
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

**Annual report pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

For the fiscal year ended December 30, 2001

Commission File No. 0-21794

GENZYME TRANSGENICS CORPORATION

(Exact name of Registrant as specified in its charter)

MASSACHUSETTS

*(State or other jurisdiction of
incorporation or organization)*

04-3186494

*(I.R.S. Employer
identification No.)*

**175 CROSSING BOULEVARD
FRAMINGHAM, MASSACHUSETTS**
(Address of principal executive offices)

01702
(Zip Code)

(508) 620-9700

(Registrant's telephone number, including area code)

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

| <u>Title of Each Class</u> | <u>Name of each exchange on which registered</u> |
|----------------------------|--|
| None | None |

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

Common Stock, par value \$0.01

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 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.

Aggregate market value of voting stock held by non-affiliates of the Registrant as of March 13, 2002: \$78,270,602

Number of shares of the Registrant's Common Stock outstanding as of March 13, 2002: 30,336,417

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for the Annual Meeting of Stockholders to be held May 22, 2002 are incorporated by reference into Part III of this Form 10-K.

ITEM 1.

BUSINESS

Overview

Genzyme Transgenics Corporation (“GTC” or the “Company”) is the leader in the application of transgenic technology to the development in milk of recombinant proteins for therapeutic uses. Currently, GTC is using its technology platform to work toward commercialization in 15 therapeutic protein programs. Twelve of the programs focus on proteins that are proprietary to our partners (external program partnerships) and three focus on proteins that GTC began developing internally (internal program partnerships). The Company generally uses collaboration agreements in developing its programs to provide the opportunity to participate in many more potential therapeutics than would be practical independently. These collaboration agreements also provide current revenues through the achievement of development milestones, and augment GTC’s capabilities in areas such as clinical development and product marketing.

GTC’s technology platform includes the ability to generate transgenic animals that express specific recombinant proteins in their milk, provide for animal husbandry, breeding and milking, and to purify the milk to a clarified intermediate bulk material that may undergo manufacturing to obtain a clinical grade product. The Company generates transgenic animals through microinjection and nuclear transfer. In microinjection, a specific DNA sequence that directs the production of a desired protein in milk is inserted into the genetic material of an animal embryo. If the developing fetus successfully incorporates this sequence, a transgenic animal may be born. Otherwise a non-transgenic animal may be born. Nuclear transfer involves the incorporation of the specific DNA sequence into at least one cell line developed in a laboratory. This cell line material is transferred to the nucleus of an animal ovum, stimulated to initiate growth, and placed into a surrogate female animal. All animals that are born through this process are transgenic. GTC expects to rely primarily on nuclear transfer techniques in new program development work. The Company uses goats in most of its commercial development programs due to the relatively short generation times and relatively high milk production volume. A goat gestates in approximately five months and reaches sexual maturity in about another seven months. A typical goat will produce about 2 liters a day of milk during most of its natural lactation cycle.

GTC’s operations in goat husbandry, breeding, milking and clarification to intermediate bulk material occur at the Company’s biopharmaceutical farm production facilities in central 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 enhance separation of the animals from uncontrolled contact with wildlife or people as well as specified and monitored feed. Milking is typically performed using modern milking equipment where the milk is processed through tubing, piping and covered vats. 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 and formulation occur either in the facilities of GTC’s partners or in contracted facilities. The Company is exploring expansion of its manufacturing capabilities. In January 2002, GTC completed the purchase of approximately 128 acres of land in eastern New York State that the Company plans to develop over the next several years to provide for herd duplication and additional capacity.

The Company believes that transgenic production offers substantial economic and technological advantages in comparison to traditional protein production systems, such as cell culture and microbial systems. These advantages include reduced capital expenditures, greater flexibility in applying the capital invested and lower direct production cost per unit. Greater flexibility in the applied capital results from the ability to breed a transgenic herd to the appropriate capacity to satisfy the market size. In contrast, traditional systems have a generally fixed capacity that requires significantly higher incremental investment than a transgenic system to obtain substantially higher capacity. 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 and proteins found in human plasma are examples of potential recombinant therapeutic proteins that have not expressed at practical levels in traditional systems. An Ig fusion protein puts a monoclonal antibody (MAB) fragment together with another protein fragment to form a single protein. A MAB is a protein that binds with a specific cell group target.

GTC's focus is on using transgenic technology to commercially develop large volume or difficult to express proteins. The economic and technical advantages of GTC's technology make it well suited to large volume applications. Many MAB and some Ig fusion proteins may become large volume products due to the anticipation of relatively large and repeated doses for chronic diseases such as rheumatoid arthritis, other autoimmune diseases and cancer. By early 2002, 18 monoclonal antibodies had been approved for use in the United States, ten for use as human therapeutics and eight for diagnostic uses. The total 2000 revenues for therapeutic antibodies, including ReoPro®, Rituxan®, Synagis®, Herceptin®, Remicade®, Zenapax®, Mylotarg®, and Campath® exceeded \$2.6 billion. Seventy-six companies and institutions list over 180 monoclonal antibodies in preclinical and clinical phases of development. The Company believes that in many cases the yearly requirement for production of these potential therapeutics will exceed 100 kilograms and may approach 300 to 1,000 kilograms. Transgenic production may provide an economically attractive means to meet the large projected volume requirements for these therapeutics.

The Company has several partnerships with pharmaceutical and other biotechnology companies to develop their MAB and Ig fusion proteins transgenically. GTC's corporate partners developing these types of proteins include Abbott, Abgenix, Alexion, Bristol-Myers Squibb, Centocor, Elan, ImmunoGen, and Progenics. The Company is also developing a protein that is not a MAB or an Ig fusion protein with Merrimack Pharmaceuticals with potential for use in myasthenia gravis. 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, anticipate the payment of royalties on product sales upon commercialization. Following characterization of the transgenic product in preclinical testing and pharmacokinetic studies, GTC will negotiate commercialization agreements that are designed to allow the Company to participate in the success of the product through royalties and supply commitments. GTC has been granted several patents covering the production of monoclonal and assembled 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 also developing its own molecules, for which the Company seeks partners to provide appropriate development support to each related program and to share in the costs of that program. The first of these programs is recombinant human antithrombin III (rhATIII). ATIII is a blood plasma protein that has anticoagulant and anti-inflammatory properties. Blood plasma proteins are difficult for traditional recombinant systems to express. In early 2001, the Steering Committee of the joint venture that was in place at that time for the management of the ATIII program decided to no longer actively pursue development of the treatment of heparin-resistant patients undergoing cardiopulmonary bypass surgery based on discussions with the US Food and Drug Administration (FDA). In late 2001, GTC was granted permission by the European Medicinal Evaluation Agency (EMEA) for clinical studies of rhATIII in those people that have a hereditary deficiency (HD) of ATIII in their blood. In December 2001, GTC began dosing patients in an HD pharmacokinetic study. Assuming this study and ongoing discussions with the regulatory authorities progress as expected, an efficacy trial of rhATIII in the HD indication may begin in late 2002. Assuming that this study progresses as planned, a regulatory filing for approval is possible in 2004. GTC believes that this would make rhATIII the first transgenically produced therapeutic protein to be considered for approval. ATIII is currently produced by human plasma fractionation, with worldwide annual sales of approximately \$250 million. Only about \$10 million of these sales were in the United States where ATIII was not widely available. The Company is currently in discussions with potential marketing partners for rhATIII.

Another plasma protein under development by GTC is Human Serum Albumin (HSA), which is being developed with Fresenius AG. The therapeutic use of HSA 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. HSA 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 product a year, GTC is developing this program in transgenic cattle to take advantage of the higher milk production of a cow. A cow will generally produce about 20 liters a day of milk during natural lactation periods. During 2001, Fresenius added to its marketing rights for HSA in Europe by exercising its option to HSA marketing rights in North America and Asia, except for Japan. GTC expects to begin clinical grade production later this year to support preclinical and eventually clinical studies that will be conducted by Fresenius. These studies are expected to begin next year.

GTC is also developing a malaria merozoite surface protein (MSP-1) for use in a malaria vaccine. The MSP-1 protein successfully protected Aotus nancymai monkeys in a preclinical vaccine study conducted by the National Institute of Allergy and Infectious Diseases (NIAID). Although MSP-1 can be produced in other recombinant systems, these other systems produce it in very limited quantities or in forms that may not induce the necessary immune response. The NIAID and GTC established a Cooperative Research and Development Agreement (CRADA) to evaluate the feasibility of developing animals capable of producing recombinant versions of MSP-1 in their milk. 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 U.S. patent has been allowed for this modification. The MSP-1 protein has been expressed at 2-4mg/ml in the milk of mice that have incorporated this gene sequence. It was this product that was used in the preclinical vaccine study. GTC has developed goats at its research facilities that express the MSP-1 protein. The Company is currently seeking additional funding for this program from government and non-profit sources to develop goats capable of producing clinical grade material at its operating facilities.

Transgenic Technology

Overview

Transgenic technology uses *in vitro* microinjection or nuclear transfer to introduce a genetically engineered segment of exogenous DNA (an "expression vector") into the genetic material of a fertilized egg or early stage animal embryo. Two types of genetic instructions are incorporated into the expression vector: the coding sequence and the promoter sequence. Coding sequences instruct the cells of the animal to express a specified protein. Promoter sequences direct the expression of proteins at appropriate times and by specific tissues or cell types. GTC utilizes promoter sequences that direct the expression of specific proteins in the mammary gland during lactation. After microinjection of the exogenous DNA, the modified embryo is then transferred to a recipient female. Transgenes are successfully integrated into the genetic makeup of only a small percentage of the embryos that are microinjected; therefore multiple microinjection candidates are required. If successful, the resulting animal, when mature and lactating, will express the desired protein. In nuclear transfer, the exogenous DNA is established in a cell line before insertion into an enucleated donor egg. All successful pregnancies resulting from this method will result in transgenic animals. Once established in the first generation of transgenic animals, the transgene is transmitted like other genetic traits to future generations through traditional breeding with either non-transgenic or other transgenic animals. To date, GTC has produced such proteins principally using goats, which offer an attractive combination of large milk volumes, relatively short generational time periods and ease of handling and milking. GTC has also used cattle, which have longer generational time periods but produce higher milk volumes.

GTC is now utilizing the nuclear transfer methodology in its programs and has been using it in the HSA program, which has transgenic cattle. Due to the long gestation and maturation periods in cattle, nuclear transfer may shorten the development time by producing a larger number of transgenic animals in one

generation. GTC has signed an exclusive, worldwide licensing agreement with Advanced Cell Technologies, Inc. (ACT) that allow 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. To date, the Company has produced 20 transgenic cows and continues to produce transgenic cattle with nuclear transfer. The US Patent and Trademark Office (PTO) has granted an interference proceeding between ACT, Geron Corporation and Infigen 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:

- *Lower Capital Investment.* Developing a herd and providing appropriate dairy facilities can be accomplished with substantially less cost than building a cell culture bioreactor facility.
- *Flexible Production and Improved Risk Management of Capital Investment.* Transgenic production offers the ability to breed sufficient animals to achieve the appropriate capacity, once the first appropriate animal is identified. If the product's market is larger than originally planned, the incremental investment to breed additional animals is 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.
- *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 simplicity of operations result in the cost of transgenically produced products, in most cases, being substantially lower than that of a cell culture derived product.
- *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 suitability 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 in cell cultures at all. 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.

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 DNA for a desired protein and establishes an appropriate expression vector of this DNA together with the appropriate coding and promoter sequences. The Company then employs either microinjection or nuclear transfer to initiate pregnancies that may produce a transgenic animal. The first animals are then born after the appropriate gestation period.
- *Transgenic Evaluation.* GTC and the appropriate partner evaluate the genetic profile of the animal. The animal's production levels under induced or natural lactation are evaluated and the protein 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 is the potential start of a herd to produce a therapeutic protein. After GTC provides protein samples from transgenic milk to the partner for initial purification and characterization, GTC and the partner 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. Next, GTC initiates an initial scale up of the transgenic herd making animals that are capable of producing sufficient product for use in expanded clinical studies. GTC provides initial quantities of product while working with the partner to develop cost and timing estimates for commercialization. Based on these estimates, the partner will make capital commitments to enable GTC to provide sufficient facility capacities specifically for the partner's product including one or several barns for housing and scaling up the herd and facilities for collection of milk and initial processing. Simultaneously, GTC will begin scaling up the production herd to breed a sufficient number of animals to meet forecasted production requirements. GTC anticipates that its future commercial supply agreements will provide for the transfer of intermediate bulk to the customer or designated processor for further processing to finished product.

External Program Partnerships

GTC's strategy includes entering into collaboration agreements with biotechnology and pharmaceutical companies to develop their therapeutic proteins transgenically. To date, the Company has formed approximately a dozen collaboration agreements which generally provide for transgenic production of targeted proteins in exchange for development fees and milestone payments, transfer payments for manufacturing and, in some cases, anticipate the payment of royalties on product sales upon commercialization. Following characterization of the transgenic product in preclinical testing and pharmacokinetic studies, GTC will negotiate commercialization agreements that are designed to allow the Company to participate in the success of the product through a mixture of manufacturing margins and royalties appropriate to each situation.

The products covered by these partnerships encompass a broad range of indications and are currently in various stages of development. Many of GTC's collaborators are marketing or engaging in clinical trials with product sourced through traditional protein production systems and are considering transitioning to a transgenically produced product. Eleven of the twelve external program partnerships are developing MAB or Ig fusion proteins transgenically. One of the twelve external program partnerships is developing a human alpha-fetoprotein transgenically.

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

Monoclonal antibodies represent one of the biotechnology industry's greatest successes. Medical researchers have now developed a better understanding of the critical variables for specificity and binding of the antibody, and have identified targets likely to affect disease progression and clinical conditions amenable to treatment with systemic biologic intervention. As a result, the last several years have witnessed the clinical success, regulatory approval and commercial launch of several breakthrough monoclonal antibody therapies. These therapies include ReoPro® for use in various acute cardiac conditions, Rituxan® for B-cell non-Hodgkin's lymphoma, Synagis® for treatment of viral respiratory disease in premature babies, Herceptin® for breast cancer, Remicade® for use in Crohn's disease and rheumatoid arthritis and Zenapax® for acute transplant rejection. These clinical successes, together with the availability of drug discovery technologies that identify potential antibody targets and technologies for developing humanized and fully human antibody candidates, will continue to drive the development of new antibody-based therapeutics.

Therapeutic antibodies are typically administered in larger doses than other protein therapeutics and in repeated doses to treat chronic illnesses. Their continued success is driving the need for commercially feasible production methods yielding significantly higher quantities than currently available using traditional protein production methods. While the annual worldwide requirement of a typical recombinant protein may be in the 10's of kilograms, the Company believes that many antibodies will require supplies in the range of 100's or 1000's of kilograms annually. Current cell culture methods (the only traditional method available for producing monoclonal antibodies) may not produce the requisite high volumes needed for antibody therapeutics, or are not economically feasible or require significant capital investment. GTC believes that using transgenic technology will enable the pharmaceutical industry to meet these market demands.

GTC is actively participating in the field of monoclonal antibodies through eight collaborations. GTC is developing transgenic versions of Remicade® and a second undisclosed MAB for Centocor, Antegren® and an undisclosed MAB for Elan, D2E7 for Abbott, 5G1.1 for Alexion, ABX-IL8 for Abgenix, and huN901 for ImmunoGen. The indications for these products include arthritis, Crohn's disease, neurological disorders, nephritis, psoriasis and cancer.

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.

Other External Program Partnerships

GTC is also working with Merrimack Pharmaceuticals, previously known as Atlantic BioPharmaceuticals, to develop ABI.001. ABI.001 has orphan drug status and is expected to enter Phase I trials shortly for the treatment of myasthenia gravis, an autoimmune disease of the voluntary muscles. ABI.001 is a recombinant version of human alpha-fetoprotein. GTC began working with Atlantic BioPharmaceuticals on ABI.001 in 2001. Early in 2002, Atlantic BioPharmaceuticals acquired Merrimack Pharmaceuticals and became known as Merrimack Pharmaceuticals.

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; Transgenic goats in evaluation | Centocor |
| Undisclosed | Monoclonal antibody | Undisclosed | Undisclosed | Undisclosed clinical status; Undisclosed transgenic status | Centocor |
| D2E7 | Fully human monoclonal antibody | Rheumatoid Arthritis | Phase III clinicals | Preclinical; Founder | Abbott |
| Antegren® | Humanized monoclonal antibody | Neurological Disorders | Phase II clinicals | Preclinical; Founder | Elan Pharmaceuticals |
| Undisclosed | Monoclonal Antibody | Undisclosed | Undisclosed | Preclinical; Transgenic goats in development | Elan Pharmaceuticals |
| CTLA4Ig | Immunoglobulin fusion/soluble receptor | Rheumatoid Arthritis | Phase II clinicals | Preclinical; Founder | Bristol-Myers Squibb |
| Undisclosed | Immunoglobulin fusion protein | Organ Transplant Rejection; Autoimmune Disorders | Phase II clinicals | Preclinical; Transgenic goats in evaluation | Bristol-Myers Squibb |
| 5G1.1 | Monoclonal antibody | Rheumatoid Arthritis; Nephritis | Phase II clinicals | Preclinical; Transgenic goats in evaluation | Alexion |
| PRO542 | CD4/Immunoglobulin fusion antibody | HIV/AIDS | Phase II clinicals | Preclinical; Transgenic goats in evaluation | Progenics |
| ABX-IL8 | Monoclonal antibody | Skin Cancer | Phase I clinicals | Preclinical; Transgenic goats in evaluation | Abgenix |
| HuN901 | Monoclonal antibody | Small Cell Lung Cancer | Preclinical with IND filed | Preclinical; Transgenic goats in evaluation | ImmunoGen |
| ABI.001 | Human alpha-fetoprotein | Myasthenia Gravis | Preclinical | Preclinical; Transgenic goats in development | Merrimack Pharmaceuticals |

Internal Program Partnerships

GTC internally continues the commercial development of three recombinant proteins; ATIII, HSA, and MSP-1. The Company has a partnership with Fresenius AG for the HSA program. GTC expects to enter into additional partnerships with other organizations for the ATIII and malaria vaccine programs at appropriate times to augment the Company's capabilities in areas such as product marketing and clinical studies as well as to help support the cost of development.

Antithrombin III. ATIII is a protein normally found in human serum that has anticoagulant and anti-inflammatory properties. Decreased levels of ATIII are found in individuals who have either a hereditary or an acquired deficiency of ATIII. The hereditary deficiency condition has an incidence rate of 1 in 2,000 to 1 in 5,000. Individuals with hereditary ATIII deficiency have an increased tendency toward blood clots known as thromboses and are treated with ATIII replacement therapy during periods when they are at high risk for clots, such as during surgery. Acquired ATIII deficiency may occur if there is 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 acute liver failure, disseminated intravascular coagulation, sepsis and septic shock, burns, multiple organ failure, pre-eclampsia, bone marrow or organ transplantation and hemodialysis.

The Company filed an Investigational New Drug (IND) application with the FDA in 1996 to evaluate use of recombinant human ATIII (rhATIII) as a potential treatment for ATIII deficiency that occurs in certain patients with heart disease. Patients undergoing cardiopulmonary bypass (“CPB”) surgery require anticoagulation with heparin to prevent clotting, which can occur when blood comes into contact with the tubing of the heart-lung machine performing the heart’s function during surgery. Patients that do not respond adequately to these heparin treatments may be described as heparin-resistant.

Two identical, double blinded, randomized placebo-controlled Phase III clinical trials began in the second quarter of 1998. These studies, which included 52 patients each, were designed to assess the activity of rhATIII in reducing the use of fresh frozen plasma to treat heparin-resistant patients while undergoing cardiac surgery requiring CPB. The two studies, conducted at medical centers in Europe and the United States, have been completed, and the primary clinical endpoint was met in both studies with a high degree of statistical significance. Moreover, the drug was well tolerated by patients. There was no detectable antibody formation to rhATIII. There was no statistically significant difference in adverse events reported among the groups of both studies. The most commonly observed trends to adverse events were bleeding and clotting disorders. In the placebo control and rhATIII groups, respectively, these events occurred in 42% and 50% of the patients in the first study, and in 22% and 41% of the patients in the second study.

In late 2000, the Company announced that it expected to re-acquire from Genzyme the rights to rhATIII that it did not already own. In early 2001, the ATIII LLC met with the U.S. Food and Drug Administration to discuss the status of the clinical development program for the rhATIII in the treatment of heparin-resistant patients undergoing cardiopulmonary bypass surgery. The ATIII LLC decided to discontinue development of this indication based on the level of additional data that would have been required to address the clinical development issues raised during the meeting with the FDA. In 2001, GTC reacquired Genzyme’s ownership interest the ATIII LLC in consideration of 4% of GTC’s future product revenue, three years after approval, up to a total of \$30 million.

In late 2001, GTC was granted permission by the EMEA for clinical studies of rhATIII in those people that have an ATIII HD. There are between 1 in 2,000 and 1 in 5,000, people that have low levels of ATIII in their blood. Of this group of people, some have levels so low that they are at risk of developing thrombosis in medical conditions such as pregnancy and surgeries. GTC believes that studying its rhATIII protein in these individuals is a reasonable clinical development plan for this program.

In December 2001, GTC began dosing patients in an HD pharmacokinetic study. Assuming this study and ongoing discussions with the regulatory authorities progress as planned, an efficacy trial of rhATIII in the HD indication may begin in late 2002. Assuming that the efficacy study progresses as planned, a regulatory filing for approval is possible in 2004. GTC believes, based on the publicly available information from its competitors in the area of transgenic technology, that this would make rhATIII the first transgenically produced therapeutic protein to be considered for approval. The Company believes that it will be able to expand rhATIII into other studies for additional indications once it achieves an approval for the HD indication. GTC also expects to begin clinical and regulatory work in the United States for the rhATIII HD indication before approval by the EMEA.

ATIII is currently produced by human plasma fractionation, with worldwide annual sales in all indications of approximately \$250 million. Only about \$10 million of this was in the United States where plasma derived ATIII was not widely available. The Company is currently in discussions with potential marketing partners for rhATIII.

In addition, in late 1997 and early 1998, GTC and Genzyme established the ATIII LLC joint venture for the marketing and distribution of rhATIII in all territories other than Asia. 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. RhATIII is being developed under a royalty-bearing license from Centeon, a wholly owned subsidiary of Aventis SA and the successor to Behringwerke AG.

Human Serum Albumin. HSA is the protein principally responsible for maintaining the osmotic pressure in the vascular system, known as oncotic pressure, 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. The therapeutic use of HSA is indicated in situations of blood loss and/or decreased blood albumin levels which can occur during shock, serious burns, pre- and post-operative conditions, congestive heart failure and gastric, liver and intestinal malfunctions. HSA is currently produced by human plasma fractionation, with worldwide sales of approximately \$1 billion to \$1.5 billion requiring 400 metric tons of product annually.

In 1999, GTC successfully produced transgenic cattle expressing this protein in their milk at commercially feasible levels. An individual transgenic cow is expected to produce 80 kilograms of albumin annually. GTC believes that this level of production should provide the Company with the ability to produce HSA at costs competitive with albumin sourced from human blood, and in the amounts required to meet market demand. GTC has refined its purification process for transgenic HSA at bench scale and developed a detailed economic model for its commercial production.

The Company has entered into an agreement with Fresenius AG of Bad Homburg, Germany, to further develop and commercialize transgenic HSA. Fresenius has marketing rights to HSA in Europe, North America and Asia, except Japan. GTC expects to begin production of clinical grade HSA later this year in anticipation of preclinical and eventually clinical studies to be conducted by Fresenius starting in 2003.

Malaria Vaccine. GTC's transgenic expression system has the potential to express the correct, immunogenic protein for use as a malaria vaccine both economically and on a large scale. Malaria is a disease that has an annual incidence of more than 300 million people worldwide and results in several million deaths annually. GTC is working with the National Institutes of Health (NIH) and the Federal Malaria Vaccine Coordinating Committee to transgenically develop a malaria protein, which is considered a promising vaccine candidate and to examine the options for commercializing the vaccine. The Company has entered into a CRADA with the NIH and during 1998 achieved high level expression of the candidate vaccine malaria antigen, MSP-1, in the milk of transgenic mice. The MSP-1 protein successfully protected *Aotus nancymai* monkeys in a preclinical vaccine study conducted by the 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*. The Company is currently seeking additional funding for this program from government and non-profit sources to develop goats capable of producing clinical grade material at its operating facilities.

Sale of Primedica Corporation

In February 2001, the Company sold Primedica Corporation, its contract research organization, to Charles River Laboratories, Inc. (NYSE: CRL). GTC received \$26 million in cash and 658,945 shares of CRL common stock valued at \$15.9 million. Charles River Laboratories assumed all of Primedica's approximately \$9 million of capital leases and long-term debt. The results of GTC's operations and the balance sheet data that are reported in this Form 10-K exclude the results of operations, assets and liabilities of Primedica Corporation.

Relationship With Genzyme

Equity Position. Genzyme is the largest single stockholder of the Company, holding 7,744,919 shares of common stock as of December 30, 2001, which represents approximately 26% 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.

Technology Transfer Agreement. Under the Technology Transfer Agreement dated May 1, 1993, Genzyme transferred substantially all of its transgenic assets and liabilities to GTC, 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 GTC is obligated to Genzyme's licensors for any royalties due them. As long as Genzyme owns less than 50% of GTC, 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.

R&D Agreement. Pursuant to a Research and Development Agreement dated May 1, 1993, Genzyme and GTC each agreed to provide to the other research and development services relating, in the case of GTC, 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 agreement expired on December 31, 1998 and the parties are continuing under this agreement on a month-to-month basis.

ATIII Collaboration. In January 1998, the Company entered into a collaboration agreement for the development of rhATIII with Genzyme forming the ATIII LLC joint venture. Under the terms of the agreement, Genzyme funded 70% of the development costs of rhATIII up to a maximum of \$33 million. The Company funded the remaining 30% of these costs. Development costs in excess of these amounts were to be funded equally by the partners. The \$33 million funding level was achieved by Genzyme in 2000.

In late 2000, the Company announced that it expected to re-acquire from Genzyme the rights to rhATIII that it did not already own. In early 2001, the ATIII LLC met with the FDA to discuss the status of the clinical development program for the rhATIII in the treatment of heparin-resistant patients undergoing cardiopulmonary bypass surgery. The ATIII LLC decided to discontinue development of this indication based on the level of additional data that would have been required to address the clinical development issues raised during the meeting with the FDA. In 2001, GTC reacquired Genzyme's ownership interest in the ATIII LLC in consideration of 4% of GTC's future product revenue, three years after approval, up to a total of \$30 million.

Services Agreement. Under a services agreement between GTC and Genzyme, GTC pays Genzyme a fixed monthly fee for basic laboratory and administrative support services. The monthly fee is adjusted annually, based on the services to be provided and changes in Genzyme's cost of providing the services. The services agreement is self-renewing annually and may be terminated upon 90 days notice by either party.

Credit Line Guaranty, Term Loan Guaranty and Lien. Genzyme guarantees a credit line and term loan with a commercial bank up to \$24.6 million. This line was originally due to expire in December 2001, but has been extended until March 28, 2002. The Genzyme guaranty was also extended until such time, although GTC has agreed not to draw on the credit line without Genzyme's prior consent. The Company

has agreed to reimburse Genzyme for any liability Genzyme may incur under such guaranty and has granted Genzyme a first lien on all of the Company's assets to collateralize such obligation.

Other Strategic Collaborations

Tufts University School of Veterinary Medicine

Pursuant to an existing cooperation and licensing agreement, Tufts University School of Veterinary Medicine ("Tufts") has agreed to collaborate exclusively with GTC through September 2002 in developing commercial applications for transgenic protein production in milk. Tufts has also granted GTC a perpetual, non-exclusive license to use certain proprietary microinjection technology and a variety of other animal husbandry techniques. Sales of products derived from transgenic goats produced by Tufts technology, or from their offspring, are subject to royalties payable to Tufts. The Company maintains a herd of goats at Tufts' facility in Massachusetts.

SMIG JV

GTC held a 22% interest in a joint venture with Sumitomo Metal Industries Ltd. (the "SMIG JV"). Under this joint venture, GTC granted to the SMIG JV an exclusive license in Asia to use GTC's transgenic technology to make, use and sell transgenic products, including ATIII, until the later of 2008 or the expiration of any applicable Japanese patent, subject to various reciprocal royalty obligations.

The Company acquired full ownership of the SMIG JV from Sumitomo and thereby reacquired the rights to its technology in the 18 Asian countries included in the joint venture. The 10 year-old joint venture has been dissolved. GTC can now directly develop its technology and the associated products in all 18 Asian countries or enter into separate agreements on a country-by-country or product-by-product basis. The Asian rights were re-acquired by issuing an aggregate of 333,334 shares of GTC common stock valued at approximately \$11.1 million plus transaction costs of \$143,000 which was capitalized.

Patents and Proprietary Rights

Currently, GTC holds 7 issued United States patents and 40 corresponding foreign patents. In accordance with ongoing research and development efforts, GTC has 27 pending United States patent applications and 62 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. In addition, GTC holds exclusive and non-exclusive licenses from Genzyme Corporation to rights under a number of issued patents and patent applications in the United States and the corresponding cases abroad for a variety of technologies. Of note is the fact that GTC is licensing a European patent with broad claims covering DNA constructs and their use in the production of proteins in the milk of non-human, transgenic animals. Pending GTC applications providing claim coverage with regard to specific proteins, classes of proteins, techniques to enhance expression and purification technologies remain pending. 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. GTC has also purchased the U.S. and European rights to a patent that includes claims for the filtration of milk.

GTC has exclusive and nonexclusive licenses to technologies owned by other parties, including DNX, Inc. as to microinjection, Stanford University as to gene transfer, Centeon L.L.C. (the successor to Behringwerke AG) as to ATIII, as well as promoter cross-licenses in place with PPL Therapeutics PLC (PPL), Pharming B.V. (Pharming) and ACT as to 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. The U.S. PTO has

granted 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 may have on its ability to practice nuclear transfer.

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

Government Regulation

The manufacturing and marketing of GTC's potential products and certain areas of research related to them are subject to regulation by governmental authorities in the United States, 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 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 issues raised by these documents and generally views them as a very positive milestone in the acceptance of the transgenic form of production. Based on discussions with the FDA and others, GTC believes that the basic United States regulatory framework for the transgenic production of recombinant proteins in animals will be similar to that described in the Points to Consider.

The FDA licenses biological products under the authority of the Public Health Service ("PHS") Act. 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. Prior to passage of the FDA Modernization Act of 1997 ("FDAMA"), applicants for a license to market a biological product filed both an establishment license application (an "ELA") and a product license application (a "PLA"). Since the passage of FDAMA, the FDA has taken actions to make the licensing process for biological products more consistent with the process for the approval of new drugs. Accordingly, since October 20, 2000, all manufacturers seeking a license to market a biological product in interstate commerce must file a single Biological License Application (a "BLA"). PLAs and ELAs filed in the interim will be administratively handled by the FDA as a BLA. If a manufacturer successfully demonstrates that the biological product meets PHS 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. The approval process for the

Company's protein production programs may be undertaken either by the Company, by a collaborator for which the Company is producing proteins, or jointly, depending upon the nature of the relationship involved.

Research and Development Costs

During its fiscal years ended December 30, 2001, December 31, 2000 and January 2, 2000, GTC spent \$22,428,000, \$18,976,000 and \$15,092,000, respectively, on research and development. These costs include labor, materials and supplies and overhead, as well as certain subcontracted research projects. Also included are the costs of operating the transgenics production facility such as feed and bedding, veterinary costs and utilities.

Employees

As of December 30, 2001, GTC employed 168 people. Of GTC's total employees, 100 were engaged in farm operations, clarification processes, quality assurance and control, 28 were engaged in research and development and 40 were engaged in administration, business development and marketing. Of GTC's employees, approximately 17 have Ph.D. degrees and 5 have D.V.M. degrees. None of GTC's employees are covered by collective bargaining agreements. GTC believes its employee relations are satisfactory.

ITEM 1A.

EXECUTIVE OFFICERS OF THE REGISTRANT

The current executive officers of the Company and their respective ages and positions are as follows:

| <u>Name</u> | <u>Age</u> | <u>Position</u> |
|----------------------------------|------------|--|
| Geoffrey F. Cox, Ph.D. | 58 | Chairman of the Board and Chief Executive Officer |
| John B. Green | 47 | Senior Vice President, Chief Financial Officer and Treasurer |
| Harry M. Meade, Ph.D. | 55 | Senior Vice President, Transgenics Research |

Dr. Cox was appointed as Chairman of the Board and Chief Executive Officer of GTC on July 19, 2001. Before joining GTC, Dr. Cox was Chairman and Chief Executive Officer of Aronex Pharmaceuticals, Inc. from 1997 until July 2001. Prior to joining Aronex, Dr. Cox joined Genzyme Corporation in the UK and, in 1988, became Senior Vice President of Operations in the United States. Subsequently, he was promoted to Executive Vice President for Genzyme, responsible for operations and pharmaceutical, diagnostic and genetics business units. Prior to joining Genzyme, Dr. Cox was General Manager of the UK manufacturing operations for Gist-Brocades.

Mr. Green has been the Vice President and Chief Financial Officer of GTC since December 1994 and Treasurer since August 1997. Prior to that, he was Vice President and Assistant Treasurer of TSI from December 1989 until its acquisition by GTC in 1994.

Dr. Meade has been Vice President, Transgenics Research for GTC since August 1994 and has served as Research Director of GTC since May 1993. Prior to joining GTC, Dr. Meade was a Scientific Fellow at Genzyme, where he was responsible for directing the transgenic molecular biology program. From 1981 to March 1990, 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.

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. GTC's research facility for the transgenics business is located in approximately 6,300 square feet of laboratory and office space leased from Genzyme in Framingham, Massachusetts. This lease expired in May 1998, at which time the lease automatically renewed, and continues to renew annually, on a year-to-year basis until terminated by either party on 90 days' notice. (See "Item 1—Business—Relationship with Genzyme.")

GTC owns a 383-acre facility in central Massachusetts. This facility contains 106,793 square feet of production, laboratory and administrative space dedicated to its transgenic segment. The facility also currently houses more than 1,900 goats. GTC believes its owned and leased facilities are adequate for significant further development of commercial transgenic products. GTC also currently utilizes animal housing, care and treatment facilities operated by Tufts University School of Veterinary Medicine in Massachusetts. In January 2002, the Company completed the purchase of approximately 128 acres of farm land in eastern New York State to be developed 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 intends to vigorously defend 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 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 2001, no matter was submitted to a vote of the security holders of the Company.

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

GTC's common stock commenced trading on July 9, 1993 on the Nasdaq National Market System under the symbol GZTC. Quarterly high and low sales prices for the stock as reported by the Nasdaq National Market System are shown below.

| | | <u>High</u> | <u>Low</u> |
|--------------|-------|-------------|------------|
| 2001: | | | |
| 1st Quarter | | 15½ | 3⅞ |
| 2nd Quarter | | 10⅞ | 4¾ |
| 3rd Quarter | | 9¾ | 3¼ |
| 4th Quarter | | 6⅞ | 3 |
| 2000: | | | |
| 1st Quarter | | 50 | 10 |
| 2nd Quarter | | 31½ | 12⅞ |
| 3rd Quarter | | 40⅞ | 25½ |
| 4th Quarter | | 36⅞ | 14 |

The records held by the transfer agent indicate that on March 13, 2002 there were approximately 853 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.

In November 1999, the Company completed a \$6.6 million private placement of Series B Convertible Preferred Stock (the "Series B Preferred Stock") to Genzyme. The proceeds from this placement were used to redeem \$6.6 million of the Company's Series A Convertible Preferred Stock (the "Series A Preferred Stock"). In connection with the issuance of 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, the Company issued a Notice of Redemption to Genzyme for all outstanding shares of the Company's Series B Preferred Stock. Prior to redemption, Genzyme converted the Series B Preferred Stock into 1,048,021 shares of common stock on February 8, 2000. The Company believes that the issuance of the Series B Preferred Stock, the related warrant and the shares of common stock issued upon conversion of the Series B Preferred Stock qualified as transactions by an issuer not involving a public offering within the meaning of Section 4(2) of the Securities Act of 1933, as amended (the "Securities Act"), based on the fact there was one holder.

In March 2000, the Company issued a warrant call notice for outstanding warrants to purchase 450,000 shares of common stock that had been issued in connection with the Series A Preferred Stock. Each warrant had an exercise price of \$15.1563 per share. As of March 31, 2000, all the warrants were exercised with proceeds to the Company of \$6.8 million. The Company believes that the issuance of the common stock upon exercise of the warrants qualified as a transaction by an issuer not involving a public offering within the meaning of Section 4(2) of the Securities Act.

In September 2000, in order to terminate the SMIG JV, the Company issued an aggregate of 333,334 shares of its common stock to Sumitomo Metal Industries, Ltd. and an affiliate ("Sumitomo"). In exchange, Sumitomo transferred to a wholly owned subsidiary of the Company all of the outstanding shares of SMI Genzyme Ltd., a Japanese corporation, held by Sumitomo. As a result, the Company directly and indirectly holds all of the outstanding equity in SMI Genzyme Ltd. The Company believes that the issuance to Sumitomo qualified as a transaction by an issuer not involving a public offering within the meaning of Section 4(2) of the Securities Act.

ITEM 6. SELECTED FINANCIAL DATA

The selected financial data set forth below as of December 30, 2001 and December 31, 2000 and for each of the three fiscal years in the period ended December 30, 2001 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 January 2, 2000, January 3, 1999 and December 28, 1997, and for the years ended January 3, 1999 and December 28, 1997 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 30, 2001 | December 31, 2000 | January 2, 2000 | January 3, 1999 | December 28, 1997 |
| Statement of Operations Data: | | | | | |
| Revenues: | | | | | |
| Research and development revenue | \$ 12,767 | \$ 12,880 | \$ 9,334 | \$ 8,278 | \$ 19,521 |
| Research and development revenue from joint venture | 973 | 3,283 | 4,491 | 3,318 | — |
| | <u>13,740</u> | <u>16,163</u> | <u>13,825</u> | <u>11,596</u> | <u>19,521</u> |
| Costs of revenue and operating expenses: | | | | | |
| Cost of research and development revenue . . . | 15,075 | 15,619 | 11,402 | 10,486 | 12,558 |
| Research and development | 7,353 | 3,357 | 3,690 | 6,155 | 5,282 |
| Selling, general and administrative | 11,078 | 9,148 | 7,875 | 6,042 | 7,381 |
| Equity in loss of joint venture | 4,078 | 4,625 | 3,797 | 4,285 | 811 |
| | <u>37,584</u> | <u>32,749</u> | <u>26,764</u> | <u>26,968</u> | <u>26,032</u> |
| Loss from continuing operations | (23,844) | (16,586) | (12,939) | (15,372) | (6,511) |
| Other income and (expenses): | | | | | |
| Interest income | 3,478 | 3,770 | 65 | 280 | 116 |
| Interest expense | (746) | (1,001) | (1,232) | (251) | (465) |
| Realized gain on sale of CRL stock | 2,320 | — | — | — | — |
| Other income | — | — | 484 | 100 | 50 |
| | <u>—</u> | <u>—</u> | <u>484</u> | <u>100</u> | <u>50</u> |
| Loss from continuing operations | \$ (18,792) | \$ (13,817) | \$ (13,622) | \$ (15,243) | \$ (6,810) |
| Discontinued operations | | | | | |
| Income (loss) from discontinued contract research operations, net of taxes | — | (324) | (5,139) | (4,347) | (2,533) |
| Gain from sale of discontinued contract research operations | 2,236 | — | — | — | — |
| | <u>—</u> | <u>—</u> | <u>—</u> | <u>—</u> | <u>—</u> |
| Net loss | \$ (16,556) | \$ (14,141) | \$ (18,761) | \$ (19,590) | \$ (9,343) |
| Dividends to preferred shareholders | — | (74) | (1,497) | (1,156) | — |
| | <u>—</u> | <u>(74)</u> | <u>(1,497)</u> | <u>(1,156)</u> | <u>—</u> |
| Net loss available to common shareholders | \$ (16,556) | \$ (14,215) | \$ (20,258) | \$ (20,746) | \$ (9,343) |
| Net loss available to common shareholders per weighted average number of common shares (basic and diluted): | | | | | |
| From continuing operations | \$ (0.63) | \$ (0.49) | \$ (0.76) | \$ (0.91) | \$ (0.39) |
| From discontinued contract research operations | \$ 0.08 | \$ (0.01) | \$ (0.26) | \$ (0.24) | \$ (0.15) |
| | <u>—</u> | <u>—</u> | <u>—</u> | <u>—</u> | <u>—</u> |
| Net loss | \$ (0.55) | \$ (0.50) | \$ (1.02) | \$ (1.15) | \$ (0.54) |
| Weighted average number of shares outstanding (basic and diluted) | | | | | |
| | 29,975,167 | 28,373,283 | 19,876,904 | 17,978,677 | 17,253,292 |
| | <u>December 30, 2001</u> | <u>December 31, 2000</u> | <u>January 2, 2000</u> | <u>January 3, 1999</u> | <u>December 28, 1997</u> |
| Balance Sheet Data: | | | | | |
| Cash, cash equivalents and marketable securities . . | \$ 90,448 | \$ 66,532 | \$ 7,813 | \$12,097 | \$ 6,777 |
| Working capital | 74,458 | 88,389 | 16,715 | 26,903 | 22,567 |
| Total assets | 120,443 | 134,403 | 58,518 | 60,052 | 50,187 |
| Long-term liabilities | 80 | 294 | 6,256 | 3,063 | 2,162 |
| Shareholders' equity | 101,950 | 114,843 | 26,206 | 36,220 | 27,378 |

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

The Company was incorporated in February 1993 and is engaged in the application of transgenic technology to the development and production of recombinant proteins for therapeutic and diagnostic uses.

Discontinued operations

In February 2001, GTC completed the sale of Primedica Corporation ("Primedica") to Charles River Laboratories, Inc. ("CRL"). GTC received \$26 million in cash, 658,945 shares of CRL common stock valued at \$15.9 million and CRL 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.

ATIII LLC Joint Venture

In 1997, GTC and Genzyme Corporation ("Genzyme") established the ATIII LLC joint venture ("ATIII LLC") 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 ATIII LLC 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. As a result of the reacquisition the accounts of the ATIII LLC, in the amount of \$2.3 million, were consolidated for reporting purposes.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation of consolidated financial statements requires that GTC 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, 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 records revenue under the EITF 91-6 model in accordance with SAB 101 as this model has been deemed to be the most appropriate for the nature of GTC's business. The Company has made the assumption that it can perform all activities through the development phase of its externally funded programs and can reasonably estimate the time and cost associated with the development phase. There have been no significant changes to GTC's business model during 2001. The results of using this model are such that GTC's revenues are matched to the costs incurred for any given period. The Company believes that the results of using a different model such as substantive milestones, would not be appropriate based on the Company's operations. The Company recognizes revenue and profit as work progresses on contracts using a percentage-of-completion method, which relies on estimates of total expected contract

revenue and costs. The Company follows this method when reasonably dependable estimates of the revenue and costs applicable to various stages of a contract can be made. Recognized revenues and profit are subject to revisions as the contract progresses to completion. Material changes in estimated costs to complete, therefore, could have a material impact on revenue recognized in current and future periods.

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 GTC 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 GTC's use of the acquired assets or the strategy for GTC's overall business;
- 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 GTC's management to be commensurate with the risk inherent in its current business model. There have been no factors currently that would trigger an impairment review, therefore, no impairment reviews have been performed. Net intangible assets amounted to \$11.6 million as of December 30, 2001.

Estimating accrued liabilities

Management must make estimates of costs incurred in the period for which services have been performed but not yet invoiced. Material differences may result in the amount and timing of the Company's expenses for any period if management were to make alternate or incorrect judgements or utilize alternate or incorrect estimates.

Accounting for income taxes

As part of the process of preparing GTC's consolidated financial statements, GTC is required to estimate its income taxes in each of the jurisdictions in which GTC operates. This process involves GTC 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. GTC must then assess the likelihood that its deferred tax assets will be recovered from future taxable income and to the extent GTC believes that recovery is not likely, it must establish a valuation allowance. To the extent it establishes a valuation allowance or increase 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 its provision for income taxes, its deferred tax assets and liabilities and any valuation allowance recorded against its net deferred tax assets. GTC has recorded a

valuation allowance of \$50.9 million as of December 30, 2001, due to uncertainties regarding its ability to utilize some of its deferred tax assets, primarily consisting of certain net operating losses carried forward. 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. In the event that actual results differ from these estimates or it adjusts these estimates in future periods it may need to establish a valuation allowance which could materially impact its financial position and results of operations. 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 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 no longer receiving partial funding from Genzyme for the rhATIII program of the ATIII LLC joint venture.

Cost of research and development revenue decreased to \$15.1 million in 2001 from \$15.6 million in 2000, a decrease of \$.5 million or 3%. Internal 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 its 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, rhATIII related costs subsequent to July 31, 2001, in the amount of \$2.3 million are included in the Company's research and development expenses.

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 to an increased investment in information technology personnel-related expenses, higher professional fees and recruiting costs, as well as primarily, to a charge related to contractual obligations in connection with the resignation of the Company's former President and Chief Executive Officer.

The Company recognized \$4.1 million of joint venture losses incurred on ATIII LLC between the Company and Genzyme 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 of \$30 million. Following the reacquisition, the results of ATIII LLC are 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 CRL common stock received as part of the proceeds from the sale of Primedica.

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

YEAR ENDED DECEMBER 31, 2000 AS COMPARED TO YEAR ENDED JANUARY 2, 2000

Total revenues for 2000 were \$16.2 million, compared with \$13.8 million in 1999, an increase of \$2.3 million or 17%. The increase in revenues is due to a greater number of transgenic programs in 2000 as well as milestone based revenues earned during 2000 in association with progress on previously existing transgenic programs.

Cost of research and development revenue increased to \$15.6 million in 2000 from \$11.4 million in 1999, an increase of \$4.2 million or 37%. The increase in cost of revenue is primarily due to an increase in the number of transgenic programs. Internal research and development expenses decreased to \$3.4 million in 2000 from \$3.7 million in 1999, a decrease of \$.3 million or 9%. The decrease in research and development expenses was primarily due primarily to a shifting of resources in relation to the increase in the number of transgenic programs during 2000.

Selling, general and administrative expenses increased to \$9.1 million in 2000 from \$7.9 million in 1999, an increase of \$1.3 million or 16%. The increase is primarily due to a one-time charge associated with the acceleration of vesting of non-employee stock options.

Interest income increased to \$3.8 million in 2000, from \$65,000 in 1999, due to the investment of proceeds generated by the secondary public offering in February 2000.

Interest expense decreased to \$1 million in 2000, from \$1.2 million in 1999. Of the 2001 interest expense total, approximately \$306,000 represents interest for the financing of the transgenic production facility and \$358,000 represents amortization of deferred financing costs.

The Company did not recognize any non-operating income in 2000. In 1999, the Company recognized \$484,000 of non-operating income from the receipt of an insurance settlement.

The Company recognized \$4.6 million of losses incurred in connection with the ATIII LLC joint venture in 2000 as compared to \$3.8 million in 1999, an increase of 22%. The increase is due to a higher spending rate in 2000.

The Company recognized a loss of \$324,000 from discontinued contract research operations in 2000 versus a loss of \$5.1 million in 1999. The decrease in the loss is due to an increase in Primedica's revenues in 2000 as a result of an intentional shift in the mix of Primedica services to faster growing service areas such as metabolism and pharmacokinetics, formulation chemistry, analytical chemistry and bioproduction.

RESEARCH AND DEVELOPMENT COSTS

All research and development costs are expensed as incurred. During its fiscal years ended December 30, 2001, December 31, 2000 and January 2, 2000, GTC spent \$22.4 million, \$19 million and \$15.1 million, respectively, on research and development. These costs include labor, materials and supplies and overhead, as well as certain subcontracted research projects. Also included are the costs of operating the transgenics 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 program partnerships was \$27.1 million at December 30, 2001. The aggregate estimated costs to complete for the external programs through the development phase was \$7.3 million at December 30, 2001 with associated minimum revenues of \$7.9 million excluding success based milestones. Subsequent to the development phase of the programs, the activities to be performed by the Company, if any, are outside of the Company's control, therefore, the related costs are unknown.

In aggregate, the total cost incurred since inception on internal programs was \$22.6 million at December 30, 2001. The costs to complete these programs are not estimatable due to significant variability in clinical trial costs and FDA regulatory processes.

NEW ACCOUNTING PRONOUNCEMENTS

In July 2001, the Financial Accounting Standards Board (“FASB”) issued FASB Statement No. 141 (“SFAS No. 141”), *Business Combinations* and FASB Statement No. 142 (“SFAS No. 142”), *Goodwill and Other Intangible Assets*. SFAS No. 141 requires that all business combinations be accounted for under the purchase method only and that certain acquired intangible assets in a business combination be recognized as assets apart from goodwill. SFAS No. 142 requires that ratable amortization of goodwill be replaced with periodic tests of the goodwill’s impairment and that intangible assets other than goodwill be amortized over their useful lives. SFAS No. 141 is effective for all business combinations initiated after June 30, 2001 and for all business combinations accounted for by the purchase method for which the date of acquisition is after June 30, 2001. The provisions of SFAS No. 142 will be effective for fiscal years beginning after December 15, 2001, and will thus be adopted by the Company, as required, in fiscal year 2002. The Company does not expect any significant impact from the adoption of SFAS No. 141 and SFAS No. 142 on the Company’s financial statements.

On October 3, 2001, FASB issued FASB Statement No. 144 (“SFAS No. 144” or the “Standard”), *Accounting for the Impairment or Disposal of Long-Lived Assets*. The objectives of SFAS 144 are to address significant issues relating to the implementation of FASB Statement No. 121 (“SFAS No. 121”), *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of*, and to develop a single accounting model, based on the framework established in SFAS No. 121, for long-lived assets to be disposed of by sale, whether previously held and used or newly acquired. SFAS No. 144 is effective for financial statements issued for fiscal years beginning after December 15, 2001 and, generally, its provisions are to be applied prospectively. The Company does not expect the above accounting pronouncements to have a significant impact on the Company.

LIQUIDITY AND CAPITAL RESOURCES

In February 2001, the Company completed the sale of its clinical research organization, Primedica, to CRL. Net proceeds to the Company were \$39.7 million in cash and CRL stock (see Note 13 of the “Notes to the Consolidated Financial Statements”).

The Company had cash, cash equivalents and marketable securities of \$90.4 million at December 30, 2001. This amount includes cash and cash equivalents of \$26.9 million.

During 2001, the Company had a \$14.2 million net decrease in cash and cash equivalents. Sources of funds during the period included \$23.9 million of net proceeds from the sale of Primedica, \$18.2 million from the sale of the CRL common stock, \$45.3 million from the redemption of marketable securities and \$2.4 million from the issuance of common stock under various employee stock plans. Uses of funds during the period included \$12 million used in operations, \$3.4 million invested in capital equipment and further expansion of the transgenic production facility, \$4.1 million of funding of the ATIII LLC, \$83.6 million used to purchase marketable securities and \$974,000 used to pay down long-term debt.

The Company had working capital of \$74.5 million at December 30, 2001 compared to \$88.4 million at December 31, 2000. The decrease in working capital is due to the funding of operations. As of December 30, 2001 the Company had \$15.8 million available under a line of credit with a commercial bank.

The Company’s total debt consists of \$6 million, which is primarily mortgage financing for its production facilities. There are no other long-term debt commitments and no off-balance sheet financing vehicles.

As programs progress from the development stage to the commercialization stage, the Company expects to incur additional capital expenditures. The Company is preparing plans to expand its existing transgenic production facilities in central Massachusetts as well as to establish a second production site in order to facilitate growth in the number of development programs and the commercialization of ongoing transgenic programs. In January 2002, the Company completed the purchase of approximately 128 acres of farm land

in eastern New York State for \$426,000, to be developed as a second production site. The Company anticipates investing between \$6 million and \$10 million in capital expenditures for buildings and equipment over the next 18-24 months.

In July 2001, the Company reacquired Genzyme's ownership interest in the ATIII LLC in exchange for a royalty to Genzyme based on the Company's sales of rhATIII, if any, commencing three years after the first commercial scale, up to a cumulative maximum of \$30 million. Accordingly, the Company will be required to fully fund any development costs for ATIII until a development partner is obtained. At this time, these costs are unknown as they are dependent upon a number of factors such as length of time to find a partner, to complete clinical studies and the ultimate receipt of regulatory approval. The Company both filed for and received acceptance of their clinical trial exemption for rhATIII in Europe to begin clinical study of ATIII patients with a hereditary deficiency. A pharmacokinetic trial in Europe began in the fourth quarter of 2001.

The following summarizes the Company's contractual obligations at December 30, 2001, and the effect such obligations are expected to have on its liquidity and cash flow in future periods.

| | <u>Total</u> | <u>Within 1 Year</u> | <u>1 to 3 Years</u> | <u>After 3 Years</u> |
|---|----------------|----------------------|---------------------|----------------------|
| Contractual Obligations: | | | | |
| Long-term debt and capital lease obligations | \$5,966 | \$5,940 | \$ 26 | \$ — |
| Other lease obligations | 2,465 | 1,087 | 892 | 486 |
| Service agreement with Genzyme (see Note 11 of the "Notes to the Consolidated Financial Statements") | <u>1,012</u> | <u>1,012</u> | <u>—</u> | <u>—</u> |
| Total contractual cash obligations | <u>\$9,443</u> | <u>\$8,039</u> | <u>\$918</u> | <u>\$486</u> |

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 30, 2001.

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 unestimatable 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 the Consolidated Financial Statements") in the normal course of business. These transactions are considered to be at arms-length. There are no ongoing contractual or other commitments as a result of these arrangements other than Genzyme.

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 30, 2001, including a guaranty, a revolving line of credit, a standby letter of credit and a loan outstanding which are sensitive to changes in interest rates. The Company has a guaranty by Genzyme Corporation, obtained in December 1998, of the Company’s credit facility with a commercial bank, whose carrying value of \$969,000 approximates fair value. Also, the Company has a revolving line of credit with a commercial bank for \$15.8 million, which accrues interest at a variable rate and a standby letter of credit of \$249,360 in support of a facility lease. At December 30, 2001, nothing is outstanding under the line of credit and nothing has been drawn down on the standby letter of credit. As part of the revolving credit facility, the Company had been issued a \$1.5 million standby letter of credit in support of a facility lease for the Company’s Primedica subsidiary which was cancelled as a part of the sale of Primedica in February 2001. Additionally, the Company has one loan outstanding. These instruments are not leveraged and are held for purposes other than trading.

For the loan outstanding, the table below presents the principal cash flows that exist by maturity date and the related average interest rate.

| | <u>2002</u> | <u>2003</u> | <u>2004</u> | <u>2005</u> | <u>2006</u> | <u>Thereafter</u> | <u>Total</u> |
|---|-------------|-------------|-------------|-------------|-------------|-------------------|--------------|
| Variable rate debt (\$in 000’s) | 5,735 | — | — | — | — | — | — |

The interest rate of the variable debt was 2.48% at December 30, 2001. At December 30, 2001, the fair value of this loan approximates carrying value.

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 bank’s base rate. The aggregate hypothetical loss in earnings for one year on the borrowing held by us at December 30, 2001, assuming a hypothetical 6 percent interest rate is approximately \$344,000 after tax. The hypothetical loss was based on financial instruments held by the Company at December 30, 2001. 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 14.

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 2002 Annual Meeting of Stockholders to be held on May 22, 2002 (the “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 caption “EXECUTIVE COMPENSATION” in the Proxy Statement is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information set forth under the caption “SHARE OWNERSHIP” in the Proxy Statement is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information set forth under the captions “EXECUTIVE EMPLOYMENT AGREEMENTS” and “COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION” in the Proxy Statement is incorporated herein by reference. See also, Notes 2, 6 and 11 to the Consolidated Financial Statements included herewith.

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULE AND REPORTS ON FORM 8-K

- (a) The Company’s Financial Statements and Financial Statement Schedule appear as a separate section of this report immediately following Item 14.

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.

The Exhibits to this report are listed below under Part IV, Item 14(c) hereof.

- (b) Reports on Form 8-K

No reports on Form 8-K were filed by the Company during the quarter ended December 30, 2001.

- (c) Exhibits

The exhibits filed as part of this Form 10-K are listed on the Exhibit Index immediately preceding such Exhibits, which Exhibit Index is incorporated herein by reference.

FORM 10-K-ITEMS 8, 14 (a) (1), (a) (2), and (d)
GENZYME TRANSGENICS CORPORATION AND SUBSIDIARIES
List Of Financial Statements And Financial Statement Schedule

The following consolidated financial statements of Genzyme Transgenics Corporation and subsidiaries are included in Item 8:

| | <u>Page #</u> |
|--|---------------|
| Report of PricewaterhouseCoopers LLP—Independent Accountants | 26 |
| Consolidated Balance Sheets—December 30, 2001 and December 31, 2000 . . | 27 |
| Consolidated Statements of Operations—For the fiscal years ended December 30, 2001, December 31, 2000 and January 2, 2000 | 28 |
| Consolidated Statements of Shareholders' Equity—For the fiscal years ended December 30, 2001, December 31, 2000 and January 2, 2000 | 29 |
| Consolidated Statements of Cash Flows—For the fiscal years ended December 30, 2001, December 31, 2000 and January 2, 2000 | 30 |
| Notes to Consolidated Financial Statements | 31 |
| Report of PricewaterhouseCoopers LLP on Financial Statement Schedule— Independent Accountants | 50 |
| Schedule II—Supplemental Valuation and Qualifying Accounts | 51 |
| SIGNATURES | 52 |
| EXHIBIT INDEX | 53 |

All other schedules for which provision is made in the applicable regulation of the Securities and Exchange Commission are not required under the related instructions or are inapplicable, and therefore have been omitted.

REPORT OF INDEPENDENT ACCOUNTANTS

To the Board of Directors and Shareholders of
Genzyme Transgenics Corporation:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations and comprehensive loss, shareholders' equity and of cash flows present fairly, in all material respects, the financial position of Genzyme Transgenics Corporation and its subsidiaries at December 30, 2001 and December 31, 2000, and the results of their operations and their cash flows for each of the three years in the period ended December 30, 2001 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.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
February 14, 2002

GENZYME TRANSGENICS CORPORATION
CONSOLIDATED BALANCE SHEETS
(Dollars in thousands except share amounts)

| | December 30, 2001 | December 31, 2000 |
|--|----------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 26,850 | \$ 41,024 |
| Marketable securities | 63,598 | 25,508 |
| Accounts receivable and unbilled contract revenue, net of allowance of \$361 at December 30, 2001 and December 31, 2000 | 1,862 | 2,753 |
| Other current assets | 561 | 1,098 |
| Net assets of discontinued contract research operations held for sale | — | 37,272 |
| Total current assets | 92,871 | 107,655 |
| Net property, plant, and equipment | 15,957 | 13,841 |
| Net intangible assets | 11,595 | 12,529 |
| Other assets | 20 | 378 |
| | \$120,443 | \$134,403 |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 1,923 | \$ 1,073 |
| Accounts payable—Genzyme | 1,852 | 1,344 |
| Payable to ATIII LLC | — | 1,096 |
| Accrued expenses | 5,078 | 4,514 |
| Deferred contract revenue | 3,620 | 4,522 |
| Current portion of long-term debt and capital leases | 5,940 | 6,717 |
| Total current liabilities | 18,413 | 19,266 |
| Long-term debt and capital leases, net of current portion | 26 | 223 |
| Deferred lease obligation | 54 | 71 |
| Total liabilities | 18,493 | 19,560 |
| 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; 30,200,219 and 29,697,151 shares issued and outstanding at December 30, 2001 and December 31, 2000, respectively | 302 | 297 |
| Capital in excess of par value | 197,742 | 194,255 |
| Accumulated deficit | (96,322) | (79,766) |
| Accumulated other comprehensive income | 228 | 57 |
| Total shareholders' equity | 101,950 | 114,843 |
| | \$120,443 | \$134,403 |

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

GENZYME TRANSGENICS CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Dollars in thousands except share and per share amounts)

| | For the Fiscal Years Ended | | |
|---|----------------------------|----------------------|--------------------|
| | December 30, 2001 | December 31, 2000 | January 2, 2000 |
| Revenues: | | | |
| Research and development revenue | \$ 12,767 | \$ 12,880 | \$ 9,334 |
| Research and development revenue from joint venture . . . | 973 | 3,283 | 4,491 |
| | <u>13,740</u> | <u>16,163</u> | <u>13,825</u> |
| Costs of revenue and operating expenses: | | | |
| Cost of research and development revenue | 15,075 | 15,619 | 11,402 |
| Research and development | 7,353 | 3,357 | 3,690 |
| Selling, general and administrative | 11,078 | 9,148 | 7,875 |
| Equity in loss of joint venture | 4,078 | 4,625 | 3,797 |
| | <u>37,584</u> | <u>32,749</u> | <u>26,764</u> |
| Loss from continuing operations | (23,844) | (16,586) | (12,939) |
| Other income (expense): | | | |
| Interest income | 3,478 | 3,770 | 65 |
| Interest expense | (746) | (1,001) | (1,232) |
| Realized gain on sale of CRL stock | 2,320 | — | — |
| Other income | — | — | 484 |
| Loss from continuing operations | (18,792) | (13,817) | (13,622) |
| Discontinued operations | | | |
| Loss from discontinued contract research operations (less applicable taxes of \$248 and \$320) | — | (324) | (5,139) |
| Gain from sale of discontinued contract research operations | 2,236 | — | — |
| Net loss | <u>\$ (16,556)</u> | <u>\$ (14,141)</u> | <u>\$ (18,761)</u> |
| Dividend to preferred shareholders | — | (74) | (1,497) |
| Net loss available to common shareholders | <u>\$ (16,556)</u> | <u>\$ (14,215)</u> | <u>\$ (20,258)</u> |
| Net loss available per common share (basic and diluted): | | | |
| From continuing operations | <u>\$ (0.63)</u> | <u>\$ (0.49)</u> | <u>\$ (0.76)</u> |
| From discontinued contract research operations | <u>\$ 0.08</u> | <u>\$ (0.01)</u> | <u>\$ (0.26)</u> |
| Net loss | <u>\$ (0.55)</u> | <u>\$ (0.50)</u> | <u>\$ (1.02)</u> |
| Weighted average number of common shares outstanding (basic and diluted) | <u>29,975,167</u> | <u>28,373,283</u> | <u>19,876,904</u> |
| Comprehensive loss: | | | |
| Net loss | \$ (16,556) | \$ (14,141) | \$ (18,761) |
| Other comprehensive income: | | | |
| Unrealized holding gains on available for sale securities . | 171 | 57 | — |
| Total other comprehensive income | 171 | 57 | — |
| Comprehensive loss | <u>\$ (16,385)</u> | <u>\$ (14,084)</u> | <u>\$ (18,761)</u> |

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

GENZYME TRANSGENICS CORPORATION
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(In Thousands)

| | Series A Convertible Preferred Stock | | Capital in Excess of Par Value Preferred | Common Stock | | Dividend | Capital in Excess of Par Value Common Stock | Stock Based Compensation | Accumulated Deficit | Accumulated Other Comprehensive Income | Total Shareholders' Equity |
|--|--------------------------------------|--------|--|--------------|--------|-----------|---|--------------------------|---------------------|--|----------------------------|
| | Shares | Amount | Stock | Shares | Amount | | Stock | | | | |
| Balance, January 3, 1999 | 20 | \$— | \$ 18,777 | 18,384 | \$184 | \$(1,156) | \$ 65,716 | \$(437) | \$(46,864) | \$ — | 36,220 |
| Net loss | | | | | | | | | (18,761) | | (18,761) |
| Sale of common stock in a private placement, net of expenses | | | | 686 | 7 | | 5,421 | | | | 5,428 |
| Common stock sold under Employee Stock Purchase Plan | | | | 239 | 4 | | 992 | | | | 996 |
| Common stock issuance to the GTC Savings and Retirement Plan | | | | 95 | 1 | | 510 | | | | 511 |
| Conversion of Series A Preferred Stock | (14) | | (13,035) | 2,830 | 27 | | 13,008 | | | | — |
| Common stock issuance for ACT License Agreement | | | | 217 | 2 | | 998 | | | | 1,000 |
| Redemption of Series A Preferred Stock | (6) | | (5,741) | | | (861) | | | | | (6,602) |
| Issuance of Series B Preferred Stock and related warrants, net of issuance costs | 7 | | 6,563 | | | (343) | 343 | | | | 6,563 |
| Dividend attributed to beneficial conversion | | | | | | (210) | 210 | | | | — |
| Dividend accrued on Series B Preferred Stock | | | 83 | | | (83) | | | | | — |
| Stock based compensation | | | | | | | (37) | 153 | | | 116 |
| Proceeds from the exercise of stock options | | | | 150 | 1 | | 734 | | | | 735 |
| 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 |

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

GENZYME TRANSGENICS CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Dollars in thousands)

| | FOR THE FISCAL YEARS ENDED | | |
|--|----------------------------|----------------------|--------------------|
| | December 30, 2001 | December 31, 2000 | January 2, 2000 |
| Cash flows for operating activities: | | | |
| Net loss from continuing operations | \$(18,792) | \$(13,817) | \$(13,622) |
| Adjustments to reconcile net loss from continuing operations to net cash used in operating activities: | | | |
| Depreciation and amortization | 2,614 | 2,070 | 1,862 |
| Stock based compensation | 355 | 1,815 | 116 |
| Non cash interest income (loss) from marketable securities | 305 | (815) | — |
| Common stock issuance to GTC savings and retirement plan | 725 | 567 | 511 |
| Equity in loss of joint venture | 4,078 | 4,625 | 3,674 |
| Realized gain on sale of CRL stock | (2,320) | — | — |
| Changes in assets and liabilities: | | | |
| Accounts receivable and unbilled contract revenue | 891 | (1,828) | 2,437 |
| Other assets and liabilities | 236 | (167) | (1,658) |
| Accounts payable | 850 | 439 | (618) |
| Accounts payable—Genzyme Corporation | 508 | 785 | (928) |
| Payable to ATIII LLC | (1,096) | — | — |
| Other accrued expenses | 564 | 708 | 165 |
| Deferred contract revenue | (902) | 2,139 | 1,365 |
| Net cash used by in operating activities | (11,984) | (3,479) | (6,696) |
| Cash flows for investing activities: | | | |
| Purchase of property, plant and equipment | (3,438) | (1,964) | (3,276) |
| Investment in joint venture | (4,077) | (5,680) | (3,941) |
| Purchase of marketable securities | (83,593) | (46,636) | — |
| Redemption of marketable securities | 45,267 | 22,000 | — |
| Proceeds from the sale of CRL stock | 18,192 | — | — |
| Cash paid for acquisition of SMIG | — | (26) | — |
| Net cash used in investing activities | (27,649) | (32,306) | (7,217) |
| Cash flows from financing activities: | | | |
| Net proceeds from the issuance of common stock | — | 75,130 | 5,428 |
| Dividends paid | — | (157) | — |
| Redemption of Series A convertible preferred stock | — | — | (6,602) |
| 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 | 424 | 1,211 | 996 |
| Net proceeds from the exercise of stock options | 1,988 | 6,301 | 735 |
| Net proceeds from the issuance of Series B convertible preferred stock and related warrants | — | — | 6,563 |
| Proceeds from long-term debt | — | 609 | 4,544 |
| Repayment of long-term debt | (974) | (727) | (434) |
| Net (payments) borrowings under revolving line of credit | — | (15,750) | 4,654 |
| Net cash provided by financing activities | 25,314 | 73,437 | 15,884 |
| Net cash (used) provided by discontinued operations | 145 | (4,441) | (6,255) |
| Net increase (decrease) in cash and cash equivalents | (14,174) | 33,211 | (4,284) |
| Cash and cash equivalents at beginning of the period | 41,024 | 7,813 | 12,097 |
| Cash and cash equivalents at end of period | <u>\$ 26,850</u> | <u>\$ 41,024</u> | <u>\$ 7,813</u> |
| Supplemental disclosure of cash flow information: | | | |
| Cash paid during the period for interest | \$ 349 | \$ 544 | \$ 1,245 |
| Assets purchased under capital lease | — | — | 111 |

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Fiscal years ended December 30, 2001, December 31, 2000 and January 2, 2000 (all tabular \$ in thousands, except per share data)

NOTE 1. NATURE OF BUSINESS

The Company was incorporated in February 1993 and is engaged in the application of transgenic technology to the development and production of recombinant proteins for therapeutic and diagnostic uses.

In February 2001, Genzyme Transgenics Corporation (“GTC” or the “Company”) completed the divestiture of its wholly-owned contract research organization (“CRO”) subsidiary, Primedica Corporation (“Primedica”). Accordingly, Primedica is reported as a discontinued operation in these financial statements.

Genzyme is the Company’s largest single stockholder. As a result of various equity transactions, Genzyme owned 26% of the Company’s outstanding common stock at December 30, 2001, and 27% 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 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 30, 2001, December 31, 2000 and January 2, 2000. The Company had working capital of \$74.5 million at December 30, 2001.

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 22% investment in the joint venture between SMI Genzyme Ltd. and Sumitomo Metals Industries Ltd. (“SMIG JV”) using the equity method. In September 2000, the Company acquired full ownership of the SMIG JV by issuing an aggregate of 333,334 shares of its common stock valued at approximately \$11.1 million, plus transaction costs of \$143,000. As a result, the Company directly and indirectly holds all of the outstanding equity of the SMIG JV which is now a wholly-owned subsidiary of the Company (see Note 13).

The Company accounted for its 50% investment in the ATIII LLC under the equity method through February 2001. In July 2001, the Company completed the reacquisition of Genzyme’s ownership interest in ATIII LLC and the results of ATIII LLC were thereafter consolidated for reporting purposes (see Note 13).

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles 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, account

receivable and unbilled reserves, 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 with initial maturities of three months or less, are valued at market value.

Marketable Securities

Marketable securities, which include the Company’s investment in equity 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 30, 2001 can be summarized as follows:

| | <u>Amortized Cost</u> | <u>Estimated Fair Value</u> |
|---|-----------------------|-----------------------------|
| Government backed obligations | \$40,521 | \$43,729 |
| Corporate obligations | 23,007 | 19,869 |
| Total marketable securities | <u>\$63,528</u> | <u>\$63,598</u> |

At December 30, 2001 and December 31, 2000, the marketable securities had an associated \$228,000 and \$57,000 of unrealized gain included in other comprehensive income and equity. No marketable securities were held at January 2, 2000. The Company had a realized gain of \$2.3 million on the sale of the CRL stock in 2001. All other realized gains on available for sale securities in 2001 and 2000 were immaterial. There were no realized gains in 1999. At December 30, 2001, 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 30, 2001 and December 31, 2000, approximately 94% and 99%, respectively, of cash, cash equivalents and marketable securities were held by one United States highly rated financial institution. Total credit facilities at one commercial bank are \$24.6 million at December 30, 2001 and December 31, 2000.

The Company performs ongoing credit evaluations of its customers’ financial conditions and maintains reserves for potential credit losses. There has been minimal writeoff activity for fiscal 2001, 2000 and 1999.

At December 30, 2001 and December 31, 2000, five customers and three customers, respectively, accounted for 100% of accounts receivable. For the year ended December 30, 2001, four customers accounted for 72% of the revenue, three customers accounted for 59% of the revenue for the year ended December 31, 2000 and five customers accounted for 86% of the revenue for the year ended January 2, 2000. The majority of the outstanding accounts receivable balance at December 30, 2001 has been subsequently collected.

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”) and related costs to bring them to the United States are capitalized and amortized using the straight-line method over three years.

The following is the summary of property, plant and equipment and related accumulated amortization and depreciation as of December 30, 2001 and December 31, 2000.

| | Years of Life | December 30, 2001 | December 31, 2000 |
|---|------------------|----------------------|----------------------|
| Land | — | \$ 987 | \$ 909 |
| Buildings | 20 - 30 | 12,848 | 11,120 |
| Livestock | 3 | 2,523 | 2,146 |
| Leasehold improvements | lease life | 942 | 860 |
| Laboratory, manufacturing and office equipment | 3 - 10 | 3,985 | 2,349 |
| Laboratory, manufacturing and office equipment—capital lease | 3 - 10 | 1,143 | 1,143 |
| Construction in process | — | 158 | 621 |
| | | <u>\$22,586</u> | <u>\$19,148</u> |
| Less accumulated amortization and depreciation | | <u>6,629</u> | <u>5,307</u> |
| Net property, plant and equipment | | <u>\$15,957</u> | <u>\$13,841</u> |

Depreciation and amortization expense was \$1,237,000, \$1,274,000, and \$1,013,000 for the fiscal years ended December 30, 2001, December 31, 2000 and January 2, 2000, respectively. Accumulated amortization for equipment under capital lease was \$616,000 and \$455,000 at December 30, 2001 and December 31, 2000, respectively.

In January 2002, the Company completed the purchase of approximately 128 acres of farm land in eastern New York for \$426,000, to be developed as a second production site.

Non Cash Transactions

During fiscal 1999, the Company purchased \$111,000 of fixed assets and financed these additions with capital lease obligations. The Company issued common stock valued at \$1,000,000 in connection with a license agreement with Advanced Cell Technology, Inc. This license has been recorded as a long term asset and is being amortized over 10 years.

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

During fiscal 2001, in connection with the sale of the Primedica subsidiary, the Company accelerated options to employees of the discontinued operations valued at \$284,000, received CRL common stock from the sale of the discontinued operations valued at \$15.9 million and CRL assumed all of Primedica’s debt of approximately \$9 million. 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. The valuation of these options was determined to be \$71,000 using the Black-Scholes option pricing model. 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.

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:

| | <u>At December 30, 2001</u> | <u>At December 31, 2000</u> |
|--|---------------------------------|---------------------------------|
| Accrued payroll and benefits | \$1,689 | \$1,544 |
| Other | <u>3,389</u> | <u>2,970</u> |
| Total accrued expenses | <u>\$5,078</u> | <u>\$4,514</u> |

There have been various employee terminations for which the Company recorded 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 30, 2001 and December 31, 2000, approximately \$315,000 and \$278,000 had been paid out of the reserve, respectively. At December 30, 2001, \$659,000 remained in accrued expenses in relation to termination costs.

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 or the result achieved using percentage of completion accounting. Under percentage of completion 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. Where milestones are performance based, or where the Company is uncertain as to their achievement since they rely on new technologies or are dependent on an outcome outside of the Company's control, revenue is recognized once the milestone is achieved or the outcome can be determined with an appropriate degree of certainty. 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 milestones 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 consisted of \$973,000, \$3,283,000 and \$4,491,000 for the fiscal years ended 2001, 2000 and 1999, respectively, from the ATIII LLC (see Note 13) 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 30, 2001, December 31, 2000 and January 2, 2000, GTC spent \$22.4 million, \$19 million and \$15.1 million, respectively, on research and development of which \$15.1 million, \$15.6 million and \$11.4 million, respectively, was related to external programs. Of the total spent on research and development, \$2.3 million, \$3.3 million and \$4.5 million, respectively, was spent on the ATIII LLC. These costs include labor, materials and supplies and overhead, as well as certain subcontracted research projects. Also included are the costs of operating the transgenics 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 ("EPS"). 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 2001, 2000 and 1999, therefore 3.1 million, 3 million and 4.8 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 July 2001, the Financial Accounting Standards Board ("FASB") issued FASB Statement No. 141 ("SFAS No. 141"), *Business Combinations* and FASB Statement No. 142 ("SFAS No. 142"), *Goodwill and Other Intangible Assets*. SFAS No. 141 requires that all business combinations be accounted for under the purchase method only and that certain acquired intangible assets in a business combination be recognized as assets apart from goodwill. SFAS No. 142 requires that ratable amortization of goodwill be replaced with periodic tests of the goodwill's impairment and that intangible assets other than goodwill be amortized over their useful lives. SFAS No. 141 is effective for all business combinations initiated after June 30, 2001

and for all business combinations accounted for by the purchase method for which the date of acquisition is after June 30, 2001. The provisions of SFAS No. 142 will be effective for fiscal years beginning after December 15, 2001, and will thus be adopted by the Company, as required, in fiscal year 2002. The Company does not expect any significant impact from the adoption of SFAS No. 141 and SFAS No. 142 on the Company's financial statements.

On October 3, 2001, FASB issued FASB Statement No. 144 ("SFAS No. 144" or the "Standard"), *Accounting for the Impairment or Disposal of Long-Lived Assets*. The objectives of SFAS 144 are to address significant issues relating to the implementation of FASB Statement No. 121 ("SFAS No. 121"), *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of*, and to develop a single accounting model, based on the framework established in SFAS No. 121, for long-lived assets to be disposed of by sale, whether previously held and used or newly acquired. SFAS No. 144 is effective for financial statements issued for fiscal years beginning after December 15, 2001 and, generally, its provisions are to be applied prospectively. The Company does not expect the above accounting pronouncements to have a significant impact on the Company.

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 30, 2001, December 31, 2000 and January 2, 2000 was approximately \$1,037,000, \$723,000 and \$823,000, respectively.

At December 30, 2001, the Company's future minimum payments required under these leases are as follows:

| | <u>Operating</u> | <u>Capital</u> | <u>Total</u> |
|---|------------------|----------------|----------------|
| 2002 | \$1,087 | \$ 224 | \$1,311 |
| 2003 | 499 | 26 | 525 |
| 2004 | 393 | — | 393 |
| 2005 | 343 | — | 343 |
| 2006 | 143 | — | 143 |
| Thereafter | — | — | — |
| Total | <u>\$2,465</u> | <u>250</u> | <u>\$2,715</u> |
| Less amount representing interest | | <u>19</u> | |
| Present value of minimum lease payments | | <u>\$ 231</u> | |

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 unestimatable since the level of future sales, if any, is uncertain.

Under a Service Agreement with Genzyme (see Note 11), the Company is committed to make a minimum annual payment of \$1,011,996 in 2002.

NOTE 4. INTANGIBLE ASSETS

Intangible assets consist of:

| | <u>Amortization Life</u> | <u>December 30, 2001</u> | <u>December 31, 2000</u> |
|---|--------------------------|--------------------------|--------------------------|
| Asian marketing rights for SMIG | 15 years | \$11,210 | \$11,210 |
| License agreement with ACT | 10 years | <u>1,862</u> | <u>1,862</u> |
| | | \$13,072 | \$13,072 |
| Less accumulated amortization | | <u>(1,477)</u> | <u>(543)</u> |
| Intangible assets, net | | <u>\$11,595</u> | <u>\$12,529</u> |

Amortization expense was \$934,000, \$436,000 and \$187,000 in 2001, 2000 and 1999, respectively.

NOTE 5. BORROWINGS

In December 1998, the Company obtained credit facilities (the "Credit Line", the "Term Loan" and the "Standby Letter of Credit") from a commercial bank which has been extended until March 28, 2002. Under the Credit Line, the Company may borrow up to \$16 million, of which \$249,360 may be utilized for the Standby Letter of Credit. At December 30, 2001, nothing is outstanding under the Credit Line and nothing has been drawn down on the Standby Letter of Credit. A Standby Letter of Credit with a face amount of \$1.5 million was issued under the Credit Line to support a facility lease for the Company's Primedica subsidiary which was cancelled as a part of the sale of Primedica, in February 2001. As of December 30, 2001 and December 31, 2000, \$5,734,796 and \$6,429,570, respectively, was outstanding on the \$7.1 million Term Loan and at December 30, 2001, no additional amounts were available for borrowing. The Term Loan was payable in quarterly payments through December 2001 with a balloon payment for the remaining balance which is due March 28, 2002. The Term Loan is guaranteed by Genzyme and such guaranty was also extended until March 28, 2002, although GTC has agreed not to draw on the credit line without Genzyme's prior consent.

At the Company's option, interest on loans under the Credit Line (other than the standby letter of credit) and the Term Loan accrues either at the Prime rate or at an adjusted libor rate. The interest rate on the Term Loan was 2.48% and 7% at December 30, 2001 and December 31, 2000, respectively. The weighted average interest rate on all outstanding lines of credit was approximately 0.7% and 5.1% for the fiscal years ended December 31, 2000 and January 2, 2000, respectively. During 2001, no amounts were outstanding under the line. Under the terms of the credit facilities, the Company is not permitted to pay any dividends.

In connection with the 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 granted a first lien on all assets of the Company to Genzyme as well as 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).

Under the various debt agreements, a restrictive covenant commencing with the fiscal quarter ending on March 31, 2000, states that the Company could not, as at the last day of each fiscal quarter, permit its consolidated earnings before interest, taxes, depreciation and amortization for the period of four consecutive fiscal quarters ending or most recently ended prior to such date to be less than zero.

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

| | <u>December 30, 2001</u> |
|--|------------------------------|
| Term loan, with quarterly payments of \$177,500 through March 28, 2002, interest varies as described above, collateralized by real estate. | \$5,735 |
| Capital lease obligations, with monthly payments of \$16,719 through December 2002 and September 2003, interest from 9.79% to 16.4%, collateralized by property. | <u>231</u> |
| | \$5,966 |
| Less current portion | <u>5,940</u> |
| Amount due in 2003 (none due thereafter) | <u>\$ 26</u> |

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 30, 2001, December 30, 2000, and January 2, 2000 was \$349,000, \$544,000 and \$1,245,000, respectively. Interest expense in the amount of \$657,000, \$0 and \$105,000 was capitalized in 2001, 2000 and 1999, 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 of which 20,000 shares have been designated as Series A Preferred Stock at December 31, 2000 and 12,500 have been designated as Series B Preferred Stock at December 31, 2000. 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.

Shareholder Rights Plan (the "Plan")

On May 31, 2001, the Board of Directors adopted a Shareholder Rights 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 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

During fiscal 1999, several institutional investors converted 9,000 shares of the Series A Preferred Stock, \$.01 par value per share, into 1,927,503 shares of the Company's common stock at conversion prices

ranging from \$3.34 to \$5.98 per share. After these conversions, 11,000 shares of the Series A Preferred Stock remained outstanding.

In November 1999, the Company issued a redemption call on the outstanding \$11 million of Series A Preferred Stock. The holders of the Series A Preferred Stock converted \$5.3 million into 901,807 common shares at a conversion price of \$5.83 per share. The remaining amount was redeemed in cash by the holders at 115% of par value. The 15% premium was recognized as a dividend payment to preferred shareholders in the amount of \$861,000, or \$0.15 per share.

In conjunction with the redemption call, the Company issued \$6.6 million of Series B Preferred Stock to Genzyme. The Series B Preferred Stock carried an initial dividend of 11% and was convertible by the holder into common stock at a fixed rate of \$6.30 per common share. All accumulated or accrued and unpaid dividends were required to be paid upon conversion, liquidation or redemptions of the Series B Preferred Stock. The Company had the sole right to redeem unconverted Series B Preferred Stock for cash at any time at its original value plus accrued dividends. The Series B Preferred Stock was converted into common stock in February 2000.

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. In connection with both the warrants issued and a beneficial conversion feature, the Company recorded a dividend of \$636,000, or \$7.45 per share, to preferred shareholders in the fourth quarter of 1999.

Common Stock Placements

In December 1999, the Company completed a privately negotiated sale of 685,545 shares of common stock at \$8.00 per share under a previously filed shelf registration to two purchasers raising approximately \$5.5 million in new equity.

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 over-allotments which was exercised. In total, the Company issued 4,025,000 shares, including underwriter's overallotment, with net proceeds to the Company of \$75 million. Subsequent to the completion of the secondary public offering, the Company paid down its revolving credit lines in the amount of \$15.8 million. Following this pay down, the full \$15.8 million was available for borrowing under these credit lines.

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 the 450,000 warrants issued in connection with the 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 30, 2001, of which 538,324 are currently exercisable, is as follows:

| <u>Common Shares Issuable for</u> | <u>Exercise Price Per Share</u> | <u>Warrant Expiration Date</u> |
|---------------------------------------|-------------------------------------|--|
| 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 |
| <u>538,324</u> | | |

In September 2000, the Company terminated the SMIG JV by issuing an aggregate of 333,334 shares of its common stock valued at approximately \$11.1 million, plus transaction costs of \$143,000 (see Note 13).

As of December 30, 2001, the Company has reserved 4,406,076 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 stockholders 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 March 2001, the Equity Plan was amended to (i) establish that non-employee directors are eligible for grants under the 1993 Equity Plan, (ii) provide for automatic grant of options to non-employee directors (other than a Chairman of the Board) 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) provide for automatic grants of options 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, commencing with the first election or re-election of a non-employee Chairman in 2001.

Under the 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.

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. A total of 104,385 shares of common stock remained available for issuance under the plan at December 30, 2001. The purchases of common stock under the plan during fiscal 2001 and fiscal 2000 were 101,847 shares at an aggregate purchase price of approximately \$426,000 and 236,530 shares at an aggregate purchase price of approximately \$1,211,000, respectively. No compensation expense has been recorded related to the Purchase Plan.

The Company applies APB Opinion 25 and related interpretations in accounting for its 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*. Had compensation cost for the Company’s stock-based compensation plans to employees 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 30, 2001, December 31, 2000, and January 2, 2000 would have been increased to the pro forma amounts indicated below:

| | December 30, 2001 | | December 31, 2000 | | January 2, 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) |
| As Reported . . . | \$(16,556) | \$(0.55) | \$(14,141) | \$(0.50) | \$(18,761) | \$(1.02) |
| Pro Forma | (19,259) | (0.64) | (18,442) | (0.65) | (21,552) | (1.16) |

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.

A summary of the status of the Company’s stock option plans as of December 30, 2001, December 31, 2000 and January 2, 2000 and changes during the years ending on those dates is presented below:

| | Shares | Weighted Average Exercise Price |
|--|-------------|---------------------------------|
| Balance at January 3, 1999 | 2,513,435 | \$ 7.1560 |
| Granted at Fair Value | 616,090 | \$ 4.7849 |
| Exercised | (151,626) | \$ 4.9580 |
| Cancelled | (151,702) | \$ 7.7554 |
| 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 |

At December 30, 2001, December 31, 2000 and January 2, 2000, there were 1,298,463, 1,354,984 and 1,678,156 shares exercisable at a weighted average exercise price of \$8.2781, \$8.5198 and \$6.6906, respectively.

The following table summarizes information about stock options outstanding at December 30, 2001:

| <u>Range of Exercise Prices</u> | <u>Number Outstanding</u> | <u>Remaining Contractual Life</u> | <u>Weighted-Average Exercise Price</u> | <u>Number Exercisable</u> | <u>Weighted-Average Exercise Price</u> |
|---------------------------------|---------------------------|-----------------------------------|--|---------------------------|--|
| \$ 2.7500 - \$ 5.0313 | 613,735 | 8.21 | \$ 4.6067 | 282,629 | \$ 4.3063 |
| \$ 5.2500 - \$ 7.5000 | 521,313 | 4.06 | \$ 6.8409 | 488,593 | \$ 6.8849 |
| \$ 7.5400 - \$ 8.8100 | 440,870 | 8.92 | \$ 8.1967 | 141,460 | \$ 8.2188 |
| \$ 8.8750 - \$17.3125 | 478,626 | 6.94 | \$12.3683 | 345,381 | \$11.2338 |
| \$17.7500 - \$37.7500 | 98,900 | 8.57 | \$28.0653 | 40,400 | \$28.1395 |
| \$ 2.7500 - \$37.7500 | <u>2,153,444</u> | 7.08 | \$ 8.6850 | <u>1,298,463</u> | \$ 8.2871 |

At December 30, 2001, 1,609,618 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 90% for fiscal 2001 and 80% for each of fiscal 2000 and 1999, respectively, a dividend yield of 0% and a risk-free interest rate of 4.69% and 3.95% for fiscal 2001, 6.18% for fiscal 2000 and 5.82% for fiscal 1999.

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 90% for fiscal 2001 and 80% for each of fiscal 2000 and 1999, an expected life of five years for fiscal 2001, 2000 and 1999 and a risk-free interest rate of 4.64% for fiscal 2001, 4.99% for fiscal 2000 and 4.81% for fiscal 1999. The average fair value of those purchase rights granted during fiscal 2001, 2000 and fiscal 1999 was \$3.30, \$3.01 and \$2.10, 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 \$243,000, \$185,000 and \$125,000 for the fiscal years ended December 30, 2001, December 31, 2000 and January 2, 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:

| | <u>2001</u> | <u>2000</u> | <u>1999</u> |
|---|-------------|-------------|-------------|
| Current: | | | |
| Federal | \$ — | \$ — | \$ — |
| State | — | — | — |
| Total Current | <u>\$ —</u> | <u>\$ —</u> | <u>\$ —</u> |
| Deferred: | | | |
| Federal | (6,783) | (4,423) | (5,137) |
| State | (641) | (928) | (1,009) |
| Change in Valuation Allowance | 7,424 | 5,351 | 6,146 |
| Total Deferred | <u>\$ —</u> | <u>\$ —</u> | <u>\$ —</u> |

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:

| | <u>Fiscal Years Ended</u> | | |
|--|------------------------------|------------------------------|----------------------------|
| | <u>December 30, 2001</u> | <u>December 31, 2000</u> | <u>January 2, 2000</u> |
| Federal tax—expense (benefit) | (34.0)% | (34.0)% | (34.0)% |
| State taxes—net | (3.5) | (5.9) | (7.4) |
| Research and development tax credits | (4.9) | (1.7) | (3.8) |
| Other | 1.6 | 3.6 | — |
| Change in valuation allowance | 40.8 | 38.0 | 45.2 |
| Effective tax rate | <u>0%</u> | <u>0%</u> | <u>0%</u> |

The components of the deferred tax assets and liabilities at December 30, 2001 and December 31, 2000 respectively, are as follows (dollars in thousands):

| | <u>December 30, 2001</u> | <u>December 31, 2000</u> |
|--|--------------------------|--------------------------|
| Deferred Tax Assets/(Liabilities): | | |
| Advance payments | \$ 1,458 | \$ 4,689 |
| Accrued compensation | 861 | 1,465 |
| Other accruals | 498 | 768 |
| Tax credits | 3,333 | 2,369 |
| Net operating loss carryforwards | 45,702 | 43,756 |
| Depreciation | (997) | (690) |
| Other | 9 | 27 |
| Total deferred tax asset | <u>50,864</u> | <u>52,384</u> |
| Valuation allowance | <u>(50,864)</u> | <u>(52,384)</u> |
| | <u>\$ —</u> | <u>\$ —</u> |

As of December 30, 2001, the Company had federal net operating loss (“NOL”) and research and experimentation credit carryforwards of approximately \$123 million and \$2.1 million, respectively, which may be available to offset future federal income tax liabilities and expire at various dates starting 2004 and going through 2021. 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 \$51 million has been established at December 30, 2001.

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 to external customers are based on the location of the customer.

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

| | <u>United States</u> | <u>Japan</u> | <u>Europe</u> | <u>Total</u> |
|----------------|----------------------|--------------|---------------|--------------|
| 2001 | \$ 8,913 | \$31 | \$4,796 | \$13,740 |
| 2000 | 14,368 | 30 | 1,765 | 16,163 |
| 1999 | 10,238 | 62 | 3,525 | 13,825 |

Of the Company's long-lived assets, \$10.2 million of intangible assets are located in a subsidiary in the Cayman Islands and the remaining \$1.4 million are located in the United States.

NOTE 10. UNAUDITED RESULTS OF QUARTERLY OPERATIONS

| <u>2001</u> | <u>First Quarter</u> | <u>Second Quarter</u> | <u>Third Quarter</u> | <u>Fourth Quarter</u> |
|---|--------------------------|---------------------------|--------------------------|---------------------------|
| 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) |
| | | | | |
| <u>2000</u> | <u>First Quarter</u> | <u>Second Quarter</u> | <u>Third Quarter</u> | <u>Fourth Quarter</u> |
| Revenue | \$ 3,570 | \$ 4,167 | \$ 3,169 | \$ 5,257 |
| Operating profit (loss) | 3,127 | (3,950) | (4,826) | (5,005) |
| Discontinued contract research operations . . . | (469) | 84 | 557 | 1,102 |
| Net loss | (2,963) | (3,150) | (3,875) | (4,451) |
| Net loss per share—basic and diluted | (0.11) | (0.11) | (0.13) | (0.15) |

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 \$1,238,880, \$826,000 and \$1,605,000 for the fiscal years ended December 30, 2001, December 31, 2000 and January 2, 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. 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 stockholder of the Company, holding 7,744,919 shares of common stock as of December 30, 2001, which represents approximately 26% 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. All of the shares held by Genzyme (including shares issuable on exercise of Genzyme warrants) are entitled to registration rights.

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 support services in exchange for a fixed monthly payment (\$75,417 per month during 2001) adjusted annually. These basic services include laboratory support, as well as assistance with certain administrative functions including purchasing, data processing, risk management, corporate communications and treasury activities. 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 \$905,000, \$730,000 and \$446,000 for the fiscal years ended December 30, 2001, December 31, 2000 and January 2, 2000, respectively, and is committed to make a minimum annual payment of \$1,011,996 in 2002.

Sublease Agreement

Under the Sublease Agreement, the Company has leased certain laboratory, research and office space from Genzyme through May 1998 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 30, 2001, December 31, 2000 and January 2, 2000, of \$368,000, \$146,000 and \$137,000, respectively, and is committed to make a minimum annual rental payment of \$489,108 in 2002.

Technology Transfer Agreement

Under the Technology Transfer Agreement dated May 1, 1993, Genzyme transferred substantially all of its transgenic assets and liabilities to GTC, 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 GTC is obligated to Genzyme's licensors for any royalties due them. As long as Genzyme owns less than 50% of GTC, 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 GTC each agreed to provide to the other research and development services relating, in the case of GTC, 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 provided development services to Genzyme for which it recognized revenues of \$11,000 for the fiscal year ended January 3, 1999. The Company also receives research and development services from Genzyme, for which it incurred costs of \$43,000, \$121,000 and \$423,000 in 2001, 2000 and 1999, respectively. The agreement expired on December 31, 1998 and the parties are continuing under this agreement on a month-to-month basis.

ATIII Collaboration

In January 1998, the Company entered into a collaboration agreement for the development of rhATIII with Genzyme forming the ATIII LLC joint venture. Under the terms of the agreement, Genzyme funded 70% of the development costs of rhATIII up to a maximum of \$33 million. The Company funded the remaining 30% of these costs. Development costs in excess of these amounts were to be funded equally by the partners. The \$33 million funding level was achieved by Genzyme in 2000.

Credit Line Guaranty, Term Loan Guaranty and Lien.

Genzyme guarantees a credit line and term loan with a commercial bank up to \$24.6 million. This line was originally due to expire in December 2001, but has been extended until March 28, 2002. The Genzyme guaranty was also extended until such time, although GTC has agreed not to draw on the credit line without Genzyme's prior consent. The Company has agreed to reimburse Genzyme for any liability Genzyme may incur under such guaranty and has granted Genzyme a first lien on all of the Company's assets to collateralize such obligation

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")

Since 1988, pursuant to a cooperation agreement, the Company has funded an ongoing program to develop transgenic animals at Tufts. During the term of the agreement, which extends through August 1, 2004, Tufts has agreed to work exclusively with the Company for commercial applications within the field of transgenic protein production in milk. The Company paid Tufts \$488,000, \$242,000 and \$313,000 for the fiscal years ended December 30, 2001, December 31, 2000 and January 2, 2000, respectively. Sales of products derived from transgenic goats produced by Tufts, or from their offspring, are subject to royalties payable to Tufts.

Advanced Cell Technologies, Inc. (“ACT”)

In June 1999, GTC signed an exclusive, worldwide licensing agreement with ACT allowing GTC to utilize ACT’s patented nuclear transfer technology for the development of biopharmaceuticals in the milk of transgenic mammals. The Company believes ACT’s proprietary 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.

Pharming B.V. (“Pharming”)

In 1994, GTC entered into a license agreement with Pharming to allow GTC to use Pharming’s technology in the production of transgenic cattle. Under the terms of the agreement, GTC is required to pay royalties to Pharming on sales by GTC of products developed using Pharming’s transgenic technology in cattle.

Genzyme Corporation (“Genzyme”)

In May 1993, under a Technology Transfer Agreement, Genzyme transferred substantially all of its transgenic assets and liabilities to GTC, 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 its proteins produced in that manner. The license is worldwide and royalty free as to Genzyme, although GTC is obligated to Genzymes’ licensors for any royalties due them. As long as Genzyme owns less than 50% of GTC, 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.

The Leland Stanford Junior University (“Stanford”)

In October 2001, GTC signed an Option to Patent License Agreement (the “Option”) with Stanford to acquire a license from Stanford for the purpose of conducting research on potential commercial applications and preliminary product development. The term of the Option is until October 2002 which may be extended to October 2003 by payment of an extension fee. The Company paid Stanford \$10,000 for the fiscal year ended December 30, 2001 and has no further obligation unless they choose to extend the Option.

NOTE 13. JOINT VENTURES

GTC owned 22% of the SMIG JV joint venture with Sumitomo Metal Industries (“Sumitomo”) to develop proteins produced transgenically. In September 2000, the Company acquired full ownership of the SMIG JV by issuing an aggregate of 333,334 shares of its common stock valued at approximately \$11.1 million, plus transaction costs of \$143,000. In exchange, Sumitomo transferred to a wholly-owned subsidiary of the Company all of the outstanding shares of SMI Genzyme Ltd., a Japanese corporation, held by Sumitomo. As a result, the Company directly and indirectly holds all of the outstanding equity in SMI Genzyme Ltd., and has the exclusive marketing rights to transgenic technology in 18 Asian countries, including Japan. The value of the transaction was accounted for as a purchase. Accordingly, the entire purchase price of \$11.2 million has been allocated to the value of the marketing rights, which are being amortized over the estimated economic useful life of these rights estimated at 15 years. Accumulated amortization of the marketing rights at December 30, 2001 was \$996,000.

On January 1, 1998, a definitive collaboration agreement for the ATIII LLC joint venture between the Company and Genzyme was executed. Under the terms of the agreement, Genzyme was required to fund 70% of the development costs, excluding facility costs, up to \$33 million including costs incurred in 1997.

The Company was required to fund the remaining 30% of these costs. Development costs in excess of these amounts were to be funded equally by the partners. The Company and Genzyme were also to make capital contributions to ATIII LLC sufficient to pay 50% each of all new facility costs to be incurred. In addition to the funding, both partners were to contribute manufacturing, marketing and other resources to ATIII LLC at cost. Under the agreement to establish the joint venture, Genzyme and the Company were the only members and owned 3.7% and 96.3% interest, respectively. In accordance with the executed purchase agreement, the Company sold and assigned a 46.3% ownership interest to Genzyme so that Genzyme and GTC each owned 50% of the venture. The purchase price was \$12,500,010, payable as follows: an initial payment of \$10 upon execution of the purchase agreement, \$2.5 million after the second consecutive quarter in which net sales of collaboration products for such quarter exceed \$5 million, and \$10 million on the first full approval, if and when approved by the Food and Drug Administration (“FDA”) of a major market country or by the European Union’s European Medicines Evaluation Agency (“EMA”) of (i) a BLA filed by ATIII LLC for the use of transgenic ATIII for the treatment of sepsis or (ii) an amendment to the BLA previously filed by ATIII LLC and approved by the FDA of a major market country or by the EMA to add sepsis as an indication for transgenic ATIII. Profits and losses are shared according to ownership percentages. These agreements cover all territories other than Asia. The Company accounted for its 50% ownership of the ATIII LLC under the equity method. For the fiscal years ended December 30, 2001, December 31, 2000 and January 2, 2000, the Company recognized research and development revenue and related expenses of \$973,000, \$3,283,000 and \$4,491,000, respectively, under ATIII LLC.

In July 2001, the Company completed the reacquisition of Genzyme’s ownership interest in ATIII LLC. In consideration, Genzyme will receive a royalty based on 4% of the Company’s sales of ATIII, if any, in all territories except Asia, commencing three years after the first commercial sale and subject to a cumulative maximum of \$30 million.

NOTE 14. OTHER RELATED PARTY TRANSACTIONS

Arthur D. Little, Inc. (“ADL”)

In November 2000, the Company entered into a consulting agreement with ADL for strategic and technical assessment and due diligence within the ordinary course of business. The Company paid ADL \$963,000 and \$150,000 for fiscal years ended December 30, 2001 and December 31, 2000, respectively. A Director of the Company is also a Senior Consultant of ADL.

Board of Directors

Other than the Chairman of the Board, all Directors who are not employees of GTC or Genzyme receive an annual retainer of \$12,000, payable quarterly. One Director, who also served as Chairman of the Board, received \$43,200 in 2001, 2000 and 1999 as compensation for consulting services. Another Director received \$0, \$99,000 and \$132,000 in 2001, 2000 and 1999, respectively, 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 GTC 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 CRL. Accordingly, Primedica is reported herein as a discontinued operation.

| | <u>December 31, 2000</u> | <u>January 2, 2000</u> |
|---|--------------------------|------------------------|
| Revenues from discontinued operations before taxes | \$71,986 | \$54,959 |
| Provision for taxes | <u>247</u> | <u>320</u> |
| Revenues from discontinued operations, net of taxes | <u>\$71,739</u> | <u>\$54,639</u> |

The assets of Primedica are as follows:

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

REPORT OF INDEPENDENT ACCOUNTANTS ON FINANCIAL STATEMENT SCHEDULE

To the Board of Directors and Shareholders
of Genzyme Transgenics Corporation:

Our audits of the consolidated financial statements referred to in our report dated February 14, 2002 appearing in the 2001 Annual Report to Shareholders of Genzyme Transgenics Corporation (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 14(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
February 14, 2002

Schedule II—Supplemental Valuation and Qualifying Accounts
Years ended December 30, 2001, December 31, 2000 and January 2, 2000:

Deferred tax asset valuation allowance

| | <u>Balance at Beginning of Period</u> | <u>Charged to (benefits) Costs and Expenses</u> | <u>Balance at End of Period</u> |
|-----------------------------|---|---|---|
| December 30, 2001 | \$52,384 | (1,520) | \$50,864 |
| December 31, 2000 | \$43,615 | 8,769 | \$52,384 |
| January 2, 2000 | \$32,701 | 10,914 | \$43,615 |

Allowance for unbilled receivable and doubtful accounts

| | <u>Balance at Beginning of Period</u> | <u>Charged to Costs and Expenses</u> | <u>Write-offs</u> | <u>Balance at End of Period</u> |
|-----------------------------|---|--|-------------------|---|
| December 30, 2001 | \$316 | — | — | \$316 |
| December 31, 2000 | \$316 | (175) | 175 | \$316 |
| January 2, 2000 | \$ — | — | — | \$ — |

EXHIBIT INDEX
to Form 10-K for the Year Ended December 30, 2001

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 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) (the "GTC 1993 10-K") 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) (the "GTC 1997 10-K") 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) (the "GTC June 1997 10-Q") 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) (the "GTC June 2001 8-K") 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. 000-21794) (the "GTC July 1999 10-Q") and incorporated herein by reference. |
| 4.1 | Specimen Common Stock Certificate. Filed as Exhibit 4.1 to the Company's Registration Statement on Form S-1 (File No. 33-62782) (the "GTC S-1") and incorporated herein by reference. |
| 4.2 | Common Stock Purchase Warrant, dated July 3, 1995, issued to Genzyme Corporation ("Genzyme"). Filed as Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the period ended July 2, 1995 (File No. 0-21794) (the "GTC July 1995 10-Q") and incorporated herein by reference. |
| 4.3 | Common Stock Purchase Warrant, dated as of June 26, 1997, issued to Government Land Bank d/b/a The MassDevelopment ("MassDevelopment"). Filed as Exhibit 4 to the GTC June 1997 10-Q and incorporated herein by reference. |
| 4.4 | Common Stock Purchase Warrant, dated as of December 28, 1998, issued to Genzyme. Filed as Exhibit 4.11 to the original filing of the Company's Annual Report on Form 10-K for the year ended January 3, 1999 (the "GTC 1999 10-K") and incorporated herein by reference. |
| 4.5 | Registration Rights Agreement between the Company and certain Stockholders named therein. Filed as Exhibit 10.53 to the GTC 1997 10-K and incorporated herein by reference. |

| Exhibit No. | Description |
|-------------|---|
| 4.6 | Warrant to Purchase Common Stock, dated November 22, 1999, issued to Genzyme. Filed as Exhibit 8 to Genzyme's Amendment No. 6 to Schedule 13D (File No. 055-48837) filed with the Commission on November 24, 1999 and incorporated herein by reference. |
| 4.7 | Shareholder Rights Agreement, dated as of May 31, 2001, between GTC and American Stock Transfer and Trust Company, as Rights Agent. Files as Exhibit 4.1 to GTC June 2001 8-K 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 | Mortgage and Security Agreement, dated as of June 30, 1995, between GTC and Genzyme. Filed as Exhibit 10.6 to the GTC July 1995 10-Q and incorporated herein by reference. |
| 10.6.2 | First Amendment to Mortgage and Security Agreement, dated as of December 15, 1995, between GTC and Genzyme. Filed as Exhibit 10.7.2 to the Company's Annual Report on Form 10-K for the year ended December 29, 1996 (File No. 000-21794) and incorporated herein by reference. |
| 10.6.3 | Second Amendment to Mortgage and Security Agreement, dated as of December 28, 1998, between the GTC and Genzyme. Filed as exhibit 10.7.3 to the Company's Annual Report on Form 10-K for the year ended January 2, 2000 (File No. 0-21794) (the "GTC 1999 10-K") and incorporated herein by reference |
| 10.7* | GTC Amended and Restated 1993 Equity Incentive Plan. Filed herewith. |
| 10.8* | GTC 1993 Employee Stock Purchase Plan, as amended through May 28, 1997. Filed as Exhibit 10.4 to the GTC June 1997 10-Q and incorporated herein by reference. |
| 10.10 | 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. |
| 10.11 | GTC Form of Agreement Not to Compete. Filed as Exhibit 10.10 to the GTC S-1 and incorporated herein by reference. |
| 10.12 | Form of Indemnification Agreement between GTC and its directors. Filed as Exhibit 10.12 to the original filing of the Company's Annual Report on Form 10-K for the year ended December 31, 1994 (the "GTC 1994 10-K") and incorporated herein by reference. Such agreements are materially different only as to the signing directors and the dates of execution. |
| 10.13 | License Agreement between GTC and Biogen, Inc., dated December 26, 1990. Filed as Exhibit 10.12 to the GTC S-1 and incorporated herein by reference.** |

| Exhibit No. | Description |
|-------------|--|
| 10.14.1 | 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 the GTC 1994 10-K and incorporated herein by reference.** |
| 10.14.2 | Amendment No. 7, dated April 1, 1993, to Cooperation and Licensing Agreement. Filed as Exhibit 10.6 to the Company’s Quarterly Report on Form 10-Q for the period ended October 1, 1995 (File No. 0-294) (the “GTC October 1995 10-Q”) and incorporated herein by reference. |
| 10.14.3 | 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. |
| 10.14.4 | 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.** |
| 10.14.5 | 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. |
| 10.14.6 | 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. |
| 10.15 | United States Patent No. 4,873,191 Sublicense Agreement between 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.** |
| 10.16 | Lease dated March 26, 1999 between Genzyme Transgenics Corporation and NDNE 9/90 Corporate Center LLC. Filed as Exhibit 10.1 to GTC’s July 1999 10-Q and incorporated herein by reference. |
| 10.17.1 | Second Amended and Restated Convertible Debt Agreement, dated as of December 28, 1998, between the GTC and Genzyme. Filed as Exhibit 10.37 to Genzyme’s Annual Report on Form 10-K for the year ended December 31, 1998 (File No. 0-14680) and incorporated herein by reference. |
| 10.17.2 | Amended and Restated Convertible Revolving Credit Note in the amount of \$6,300,000, dated as of December 28, 1998, executed by GTC to Genzyme. Filed as Exhibit 10.29.2 to the original filing of the GTC 1999 10-K and incorporated herein by reference. |
| 10.17.3 | Amended and Restated Reimbursement Agreement, dated as of December 28, 1998, 1995, among GTC, certain of its subsidiaries and Genzyme. Filed as Exhibit 10.57.4 to the original filing of the GTC 1999 10-K and incorporated herein by reference. |
| 10.17.4 | Amended and Restated Security Agreement, dated as of December 28, 1998, among GTC, certain of its subsidiaries and Genzyme. Filed as exhibit 10.28.4 to the GTC 1999 10-K and incorporated herein by reference. |
| 10.17.5 | Hazardous Materials Indemnity Agreement, December 28, 1998, between the GTC and Genzyme. Filed as exhibit 10.28.5 to the GTC 1999 10-K and incorporated herein by reference. |

| Exhibit No. | Description |
|-------------|--|
| 10.18* | Amended and Restated Employment Agreement, dated as of August 28, 1997, between the Company and John B. Green. Filed as Exhibit 10.2 to the GTC September 1997 10-Q and incorporated herein by reference. |
| 10.19* | Employment Agreement, dated as of March 27, 1996, between GTC and Harry Meade. Filed as Exhibit 10.44 to the Company's Quarterly Report on Form 10-Q for the period ended March 31, 1996 and incorporated herein by reference. |
| 10.20 | Amendment Agreement, dated as of April 23, 1997, between GTC and Pharming B.V. Filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 30, 1997 (File No. 0-21794) (the "GTC March 1997 10-Q") and incorporated herein by reference. |
| 10.21 | Exclusive Development and License Agreement, dated as of June 8, 1999, between the Company and Advanced Cell Technology, Inc. Filed herewith.** |
| 10.22 | Development and Commercialization Agreement, dated as of September 25, 1997, between the Company and B. Braun Melsungen AG. Filed as Exhibit 10.6 to the GTC September 1997 10-Q and incorporated herein by reference.** |
| 10.23 | Unconditional Guaranty, dated as of May 22, 1997, executed by the Company in connection with the Loan Agreement, dated as of May 22, 1997, between Redfield and SFNB. Filed as Exhibit 10.49.7 to the GTC 1997 10-K and incorporated herein by reference. |
| 10.24 | Guaranty, dated as of June 26, 1997, executed by the Company in connection with the Loan Agreement, dated as of June 26, 1997, between Mason and MassDevelopment. Filed 10.8.4 as Exhibit to the GTC June 1997 10-Q and incorporated herein by reference. |
| 10.25.1 | Purchase Agreement between GTC and Genzyme dated as of January 1, 1998, transferring an interest in ATIII LLC from Genzyme to GTC. Filed as Exhibit 10.52.2 to the GTC 1997 10-K and incorporated herein by reference.** |
| 10.25.2 | Purchase Agreement between the Company and Genzyme Corporation, 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. ** |
| 10.25.3 | Services Agreement between the Company 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. ** |
| 10.25.4 | Amended and Restated Collaboration Agreement among the Company, 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. ** |
| 10.26* | Amendment No. 1 to Employment Agreement between the Company and John B. Green. Filed as Exhibit 10.3 to the GTC September 1998 10-Q and incorporated herein by reference. |
| 10.27* | Consulting Agreement between the Company and James A. Geraghty. Filed as Exhibit 10.4 to the GTC September 1998 10-Q and incorporated herein by reference. |
| 10.28.1 | Credit Agreement between GTC and Fleet National Bank, dated as of December 28, 1998. Filed as Exhibit 10.57.1 to the original filing of the GTC 1999 10-K and incorporated herein by reference. |

| Exhibit No. | Description |
|-------------|---|
| 10.28.2 | Revolving Credit Note in the amount of \$17,500,000, dated as of December 28, 1998, executed by GTC and issued to Fleet National Bank. Filed as Exhibit 10.57.2 to the original filing of the GTC 1999 10-K and incorporated herein by reference. |
| 10.28.3 | Term Note in the amount of \$7,100,000, dated as of December 28, 1998, executed by GTC and issued to Fleet National Bank. Filed as Exhibit 10.57.3 to the original filing of the GTC 1999 10-K and incorporated herein by reference. |
| 10.28.4 | First Amendment to Credit Agreement dated as of November 12, 1999 between Fleet National Bank and GTC. Filed as exhibit 10.51.4 to the GTC 1999 10-K and incorporated herein by reference. |
| 10.28.5 | Second Amendment to Credit Agreement, dated as of December 27, 2001, between GTC and Fleet National Bank. Filed herewith. |
| 10.28.6 | Third Amendment to Credit Agreement and Amendment to Revolving Credit Note and Term Note, dated as of January 11, 2002, between GTC and Fleet National Bank. Filed herewith. |
| 10.29* | Separation Agreement and General Release, dated as of May 16, 2001, between GTC and Sandra Nusinoff Lehrman. Filed as Exhibit 10.1 to GTC's Quarterly Report on Form 10-Q for the quarter ended July 1, 2001 (File No. 0-21794) and incorporated herein by reference. |
| 10.30* | 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. |
| 21 | List of Subsidiaries. Filed herewith. |
| 23 | Consent of PricewaterhouseCoopers LLP. Filed herewith. |
| 99 | Important Factors Regarding Forward-Looking Statements. 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

NOTES