such information is set forth under the caption "Executive Officers of the Registrant" in Part I, Item 1A hereof.

## ITEM 11. EXECUTIVE COMPENSATION

The information set forth under the captions "Compensation and Other Information Concerning Directors and Officers" in the 2003 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 2003 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 2003 Proxy Statement is incorporated herein by reference. See also Notes 6 and 11 to the Consolidated Financial Statements included herewith.

## ITEM 14. CONTROLS AND PROCEDURES

(a) *Evaluation of disclosure controls and procedures.* Our chief executive officer and our chief financial officer, after evaluating the effectiveness of our "disclosure controls and procedures" (as defined in the Securities Exchange Act of 1934 Rules 13a-14(c) and 15-d-14(c)) as of a date (the "Evaluation Date") within 90 days before the filing date of this annual report, have concluded that, as of the Evaluation Date, our disclosure controls and procedures were adequate and designed to ensure that the information required to be disclosed in the reports filed or submitted by us under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the requisite time periods.

(b) *Changes in internal controls.* There were no significant changes in our internal controls or in other factors that could significantly affect our internal controls subsequent to the Evaluation Date.

## 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. |
| 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 | 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. |

| Exhibit No. | Description |
|---|---|
| 4.8 | 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. |
| 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. |
| 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 herewith.** |
| 10.6.8 | Amendment No. 16, effective as of September 6, 2000, to Cooperation and Licensing Agreement. Filed herewith.** |
| 10.6.9 | Amendment No. 18, effective as of September 6, 2001, to Cooperation and Licensing Agreement. Filed herewith.** |
| 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 10.17 to the GTC S-1 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 | 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 | 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.** |
| 10.17 | 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. |
| 10.18 | 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. |
| 10.19 | 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.** |
| 10.20.1 | Limited Liability Company Agreement of Taurus hSA LLC dated as of December 20, 2002. Filed herewith.** |
| 10.20.2 | Contribution and License Agreement by and between GTC and Taurus hSA LLC dated as of December 20, 2002. Filed herewith.** |
| 10.21 | Service Agreement by and between GTC and Cambrex Bio Science MA, Inc. dated as of August 20, 2002. 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. |

| Exhibit No. | Description |
|---|---|
| 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. |
| 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 herewith. |
| 21 | List of Subsidiaries. Filed herewith. |
| 23 | Consent of PricewaterhouseCoopers LLP. Filed herewith. |
| 99.1 | Important Factors Regarding Forward-Looking Statements. Filed herewith. |
| 99.2 | Certifications pursuant to 18 U.S.C. Section 1350. Filed herewith. |

* Indicates a management contract or compensatory plan.

** 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.

(b) Reports on Form 8-K

No reports on Form 8-K were filed by the Company during the quarter ended December 29, 2002.

## Report of Independent Accountants

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 29, 2002 and December 30, 2001 and the results of their operations and their cash flows for each of the three years in the period ended December 29, 2002 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, 2003

GTC BIOTHERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

(Dollars in thousands except share amounts)

| | December 29, 2002 | December 30, 2001 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 26,911 | $ 26,850 |
| Marketable securities | 30,438 | 63,598 |
| Accounts receivable and unbilled contract revenue, net of allowance of $0 and $361 at December 29, 2002 and December 30, 2001, respectively | 2,179 | 1,862 |
| Other current assets | 1,932 | 561 |
| Total current assets | 61,460 | 92,871 |
| Net property, plant, and equipment | 21,701 | 15,957 |
| Net intangible assets | 12,128 | 11,595 |
| Other assets | 84 | 20 |
| | $ 95,373 | $120,443 |
| **LIABILITIES AND SHAREHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 4,448 | $ 1,923 |
| Accounts payable—Genzyme | 2,370 | 1,852 |
| Accrued expenses | 4,442 | 5,078 |
| Deferred contract revenue | 638 | 3,620 |
| Current portion of long-term debt and capital leases | 1,880 | 5,940 |
| Total current liabilities | 13,778 | 18,413 |
| Long-term debt and capital leases, net of current portion | 12,786 | 26 |
| Deferred lease obligation | 37 | 54 |
| Total liabilities | 26,601 | 18,493 |
| Commitments and contingencies (see Note 3) | | |
| 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; 30,579,064 and 30,200,219 shares issued and 27,759,064 and 30,200,219 shares outstanding at December 29, 2002 and December 30, 2001, respectively | 306 | 302 |
| Capital in excess of par value—common stock | 198,469 | 197,742 |
| Treasury stock, at cost, 2,820,000 shares | (9,545) | — |
| Accumulated deficit | (120,642) | (96,322) |
| Accumulated other comprehensive income | 184 | 228 |
| Total shareholders' equity | 68,772 | 101,950 |
| | $ 95,373 | $120,443 |

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 29, 2002 | December 30, 2001 | December 31, 2000 |
| Revenues: | | | |
| Revenue | $ 10,379 | $ 12,152 | $ 12,880 |
| Revenue from joint venture | — | 1,588 | 3,283 |
| | 10,379 | 13,740 | 16,163 |
| Costs of revenue and operating expenses: | | | |
| Cost of revenue | 13,100 | 15,075 | 15,619 |
| Research and development | 11,869 | 7,353 | 3,357 |
| Selling, general and administrative | 11,319 | 11,078 | 9,148 |
| Equity in loss of joint venture | — | 4,078 | 4,625 |
| | 36,288 | 37,584 | 32,749 |
| Operating loss from continuing operations | (25,909) | (23,844) | (16,586) |
| Other income (expense): | | | |
| Interest income | 2,028 | 3,478 | 3,770 |
| Interest expense | (439) | (746) | (1,001) |
| Realized gain on sale of CRL stock | — | 2,320 | — |
| Loss from continuing operations | (24,320) | (18,792) | (13,817) |
| Discontinued operations | | | |
| Loss from discontinued contract research operations (less applicable taxes of $248) | — | — | (324) |
| Gain from sale of discontinued contract research operations | — | 2,236 | — |
| Net loss | $ (24,320) | $ (16,556) | $ (14,141) |
| Dividend to preferred shareholders | — | — | (74) |
| Net loss available to common shareholders | $ (24,320) | $ (16,556) | $ (14,215) |
| Net loss available per common share (basic and diluted): | | | |
| From continuing operations | $ (0.86) | $ (0.63) | $ (0.49) |
| From discontinued contract research operations | $ — | $ 0.08 | $ (0.01) |
| Net loss | $ (0.86) | $ (0.55) | $ (0.50) |
| Weighted average number of common shares outstanding (basic and diluted) | 28,353,490 | 29,975,167 | 28,373,283 |
| Comprehensive loss: | | | |
| Net loss | $ (24,320) | $ (16,556) | $ (14,141) |
| Other comprehensive income: | | | |
| Unrealized holding gains (loss) on available for sale securities | (44) | 171 | 57 |
| Total other comprehensive income (loss) | (44) | 171 | 57 |
| Comprehensive loss | $ (24,364) | $ (16,385) | $ (14,084) |

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

# GTC BIOTHERAPEUTICS, INC.
## CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
### (In Thousands)

| | Series A Convertible Preferred Stock | | Capital in Excess of Par Value Preferred Stock | Common Stock | | Treasury Stock | | | Capital in Excess of Par Value Common Stock | Stock Based Compensation | Accumulated Deficit | Accumulated Other Comprehensivs Income | Total Shareholders' Equity |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | | Shares | Amount | Shares | Amount | Dividend | | | | | |
| Balance, January 2, 2000 | 7 | $ — | $ 6,647 | 22,601 | $ 226 | — | $ — | $(2,653) | $ 87,895 | $(284) | $ (65,625) | $ — | $ 26,206 |
| Net loss | | | | | | | | | | | (14,141) | | (14,141) |
| Conversion of Series B Preferred Stock, including expenses | (7) | | (6,564) | | | | | | | | | | (6,564) |
| Payment of dividend | | | (157) | | | | | | | | | | (157) |
| Conversion of Series A Preferred Stock | | | | 1,048 | 10 | | | 2,727 | 3,818 | | | | 6,555 |
| Common stock sold under Employee Stock Purchase Plan | | | | 237 | 2 | | | | 1,209 | | | | 1,211 |
| Common stock issuance in to the GTC Savings and Retirement Plan | | | | 45 | 1 | | | | 566 | | | | 567 |
| Dividend on Preferred Stock | | | 74 | | | | | (74) | | | | | — |
| Proceeds from the exercise of stock options | | | | 958 | 10 | | | | 6,291 | | | | 6,301 |
| Stock based compensation | | | | | | | | | 1,531 | 284 | | | 1,815 |
| Unrealized gain on investment | | | | | | | | | | | | 57 | 57 |
| Conversion of warrants | | | | 450 | 5 | | | | 6,815 | | | | 6,820 |
| Common stock issuance in connection with the acquisition of SMIG | | | | 333 | 3 | | | | 11,040 | | | | 11,043 |
| Common stock issuance in connection with the public offering, net of expenses | | | | 4,025 | 40 | | | | 75,090 | | | | 75,130 |
| 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 |

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 29, 2002 | December 30, 2001 | December 31, 2000 |
| Cash flows for operating activities: | | | |
| Net loss from continuing operations | $(24,320) | $(18,792) | $(13,817) |
| Adjustments to reconcile net loss from continuing operations to net cash used in operating activities: | | | |
| Depreciation and amortization | 2,416 | 2,614 | 2,070 |
| Stock based compensation | 40 | 355 | 1,815 |
| Non cash interest income (loss) from marketable securities | 759 | 305 | (815) |
| Common stock issuance to GTC savings and retirement plan | 234 | 725 | 567 |
| Equity in loss of joint venture | — | 4,078 | 4,625 |
| 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: | | | |
| Accounts receivable and unbilled contract revenue | 44 | 891 | (1,828) |
| Other assets and liabilities | (1,452) | 236 | (167) |
| Accounts payable | 2,525 | 850 | 439 |
| Accounts payable—Genzyme Corporation | 518 | 508 | 785 |
| Payable to ATIII LLC | — | (1,096) | — |
| Other accrued expenses | (636) | 564 | 708 |
| Deferred contract revenue | (2,982) | (902) | 2,139 |
| Net cash used in operating activities | (23,075) | (11,984) | (3,479) |
| Cash flows for investing activities: | | | |
| Purchase of property, plant and equipment | (6,498) | (3,438) | (1,964) |
| Intangible assets | (1,517) | — | — |
| Investment in joint venture | — | (4,077) | (5,680) |
| Purchase of marketable securities | (52,644) | (83,593) | (46,636) |
| Redemption of marketable securities | 85,001 | 45,267 | 22,000 |
| Proceeds from the sale of CRL stock | — | 18,192 | — |
| Cash paid for acquisition of SMIG | — | — | (26) |
| Net cash provided by (used in) investing activities | 24,342 | (27,649) | (32,306) |
| Cash flows from financing activities: | | | |
| Net proceeds from the issuance of common stock | — | — | 75,130 |
| Dividends paid | — | — | (157) |
| Net proceeds from the exercise of warrants | — | — | 6,820 |
| Net proceeds from the sale of discontinued operations (net of $2,124 expenses) | — | 23,876 | — |
| Net proceeds from employee stock purchase plan | 454 | 424 | 1,211 |
| Net proceeds from the exercise of stock options | 3 | 1,988 | 6,301 |
| Proceeds from long-term debt | 10,015 | — | 609 |
| Acquisition of treasury stock from Genzyme | (4,773) | — | — |
| Repayment of long-term debt | (6,725) | (974) | (727) |
| Repayment of principal on capital leases | (180) | — | — |
| Net (payments) borrowings under revolving line of credit | — | — | (15,750) |
| Net cash provided by (used in) financing activities | (1,206) | 25,314 | 73,437 |
| Net cash (used) provided by discontinued operations | — | 145 | (4,441) |
| Net increase (decrease) in cash and cash equivalents | 61 | (14,174) | 33,211 |
| Cash and cash equivalents at beginning of the period | 26,850 | 41,024 | 7,813 |
| Cash and cash equivalents at end of the period | $ 26,911 | $ 26,850 | $ 41,024 |
| Supplemental disclosure of cash flow information: | | | |
| Cash paid during the period for interest | $ 423 | $ 349 | $ 544 |
| Assets purchased under capital lease | 818 | — | — |
| Promissory note to Genzyme for treasury stock | 4,772 | — | — |

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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Fiscal years ended December 29, 2002, December 30, 2001 and December 31, 2000 (all tabular $ in thousands, except per share data)

### NOTE 1. NATURE OF BUSINESS

GTC Biotherapeutics, Inc. ("GTC" or the "Company") is the leader in the development, production, and commercialization of therapeutic proteins in the milk of transgenic animals. The genetic material expressing the therapeutic protein is introduced into the genome of an embryo to produce the desired transgenic animal. GTC focuses on using transgenic technology to establish commercial production systems for products that are anticipated to require large production volume or are difficult to express in traditional bioreactor based recombinant production systems. The Company's technology platform is being used to create internal and external product programs. Internal programs exploit GTC's own proprietary proteins and provide leadership in obtaining regulatory and market approval for products produced transgenically as well as providing future opportunities for high margin commercial sales. GTC's external program business area uses 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 and provide the opportunity for long-term product revenues as the commercial manufacturing partner.

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 for these products for use in clinical trials. This technology platform is supported by the quality systems, regulatory, clinical development, and information technology infrastructure necessary to bring therapeutic protein products 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 (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. An Ig fusion protein consists of a monoclonal antibody (MAB) fragment linked to a second protein fragment. A MAB is a protein that binds specifically to a target molecule.

The Company has three internal programs in active development. These are the recombinant human antithrombin III (rhATIII) program, the recombinant human serum albumin (rhSA) program, and a malaria vaccine program using merozoite surface protein 1 (MSP-1) as an antigen. All of these programs involve products that are difficult-to-express proteins. The rhATIII and rhSA proteins are also required in large volumes.

There are currently 12 potential products in GTC's external programs business. The most advanced of these is the program with Merrimack Pharmaceuticals, Inc. ("Merrimack") for production and purification of Merrimack's MM-093 (formerly named ABI.001), a recombinant human alpha-fetoprotein (rhAFP), for use in human clinical studies. This protein has been difficult-to-express in traditional recombinant production systems. GTC's other corporate partners in the external programs include Abbott, Alexion, Bristol-Myers Squibb, Centocor, Elan, ImmunoGen, and Progenics. These agreements generally provide for transgenic production of targeted proteins in exchange for development fees and milestone payments, transfer payments for manufacturing and, in some cases, the payment of royalties on product sales upon commercialization.

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 15).

Genzyme is the largest single shareholder of the Company, holding 4,924,919 shares of Common Stock as of December 29, 2002, which represents approximately 18% 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. Genzyme owns approximately 19% of the Company's Common Stock on a fully diluted basis.

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, development by the Company or its competitors of new technological innovations, raising additional capital, dependence on key personnel, protection of proprietary technology and compliance with the United States Food and Drug Administration (FDA) and other government regulations. The accompanying financial statements have been presented on the assumption that the Company is a going concern. The Company has incurred losses and negative operating cash flow in each of the fiscal years ended December 29, 2002, December 30, 2001 and December 31, 2000. The Company had working capital of $47.7 million at December 29, 2002.

## NOTE 2. SIGNIFICANT ACCOUNTING POLICIES

### Basis of Consolidation

The consolidated financial statements include the results of the Company and its wholly-owned subsidiaries. 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 rhATIII 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 reporting purposes (see Note 13).

### 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 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 29, 2002 and December 30, 2001 can be summarized as follows:

| | 2002 | | 2001 | |
|---|---|---|---|---|
| | Amortized Cost | Estimated Fair Value | Amortized Cost | Estimated Fair Value |
| Government backed obligations | $12,498 | $12,516 | $40,363 | $43,729 |
| Corporate obligations | 17,756 | 17,922 | 23,007 | 19,869 |
| Total marketable securities | $30,254 | $30,438 | $63,370 | $63,598 |

At December 29, 2002, December 30, 2001 and December 31, 2000, the marketable securities had associated unrealized gain of $184,000, $228,000 and $57,000, respectively, included in other comprehensive income and equity. The Company had a realized gain of $2.3 million on the sale of the Charles River stock in 2001. All other realized gains on available for sale securities in 2002, 2001 and 2000 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.

### 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 29, 2002 and December 30, 2001, approximately 97% and 94%, respectively, of cash, cash equivalents and marketable securities were held by one United States financial institution. Total credit facilities at one commercial bank are $11.6 million at December 29, 2002 and $24.6 million at December 30, 2001.

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 2002 and 2001and minimal write-off activity for fiscal 2000.

At December 29, 2002, December 30, 2001 and December 31, 2000, two customers, five customers and three customers, respectively, accounted for 100% of accounts receivable. Five customers accounted for 81% (the largest of which is 23%) of the revenue for the year ended December 29, 2002, four customers accounted for 72% (the largest of which is 34%) of the revenue for the year ended December 30, 2001 and three customers accounted for 59% (the largest of which is 28%) of the revenue for the year ended December 31, 2000.

### 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 three years. The direct costs related to obtaining regulatory approval of a facility are capitalized and depreciated over the expected life of the facility.

The following is the summary of property, plant and equipment and related accumulated amortization and depreciation as of December 29, 2002 and December 30, 2001.

| | Years of Life | December 29, 2002 | December 30, 2001 |
|---|---|---|---|
| Land | — | $ 1,401 | $ 987 |
| Buildings | 20-30 | 14,208 | 12,848 |
| Livestock | 3 | 2,744 | 2,523 |
| Leasehold improvements | lease life | 1,368 | 942 |
| Laboratory, manufacturing and office equipment | 3-10 | 7,949 | 3,985 |
| Laboratory, manufacturing and office equipment—capital lease | 3-10 | 1,960 | 1,143 |
| Construction in process | — | — | 158 |
| | | $29,630 | $22,586 |
| Less accumulated amortization and depreciation | | 7,929 | 6,629 |
| Net property, plant and equipment | | $21,701 | $15,957 |

Depreciation and amortization expense was $1,424,000, $1,237,000 and $1,274,000, for the fiscal years ended December 29, 2002, December 30, 2001 and December 31, 2000, 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 $774,000, $616,000 and $455,000 at December 29, 2002, December 30, 2001 and December 31, 2000, 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.

Non Cash Transactions

During fiscal 2000, the Company acquired full ownership of the SMIG JV by issuing an aggregate of 333,334 shares of the Company's Common Stock valued at approximately $11.1 million, plus transaction costs of $143,000 (see Note 13).

During fiscal 2001, as part of the consideration for sale of the Primedica subsidiary, the Company received Charles River 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.

The Company, in December 2001, issued 22,500 shares to a Director for consulting services considered to be outside the scope of his 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.

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 6) 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 1.40% at December 29, 2002). The principal is payable in two installments: 50% on April 3, 2005 and the remaining 50% on April 3, 2006.

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.

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

### 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.

### Accrued Expenses

Accrued expenses included the following:

| | At December 29, 2002 | At December 30, 2001 |
|---|---|---|
| Accrued payroll and benefits | $1,627 | $1,689 |
| Accrued bonuses | 851 | 975 |
| Other | 1,964 | 2,414 |
| Total accrued expenses | $4,442 | $5,078 |

There have been various employee terminations for which the Company recorded severance expenses of $975,000 and $179,000 in 2001 and 2000, respectively. These costs have been included in the Company's selling, general and administrative expenses. At December 29, 2002 and December 30, 2001, approximately $424,000 and $315,000, respectively, had been paid out of the severance reserve. At December 29, 2002, $176,000 remained in accrued expenses in relation to unpaid severance costs.

### Accounting for Employee Equity Plans

The Company applies APB Opinion 25 and related interpretations in accounting for its employee equity plans. Accordingly, 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 Statement of Financial Accounting Standards No. 123 ("SFAS 123"), *Accounting for Stock Based Compensation*. 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 29, 2002, December 30, 2001 and December 31, 2000 would have been increased to the pro forma amounts indicated below:

| | December 29, 2002 | | December 30, 2001 | | December 31, 2000 | |
|---|---|---|---|---|---|---|
| | 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 income reported . . . | $(24,320) | $(0.86) | $(16,556) | $(0.55) | $(14,141) | $(0.50) |
| Deduct: * . . . . . | (2,854) | (0.10) | (2,703) | (0.09) | (4,301) | (0.15) |
| Pro Forma net income . . | $(27,174) | $(0.96) | $(19,259) | $(0.64) | $(18,442) | $(0.65) |

* 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 7).

Revenue Recognition and Contract Accounting

The Company enters into licensing and development agreements with collaborative partners for the transgenic development in milk of recombinant proteins for therapeutic uses. 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.

Non-refundable license fees, milestones and collaborative research and development revenues under collaborative agreements, where the Company has continuing involvement, are recognized as revenue over the period of continuing involvement, using the model similar to the one prescribed by Emerging Issues Task Force Issue No. 91-6 (EITF 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. Payments received in advance of being earned are recorded as deferred revenue. When there are two or more distinct phases embedded into one contract, such as development and commercialization, the contract is considered a multiple element arrangement. When management can conclude as to the fair value of the related items, up front license fees and milestone payments are recognized over the initial phase of the contract only.

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 decisions are made based upon the current facts and circumstances and are reassessed on at least a quarterly basis.

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

exceed the amount of revenue recognized to date. Research and development revenues from the ATIII LLC (see Note 13) consisted of $0, $973,000 and $3,283,000 for the fiscal years ended 2002, 2001 and 2000, respectively, and the remainder of the revenue was from commercial clients.

### Research and Development Costs

All research and development costs are expensed as incurred. During its fiscal years ended December 29, 2002, December 30, 2001 and December 31, 2000, the Company spent, in total, $25 million, $22.4 million and $19 million, respectively, on cost of revenue and research and development expense of which $13.1 million, $15.1 million and $15.6 million, respectively, was related to external programs. Of the total spent on research and development, $5 million, $2.3 million and $3.3 million, was spent on the ATIII LLC in fiscal years 2002, 2001 and 2000, 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. Common stock equivalents of the Company consist of warrants (see Note 6), stock options (see Note 7), stock to be issued under the 401-K retirement plan (see Note 7), convertible debt (see Note 5) and convertible preferred stock (see Note 6). The Company was in a net loss position in 2002, 2001 and 2000, therefore 5.6 million, 3.1 million and 3 million common stock equivalents, 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.

### New Accounting Pronouncement

In April 2002, the FASB issued FASB Statement No. 145 ("SFAS No. 145"), *Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections as of April 2002.* SFAS No. 145 eliminates SFAS No. 4, *Reporting Gains and Losses from Extinguishment of Debt* which required companies to classify gains or losses from the extinguishment of debt as extraordinary items, net of tax. As a result of this new SFAS, gains and losses from extinguishment of debt should be classified as extraordinary items only if they meet the criteria in APB Opinion No. 30, *Reporting the Results of Operations—Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions.* The adoption of SFAS No. 145 is not anticipated to have a significant effect on the Company's financial position and results of operations.

In July 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* which nullifies EITF Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring).* SFAS No. 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred, whereas EITF No. 94-3 had allowed the liability to be recorded at the commitment date of an exit plan. The Company is required to adopt the provisions of SFAS No. 146 effective for exit or disposal activities initiated after December 31, 2002. The Company does not expect the adoption of SFAS No. 146 to have a significant impact on the Company's financial position or results of operations.

In December 2002, the FASB issued FASB No. 148 ("SFAS No. 148"), Accounting for Stock-Based Compensation—Transition and Disclosure. This Statement, which is effective for fiscal years ending after December 15, 2002, amends Statement No. 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, Statement No. 148 amends the disclosure requirements of Statement No. 123 regardless of the accounting method used to account for stock-based compensation. We have chosen to continue to account for stock-based compensation of employees using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations. The enhanced disclosure provisions as required by SFAS No. 148 have been included in the Company's notes to the financial statements for the year ended December 29, 2002.

In November 2002, the FASB Emerging Issues Task Force reached consensus on EITF No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables. EITF No. 00-21 addresses the accounting treatment for arrangements that provide the delivery or performance of multiple products or services where the delivery of a product, system or performance of services may occur at different points in time or over different periods of time. EITF No. 00-21 requires the separation of the multiple deliverables that meet certain requirements into individual units of accounting that are accounted for separately under the appropriate authoritative accounting literature. EITF No. 00-21 is applicable to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The Company does not expect the provisions of EITF 00-21 to have a material effect on its results of operations and financial position.

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, we have agreements whereby we indemnify our officers and directors for certain events or occurrences while the officer or director is, or was serving, at our 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 our exposure and enables us to recover a portion of any future amounts paid. As a result of our insurance policy coverage, we believe 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 January 31, 2003. The Company does not expect the disclosure or measurement provisions of FIN 45 to have a material effect on its results of operations and financial position.

In January 2003, the FASB issued FASB Interpretation No. 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 No. 46 changes that by requiring a variable interest entity, 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 No. 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. The consolidation requirements of FIN No. 46 apply immediately to variable interest entities created after January 31, 2003 and to older entities in the first fiscal year or interim period beginning after June 15, 2003. Certain of the disclosure requirements apply in all financial statements issued after January 31, 2003, regardless of when the variable interest entity was established. The Company does not expect the provisions of FIN 46 to have a material effect on its results of operations and financial position.

## NOTE 3. COMMITMENTS & CONTINGENCIES

The Company leases equipment and facilities under various operating and capital leases (see Note 5). 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 29, 2002, December 30, 2001 and December 31, 2000 was approximately $1,310,000, $1,037,000 and $723,000, respectively.

At December 29, 2002, the Company's future minimum payments required under these leases are as follows:

| | Operating | Capital | Total |
|---|---|---|---|
| 2003 | $ 657 | $282 | $ 939 |
| 2004 | 552 | 210 | 762 |
| 2005 | 452 | 210 | 662 |
| 2006 | 156 | 210 | 366 |
| 2007 | 4 | — | 4 |
| Thereafter | 1 | — | 1 |
| Total | $1,822 | 912 | $2,734 |
| Less amount representing interest | | 45 | |
| Present value of minimum lease payments (see also Note 5) | | $867 | |

The Company is a party to license agreements for certain technologies (see Note 12). 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.

Under a Service Agreement and Sublease Agreement with Genzyme (see Note 11), the Company is committed to make a minimum annual payment of $112,400 and 216,000, respectively, in 2003.

## NOTE 4. INTANGIBLE ASSETS

Intangible assets consist of:

| | Amortization Life | December 29, 2002 | December 30, 2001 |
|---|---|---|---|
| Asian marketing rights for SMIG | 15 years | $11,210 | $11,210 |
| Accumulated amortization—marketing rights | | (1,744) | (996) |
| Net | | 9,466 | 10,214 |
| License agreement with ACT | 10 years | 1,862 | 1,862 |
| License agreement with Pharming | 15 years | 1,517 | — |
| Accumulated amortization — license agreements | | (717) | (481) |
| Net | | 2,662 | 1,381 |
| Total intangible assets, net | | $12,128 | $11,595 |

Amortization expense was $984,000, $934,000 and $436,000 in 2002, 2001 and 2000, respectively.

## NOTE 5. BORROWINGS

In December 1998, the Company obtained credit facilities (the "Fleet Credit Line," the "Fleet Term Loan" and the "Standby Letter of Credit") from Fleet Bank ("Fleet") which expired on March 28, 2002. Under the Fleet Credit Line, the Company was able to borrow up to $16 million, of which $249,360 was to be utilized for the Standby Letter of Credit. As of December 30, 2001, $5,734,796 was outstanding on the $7.1 million Fleet Term Loan which was paid in full in March 2002.

At the Company's option, interest on loans under the Fleet Credit Line (other than the standby letter of credit) and the Fleet Term Loan accrued either at the Prime rate or at an adjusted LIBOR rate. The interest rate on the Fleet Term Loan was 2.48% at December 30, 2001. The weighted average interest rate on the outstanding lines of credit was approximately 0.7% for the fiscal year ended December 31, 2000. During 2001, no amounts were outstanding under the line.

In connection with the Fleet Credit Line, Genzyme provided a guaranty to the bank under which Genzyme would become primarily liable under the credit line in event of a default by the Company. In consideration of Genzyme's agreement to provide such a guaranty, the Company issued to Genzyme warrants to purchase 288,000 shares of the Company's Common Stock for a period of ten years, exercisable at $4.875 per share (market price at the effective date of the Credit Line).

In March 2002, the Company entered into a five year Loan and Security Agreement (the "Loan Agreement") with Silicon Valley Bank ("SVB") in the amount of $11.6 million, of which $5.5 million was used to refinance the Fleet 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 $1 million is currently available under a revolving line of credit. As a result of this refinancing, the Genzyme guaranty was eliminated. Interest on the SVB debt instruments accrues at the prime rate, which was 4.75% at December 29, 2002.

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

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.

The $4.8 million promissory note bears interest at the LIBOR plus 1% (LIBOR was at 1.40% at December 29, 2002). 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 29, 2002 |
|---|---|
| Bank term loan, with monthly payments of $143,333 through March 2008, interest varies as described above, collateralized by real estate | $ 9,026 |
| Promissory note to Genzyme, with principal payments of $2,386,000 in April 2005 and April 2006, interest varies as described above, collateralized by a subordinated lien on all assets except intellectual property | $ 4,773 |
| Capital lease obligations, with monthly payments of $18,886 through September 2003 and December 2006, interest from 3.50% to 16.4%, collateralized by property (see also Note 3) | 867 |
| | $14,666 |
| Less current portion (2003) | 1,880 |
| | $12,786 |

Maturities of long-term debt are as follows:

| | |
|---|---|
| 2004 | $ 1,917 |
| 2005 | $ 4,309 |
| 2006 | $ 4,314 |
| 2007 | $ 730 |
| 2008 and thereafter | $ 1,516 |
| | $12,786 |

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 29, 2002, December 30, 2001, and December 31, 2000 was $423,000, $349,000, and $544,000, respectively. Interest expense in the amount of $0, $657,000 and $0 was capitalized to construction in progress in 2002, 2001 and 2000, respectively.

## NOTE 6. 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.

### Genzyme Stock Buyback

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. 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 represents approximately 18% of the Company's outstanding shares. The lock-up provision will be released 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 1.40% at December 29, 2002). 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.

### Preferred Stock Placements

In 1999, the Company issued $6.6 million of Series B Preferred Stock to Genzyme. In February 2000, Genzyme converted the outstanding shares of Series B Preferred Stock into 1,048,021 shares of common stock. In connection with the issuance of the Series B Preferred Stock, the Company also issued to Genzyme 10-year warrants to purchase 85,324 shares of the Company's Common Stock at an exercise price of $6.30 per share.

### Common Stock Placements

In February 2000, the Company completed a public offering of 3.5 million shares of common stock at $20 per share. The Company granted the underwriters an option to purchase an additional 525,000 shares of its common stock to cover overallotment which was exercised. In total, the Company issued 4,025,000 shares, including the underwriter's overallotment, with net proceeds to the Company of $75 million.

In conjunction with the offering, the Company issued a Notice of Redemption to Genzyme for all outstanding shares of the Company's Series B Preferred Stock. Prior to the effectiveness of this redemption, Genzyme converted the Series B Preferred Stock into 1,048,021 shares of common stock. The Company paid a cash dividend of $157,000 in conjunction with the conversion.

In March 2000, the Company issued a warrant call notice for 450,000 warrants held by former holders of Series A Preferred Stock. Each warrant had an exercise price of $15.16 per share. All of the warrants were exercised with proceeds to the Company of $6.8 million.

A summary of the outstanding GTC warrants as of December 29, 2002, of which 538,324 are currently exercisable, is as follows:

| Common Shares Issuable for | Exercise Price Per Share | Warrant Expiration Date |
|---|---|---|
| 145,000 | $2.84375 | July 3, 2005 |
| 20,000 | $8.75000 | June 26, 2007 |
| 288,000 | $4.87500 | December 28, 2008 |
| 55,833 | $6.30000 | November 12, 2009 |
| 29,491 | $6.30000 | November 22, 2009 |
| 538,324 | | |

As of December 29, 2002, the Company has reserved 5,967,934 shares of common stock, subject to adjustment, for future issuance under the various classes of warrants, Stock Option and Employee Stock Purchase Plans (see Note 7).

## NOTE 7. 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, this 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 Company's and the Company's Affiliates' employees, consultants and directors. 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 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 29, 2002, December 30, 2001 and December 31, 2000 and changes during the years ending on those dates is presented below:

| | Shares | Weighted Average Exercise Price |
|---|---|---|
| Balance at January 2, 2000 | 2,826,197 | $ 6.7266 |
| Granted at Fair Value | 681,487 | $19.8971 |
| Exercised | (961,162) | $ 6.5434 |
| Cancelled | (91,617) | $ 9.7429 |
| Balance at December 31, 2000 | 2,454,905 | $10.3534 |
| Granted at Fair Value | 1,124,333 | $ 6.4637 |
| Exercised | (347,554) | $ 5.7314 |
| Cancelled | (1,078,240) | $11.1560 |
| Balance at December 30, 2001 | 2,153,444 | $ 8.6850 |
| Granted at Fair Value | 1,068,320 | $ 3.3771 |
| Exercised | (750) | $ 4.5625 |
| Cancelled | (42,795) | $11.6800 |
| Balance at December 29, 2002 | 3,178,219 | $ 6.9454 |

At December 29, 2002, December 30, 2001 and December 31, 2000, there were 1,804,885, 1,298,463 and 1,354,984 shares exercisable at a weighted average exercise price of $7.9062, $8.2781 and $8.5198, respectively.

The following table summarizes information about stock options outstanding at December 29, 2002:

| Range of Exercise Prices | Number Outstanding | Remaining Contractual Life | Weighted-Average Exercise Price | Number Exercisable | Weighted-Average Exercise Price |
|---|---|---|---|---|---|
| $ 0.8100 - $ 3.5700 | 314,680 | 8.21 | $ 2.1798 | 130,240 | $ 2.3229 |
| $ 3.6250 - $ 3.8000 | 794,770 | 9.04 | $ 3.7969 | 167,514 | $ 3.7887 |
| $ 3.8200 - $ 5.0313 | 539,655 | 7.82 | $ 4.7758 | 307,861 | $ 4.7186 |
| $ 5.2500 - $ 8.0000 | 836,258 | 4.89 | $ 7.2712 | 644,948 | $ 7.1101 |
| $ 8.0938 - $17.3125 | 588,006 | 6.40 | $11.5970 | 484,212 | $11.0715 |
| $17.7500 - $37.7500 | 104,850 | 7.56 | $27.5967 | 70,110 | $27.5739 |
| $ 0.8100 - $37.7500 | 3,178,219 | 7.12 | $ 6.9454 | 1,804,885 | $ 7.9062 |

At December 29, 2002, 1,884,093 shares were available for grant.

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 95% for fiscal 2002, 90% for fiscal 2001 and 80% for fiscal 2000, a dividend yield of 0% and a risk-free interest rate of 4.47% for fiscal 2002, 4.69% for fiscal 2001 and 6.18% for fiscal 2000. The average fair value of those options granted during fiscal 2002, 2001 and fiscal 2000 was $2.53, $4.36 and $13.58, respectively.

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.

In May 2002, the shareholders approved 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. A total of 366,993 shares of common stock remained available for issuance under the 2002 Purchase Plan as of December 29, 2002. The purchases of common stock under the 2002 Purchase Plan during fiscal 2002 and fiscal 2001 totaled 337,392 shares at an aggregate purchase price of approximately $441,000 and 101,847 shares at an aggregate purchase price of approximately $426,000, respectively. 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 will continue so long as a sufficient number of shares remain available to cover the purchases.

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 95% for fiscal 2002, 90% for fiscal 2001 and 80% for fiscal 2000, an expected life of five years for fiscal 2002, 2001and 2000 and a risk-free interest rate of 1.61% for 2002, 4.64% for fiscal 2001and 4.99% for fiscal 2000. The average fair value of those purchase rights granted during fiscal 2002, 2001and fiscal 2000 was $0.95, $3.30 and $3.01, respectively.

### Other

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 $349,000, $243,000 and $185,000 for the fiscal years ended December 29, 2002, December 30, 2001 and December 31, 2000, respectively.

## NOTE 8. 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:

| | 2002 | 2001 | 2000 |
|---|---|---|---|
| Deferred: | | | |
| Federal | $(9,177) | $(6,783) | $(4,423) |
| State | (1,587) | (641) | (928) |
| Change in Valuation Allowance | 10,764 | 7,424 | 5,351 |
| Total Deferred | $ — | $ — | $ — |

The provision for income taxes for continuing operations was at rates different from the U.S. Federal statutory income tax rate for the following reasons:

| | Fiscal Years Ended | | |
|---|---|---|---|
| | December 29, 2002 | December 30, 2001 | December 31, 2000 |
| Federal tax—expense (benefit) | (34.0)% | (34.0)% | (34.0)% |
| State taxes—net | (7.7) | (3.5) | (5.9) |
| Research and development tax credits | (3.6) | (4.9) | (1.7) |
| Other | 1.6 | 1.6 | 3.6 |
| Change in valuation allowance | 43.7 | 40.8 | 38.0 |
| Effective tax rate | 0% | 0% | 0% |

The components of the deferred tax assets and liabilities at December 29, 2002 and December 30, 2001, respectively, are as follows (dollars in thousands):

| | December 29, 2002 | December 30, 2001 |
|---|---|---|
| Deferred Tax Assets/(Liabilities): | | |
| Advance payments | $ 257 | $ 1,458 |
| Accrued compensation | 476 | 861 |
| Other accruals | 293 | 498 |
| Tax credits | 4,434 | 3,333 |
| Net operating loss carryforwards | 49,800 | 45,702 |
| Capitalized research and development expenses | 7,169 | — |
| Depreciation | (801) | (997) |
| Other | — | 9 |
| Total deferred tax asset | 61,628 | 50,864 |
| Valuation allowance | (61,628) | (50,864) |
| | $ — | $ — |

As of December 29, 2002, the Company had federal net operating loss and research and experimentation credit carryforwards of approximately $134 million and $3.1 million, respectively, which may be available to offset future federal income tax liabilities which expire at various dates starting in 2004 and going through 2022. The Company has recorded a deferred tax asset of approximately $4.8 million 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 $61.6 million has been established at December 29, 2002.

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 9. 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 |
|---|---|---|---|---|
| 2002 | $ 8,447 | $6 | $1,926 | $10,379 |
| 2001 | 8,913 | 31 | 4,796 | 13,740 |
| 2000 | 14,368 | 30 | 1,765 | 16,163 |

Of the Company's long-lived assets, $9.5 million of intangible assets are located in an offshore subsidiary and the remaining $2.6 million are located in the United States.

## NOTE 10. UNAUDITED RESULTS OF QUARTERLY OPERATIONS

| 2001 | First Quarter | Second Quarter | Third Quarter | Fourth Quarter |
|---|---|---|---|---|
| Revenue | $3,845 | $3,167 | $1,827 | $1,540 |
| Operating profit (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) |

| 2001 | First Quarter | Second Quarter | Third Quarter | Fourth Quarter |
|---|---|---|---|---|
| Revenue | $2,934 | $2,261 | $5,498 | $3,047 |
| Operating loss | (5,869) | (6,841) | (479) | (5,603) |
| Discontinued contract research operations | (2,236) | — | — | — |
| Net loss | (3,633) | (6,841) | (479) | (5,603) |
| Net loss per share — basic and diluted | (0.12) | (0.23) | (0.02) | (0.19) |

## NOTE 11. 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 $3,338,598, $2,478,000 and $826,000 for the fiscal years ended December 29, 2002, December 30, 2001 and December 31, 2000, respectively. These charges represent an allocation of the Company's proportionate share of Genzyme's overhead costs using formulae which management believes are reasonable based upon the Company's use of the facilities and services. See various agreements included within this note. 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 29, 2002, which represents approximately 18% 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. Genzyme owns approximately 19% 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. 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 represents approximately 18% of the Company's outstanding shares. The lock-up provision will be released 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 1.40% at December 29, 2002). 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 as 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 ($84,333 per month during 2002). 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 $1,012,000, $905,000 and $730,000 for the fiscal years ended December 29, 2002, December 30, 2001 and December 31, 2000, respectively, and is committed to make a minimum annual payment of $112,400 in 2003.

**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 29, 2002, December 30, 2001 and December 31, 2000, of $281,000, $368,000 and $146,000, respectively, and is committed to make a minimum annual rental payment of $216,000 in 2003.

**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 $17,000, $43,000 and $121,000 in 2002, 2001 and 2000, 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 ATIII program. Payments by the Company to Genzyme are on a cost plus 5% basis. Costs of $2,090,000 and $1,162,000 were incurred in 2002 and 2001, respectively.

### ATIII Collaboration

In 1997, the Company and Genzyme Corporation established the ATIII LLC joint venture for the marketing and distribution rights of rhATIII 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 rhATIII, if any, commencing three years after the first commercial sale, up to a cumulative maximum of $30 million.

The ATIII LLC formed a collaboration with Genzyme Molecular Oncology, a division of Genzyme, to jointly develop a form of transgenic ATIII for potential application as an angiogenesis inhibitor in the field of oncology. This research stage collaboration is based on a discovery by Dr. Judah Folkman from Children's Hospital, Boston, Massachusetts that certain conformations of ATIII, referred to as anti-angiogenic ATIII, inhibit angiogenesis *in vitro* and inhibit tumor growth in mice. Potential anti-angiogenic applications of rhATIII, outside the field of oncology, may be developed.

### Credit Line Guaranty, Term Loan Guaranty and Lien

Genzyme guaranteed a credit line and term loan with a commercial bank up to $24.6 million. This line and the Genzyme guarantee was eliminated in relation to the Company's refinancing of its credit facility on March 28, 2002.

### Series B Convertible Preferred Stock

In November 1999, the Company completed a $6.6 million private placement of Series B Preferred Stock to Genzyme. The proceeds from this placement were used to redeem $6.6 million of the Company's Series A Preferred Stock. In connection with the issuance of the Series B Preferred Stock, the Company issued warrants to purchase 85,324 shares of the Company's Common Stock at $6.30 per share to Genzyme. In February 2000, Genzyme converted the Series B Preferred Stock into 1,048,021 shares of the Company's Common Stock.

## NOTE 12. OTHER 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. The Company paid Tufts $679,000, $488,000 and $242,000 for the fiscal years ended December 29, 2002, December 30, 2001 and December 31, 2000, respectively. Net sales of products derived from transgenic animals produced by Tufts technology, or from their offspring, are subject to royalties payable to Tufts. The Company maintains a herd of research goats at Tufts' facility in Massachusetts.

**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 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 4). 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. 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 29, 2002 and are being amortized over a 15-year period, the remaining life of the underlying patents.

**Merrimack Pharmaceuticals, Inc. ("Merrimack")**

In the fourth quarter of 2002, the Company and Merrimack entered into agreements for clinical production and purification of MM-093 (formerly ABI-001), which is a recombinant human alpha-fetoprotein (rhAFP). Under this agreement, the Company will primarily be compensated upon delivery of MM-093, beginning in 2003. Merrimack intends to use transgenically produced MM-093 to initiate its Phase I clinical studies of rhAFP in Myasthenia Gravis in late 2003. Payment to the Company on this program is dependent upon Merrimack completing a further equity financing.

**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 29, 2002, the Company had paid approximately $280,000 to Cambrex and had accrued approximately $1.7 million for services rendered under the contract. The total contract value is estimated at approximately $4.4 million.

## NOTE 13. JOINT VENTURES

### Taurus rhSA LLC

In 2002, Fresenius AG and GTC restructured their relationship for the therapeutic blood expander market into a joint venture, called Taurus rhSA LLC (the "Taurus Joint Venture"), to include the development of rhSA as an excipient under an agreement that became effective January 1, 2003. The Taurus Joint Venture will manage development of rhSA for both the excipient and blood expander markets. GTC has a majority interest in the joint venture. GTC and Fresenius are making available all relevant commercial licenses, manufacturing rights, and intellectual property to enable the joint venture to operate worldwide in both the excipient and blood expander markets. During 2001 and 2002, Fresenius had added to its marketing rights for rhSA in Europe by exercising its option to the marketing rights in North America and Asia, including Japan. These marketing rights are now part of the joint venture. The excipient market is part of an integrated development plan that can also provide entry to the blood expander market. 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.

### Previous ATIII LLC Joint Venture

In 1997, the Company and Genzyme Corporation established the ATIII LLC joint venture for the marketing and distribution rights of rhATIII 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 rhATIII, if any, commencing three years after the first commercial sale, up to a cumulative maximum of $30 million.

The ATIII LLC formed a collaboration with Genzyme Molecular Oncology, a division of Genzyme, to jointly develop a form of transgenic ATIII for potential application as an angiogenesis inhibitor in the field of oncology. This research stage collaboration is based on a discovery by Dr. Judah Folkman from Children's Hospital, Boston, Massachusetts that certain conformations of ATIII, referred to as anti-angiogenic ATIII, inhibit angiogenesis *in vitro* and inhibit tumor growth in mice. Potential anti-angiogenic applications of rhATIII, outside the field of oncology, may be developed.

## NOTE 14. 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 relates to the evaluation of potential market opportunities for rhSA in several areas. As of December 29, 2002, the Company had paid $10,000 to the consultant for services rendered. Management believes this is an arms-length transaction and the Board of Directors has been made 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. One Director, who also served as Chairman of the Board, received $43,200 in 2001 and 2000 as compensation for consulting services. Another Director received $99,000 in 2000 as compensation for consulting services. The Company, in December 2001, issued 22,500 shares to a Director for services considered to be outside the 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 15. 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 |

The assets of Primedica were as follows:

| | December 31, 2000 |
|---|---|
| Current assets | $ 22,248 |
| Property, plant and equipment, net | 24,633 |
| Other assets | 16,660 |
| Current liabilities | (19,903) |
| Other liabilities | (6,366) |
| Net assets of discontinued operations | $ 37,272 |

## NOTE 16. SUBSEQUENT EVENT

### Malaria Vaccine Contract

The NIAID has approved a proposal to fund development of clinical grade production of MSP-1. The development work will be 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.

## REPORT OF INDEPENDENT ACCOUNTANTS 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, 2003 appearing in the 2002 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, 2003

## Schedule II—Supplemental Valuation and Qualifying Accounts

### Years ended December 29, 2002, December 30, 2001 and December 31, 2000:

### Deferred tax asset valuation allowance

| | Balance at Beginning of Period | Charges/(Benefits) to Costs and Expenses | Balance at End of Period |
|---|---|---|---|
| December 29, 2002 | $50,864 | 10,764 | $61,628 |
| December 30, 2001 | $52,384 | (1,520) | $50,864 |
| December 31, 2000 | $43,615 | 8,769 | $52,384 |

### 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 29, 2002 | $316 | (316) | — | $ — |
| December 30, 2001 | $316 | — | — | $316 |
| December 31, 2000 | $316 | 175 | (175) | $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 28th day of March 2003.

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<br>Geoffrey F. Cox | Chairman of the Board, President and Chief Executive Officer | March 28, 2003 |
| /s/ JOHN B. GREEN<br>John B. Green | Chief Financial and Accounting Officer (Principal Financial and Accounting Officer) | March 28, 2003 |
| /s/ JAMES A. GERAGHTY<br>James A. Geraghty | Director | March 28, 2003 |
| /s/ ROBERT W. BALDRIDGE<br>Robert W. Baldridge | Director | March 28, 2003 |
| /s/ ALAN W. TUCK<br>Alan W. Tuck | Director | March 28, 2003 |
| /s/ FRANCIS J. BULLOCK<br>Francis J. Bullock | Director | March 28, 2003 |
| /s/ PAMELA W. MCNAMARA<br>Pamela W. McNamara | Director | March 28, 2003 |
| /s/ MARVIN L. MILLER<br>Marvin L. Miller | Director | March 28, 2003 |

## CERTIFICATIONS

I, Geoffrey F. Cox, certify that:

1) I have reviewed this annual report on Form 10-K of GTC Biotherapeutics, Inc.;

2) Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3) Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4) The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

   a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

   c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5) The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6) The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 28, 2003

/s/ GEOFFREY F. COX

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

I, John B. Green, certify that:

1) I have reviewed this annual report on Form 10-K of GTC Biotherapeutics, Inc.;

2) Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3) Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4) The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

   a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

   c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5) The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6) The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 28, 2003

/s/ JOHN B. GREEN

John B. Green
*Senior Vice President and*
*Chief Financial Officer*

## EXHIBIT INDEX
## to Form 10-K for the Year Ended December 29, 2002

| Exhibit No. | Description |
|---|---|
| 10.6.7 | Amendment No. 14, effective as of September 6, 1997, to the Cooperation and Licensing Agreement between GTC and Tufts University dated September 6, 1988, as amended (the "Corporation and Licensing Agreement"). Filed herewith.** |
| 10.6.8 | Amendment No. 16, effective as of September 6, 2000, to Cooperation and Licensing Agreement. Filed herewith.** |
| 10.6.9 | Amendment No. 18, effective as of September 6, 2001, to Cooperation and Licensing Agreement. Filed herewith.** |
| 10.20.1 | Limited Liability Company Agreement of Taurus hSA LLC dated as of December 20, 2002. Filed herewith.** |
| 10.20.2 | Contribution and License Agreement by and between GTC and Taurus hSA LLC dated as of December 20, 2002. Filed herewith.** |
| 10.21 | Service Agreement by and between GTC and Cambrex Bio Science MA, Inc. dated as of August 20, 2002. Filed herewith.** |
| 10.30* | Executive Employment Agreement, dated as of February 9, 2002 between GTC and Paul K. Horan. Filed herewith. |
| 21 | List of Subsidiaries. Filed herewith. |
| 23 | Consent of PricewaterhouseCoopers LLP. Filed herewith. |
| 99.1 | Important Factors Regarding Forward-Looking Statements. Filed herewith. |
| 99.2 | Certifications pursuant to 18 U.S.C. Section 1350. Filed herewith. |

* Indicates a management contract or compensatory plan.

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

NOTES

## 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.
Senior Advisor
Strategic Decisions Group
Former Sr. Vice President of
Research Operations
Schering-Plough Pharmaceutical
Research Division

JAMES A. GERAGHTY
Senior Vice President
International Development
Genzyme Corporation

PAMELA W. MCNAMARA
Former CEO of Arthur D. Little

MARVIN L. MILLER
Former President and CEO of
Nextran, an affiliate of
Baxter Healthcare Corporation

ALAN W. TUCK
Principal, 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.

PAUL K. HORAN, PH.D.
Senior Vice President
Corporate Development
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

## INDEPENDENT PUBLIC ACCOUNTANTS

PricewaterhouseCoopers LLP
Boston, MA

## EXTERNAL LEGAL COUNSEL

Palmer & Dodge LLP
Boston, MA

## 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.

## MARKET FOR COMMON EQUITY

Nasdaq National Market System
Trading Symbol: GTCB

## SEC FORM 10-K

Copies of the Company's 2002 Annual Report on 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.

## ANNUAL MEETING

The 2003 Annual Meeting of Shareholders will be held on Wednesday, May 21, 2003 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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Framingham, MA 01702
508.620.9700

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