

GTC Biotherapeutics, Inc.



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2007 ANNUAL REPORT
AND FORM 10-K

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May 5, 2008

Dear Shareholders,

I am pleased to report to you that GTC Biotherapeutics has made excellent operational progress over the past year. We have made significant progress toward U.S. approval of our lead product, ATryn[®], our recombinant form of human antithrombin. We have also established clearly defined product portfolios in recombinant plasma proteins and monoclonal antibodies, including the emerging area of follow-on biologics that are referred to as biosimilars in Europe. We have expanded our partnering and strategic relationships as we pursue the growth of our company. Our product and strategic accomplishments include:

ATryn[®]

- Met the primary endpoint of the phase III study for the U.S.
- Obtained orphan drug and fast track status in the U.S.
- Initiated the Food and Drug Administration (FDA) Biologics License Application (BLA) seeking market approval in the U.S.
- Supplied our partner, LEO Pharma, in its initiation of a phase II study in Europe for disseminated intravascular coagulation (DIC) associated with severe sepsis.
- Supporting LEO in the initiation of the commercial launch in Europe in the approved hereditary antithrombin deficiency, or HD, indication.

Product Portfolios

- Established a broad portfolio of recombinant plasma proteins.
- In-licensed recombinant coagulation factors VIII and IX, as well as fibrinogen.
- Initiated a portfolio of monoclonal antibodies that includes plans for follow-on biologics.

Partnering

- Doubled revenues to \$13.9 million, primarily from products and services delivered to our partners LEO Pharma A/S, PharmAthene, Inc., and Merrimack Pharmaceuticals, Inc.
- Expanded our collaboration with LFB Biotechnologies for the development of recombinant coagulation factor VIIa to include development of a CD20 monoclonal antibody, a recombinant factor IX, and a recombinant alpha-1 antitrypsin.

Our overall strategy is to utilize our capability and expertise demonstrated in the ATryn® program to expand our portfolios of products and partners. We also plan to use the fundamental characteristics of our transgenic production technology to attract additional collaboration partners. We expect these collaboration relationships to bring clinical and marketing expertise to our product programs and add financial support to our growth.

Our fundamental value begins with our transgenic production platform, which is uniquely enabling for the development of therapeutic proteins that are difficult-to-express in other systems or where large volumes with the associated capital and cost of goods are critical considerations. We are utilizing these characteristics and our continuing clinical and regulatory success to establish our two portfolios of products. One is in the area of recombinant plasma proteins, which are generally difficult to express in standard mammalian cell culture recombinant systems. We are also developing a portfolio of monoclonal antibodies focused primarily on the emerging area of follow-on biologics, which are sometimes referred to as biogenerics in the general media. Lower cost production of large volumes of these products will be important as this business develops from the evolving legislation process.

Despite our accomplishments, the price of GTC common stock has not reflected the increase in the fundamental value of our business. Much of this has been due to general conditions in the stock markets, particularly for small biotechnology companies such as ours. We will remain focused on building long-term value by growing through success of our product programs and expanding and adding to our collaboration arrangements.

Plasma Protein Portfolio

Our current development programs in our recombinant plasma protein portfolio include ATryn[®], recombinant factors VIIa and IX, and a recombinant form of human alpha-1 antitrypsin.

ATryn[®] – recombinant human antithrombin We have completed enrollment of patients in the pivotal phase III study in the U.S. for ATryn[®] in the treatment of patients with hereditary antithrombin deficiency, or HD, undergoing high-risk procedures of surgery and childbirth. This pivotal study has met the primary endpoint of demonstration of non-inferiority to plasma-derived antithrombin in preventing clinically relevant deep vein thromboses, or DVTs, or other thromboembolisms. GTC has also initiated the filing of the associated BLA on a rolling basis by submitting the preclinical and manufacturing sections. The last section to be filed is expected to be the full clinical study results once all follow-up safety data is available.

Our marketing and development partner for ATryn[®] in Europe, Canada and the Middle East is LEO Pharma A/S of Denmark. The validation of our production technology was catalyzed by regulatory approval of ATryn[®] from the European Medicines Agency, or EMEA in 2006 for the treatment of HD patients undergoing high-risk surgical procedures. LEO launched the product in the United Kingdom in the fourth quarter of 2007 and is expanding commercial availability as pricing is established in additional countries. LEO is pursuing a premium pricing strategy compared to the plasma products that are sold in various European countries as it seeks to establish the value of ATryn[®] as the only available recombinant product and the only antithrombin that has been approved for use throughout the European Union. LEO intends to request

label expansion in the EU when we provide the data from the U.S. pivotal study that included childbirth procedures, an important treatment group in the HD population. LEO has begun a 200-patient phase II dose ranging study of ATryn® as a potential treatment for severe sepsis patients that are developing disseminated intravascular coagulation, or DIC. DIC is the widespread formation of clots within blood vessels, which often leads to organ failure. This is a large unmet medical need with approximately 500,000 sepsis patients developing DIC in the U.S. and Europe each year with up to 50% mortality. We estimate the US market for this indication is \$2 - \$3 billion. We will have access to the phase II data for use in obtaining regulatory review in countries outside of LEO's territories.

Factor VIIa We have a strategic collaboration with LFB Biotechnologies of France to develop selected recombinant plasma proteins and monoclonal antibodies using our transgenic production platform. The first program in this collaboration is for the development of a transgenically produced recombinant form of human factor VIIa (rhFVIIa), a clotting factor in coagulation. GTC has developed transgenic animals that express rhFVIIa and has begun the preclinical work necessary to support initiation of human clinical studies to evaluate its use in treating hemophiliacs that have developed inhibitors to treatment with factors VIII or IX. A rhFVIIa product (NovoSeven®) is currently commercially available from Novo Nordisk at a selling price of approximately \$1,000 per milligram. NovoSeven® sales were reported to be in excess of \$1 billion in 2007. We believe that our rhFVIIa production advantages will allow our product to be more competitively priced to allow broader utilization as a prophylactic treatment by many more hemophiliac patients and with potential for further expansion into treating acquired bleeding conditions.

Factor IX The second recombinant plasma protein program initiated in GTC's strategic collaboration with LFB is for the development of a recombinant human factor IX (rhFIX). GTC recently obtained exclusive rights from ProGenetics to develop this blood coagulation factor into a product for the treatment of type

B hemophilia in North America, Europe and Japan. ProGenetics is responsible for the expression of this product in the milk of transgenic pigs. GTC and LFB are responsible for the manufacturing, clinical development, regulatory affairs, and commercialization activities in our territories.

rhAAT GTC has produced transgenic goats that express recombinant human alpha-1 antitrypsin, or rhAAT, in their milk at significant quantities. We are initially developing rhAAT as an injectable product for treatment of patients with a hereditary deficiency of this protein. A deficiency of the alpha-1 antitrypsin protein allows the build-up of elastase, which can lead to emphysema and other respiratory conditions. Worldwide sales for plasma-derived alpha-1 antitrypsin products in 2006 were approximately \$400 million with U.S. sales estimated at just under \$300 million. We believe that as with our other recombinant plasma protein programs, the well-characterized nature and expandable source of supply of our rhAAT can provide an attractive treatment option to these patients in maintaining their lung function.

Monoclonal Antibodies

An antibody is a type of protein normally produced by our immune systems and, when produced by a single type of cell in a recombinant form, is commonly referred to as a monoclonal antibody, or MAb. As therapeutic products, MAb's are often targeted on long-term treatment of diseases such as cancer and arthritis, which typically require large production volumes for their treatments.

CD137 – A Proprietary Monoclonal Antibody We are developing a MAb to the CD137 receptor of the immune system. Early research indicates that the CD137 MAb functions as a modulator of the immune system and may be a potential treatment for solid tumors and autoimmune diseases. We have initiated a preclinical program funded by a Small Business Innovation Research (SBIR) grant from the National Institutes of Health. We are seeking partnership opportunities for further development.

CD20 – A Potential Follow-on Biologic LFB has developed a CD20 MAb which they brought into our collaboration. This product is expected to have target specificity similar to the commercial drug Rituximab (also known as Rituxan® or Mabthera®) and is intended to exploit the natural glycosylation of our technology to produce a higher antibody dependent cell-mediated cytotoxicity, or ADCC. The relevant patents surrounding the Rituximab product are due to expire in 2014.

Rituximab is currently used to treat B-cell non-Hodgkin's lymphoma, B-cell leukemia and rheumatoid arthritis. It is also being studied for applications in a range of autoimmune diseases. Worldwide sales of Rituximab in 2006 have been reported to be nearly \$4 billion and are projected to be \$5 billion by 2010.

Follow-On Biologics Portfolio

Because of our proven track record with the production of monoclonal antibodies, GTC is developing a portfolio of 4 to 5 follow-on biologic products. The currently marketed forms of these MAb products have sales of approximately \$16 billion and are expected to grow to \$30 billion over the next 5 to 6 years. We are staying involved in the emerging legislative process to define the requirements for follow-on biologics in the U.S. In the EU, the legislative framework is already in place to support approval of biosimilars. We will seek partners to help finance and commercialize these programs.

Innovation and Proven Product Development

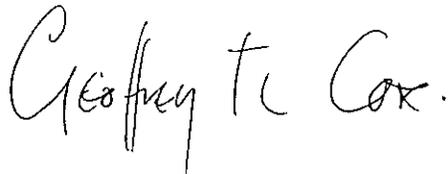
The innovation of GTC has always been based on our taking the elegant science of transgenic production technology and successfully applying it to the innovative development of largely known therapeutic proteins where our production advantages in expression and cost can expand market opportunities and create markets that do not exist today. Our progress has enabled our partners to recognize not only the success of our science, but also the expertise we have in reducing the science to practice in the exacting demands of developing, approving, and supporting a commercially approved product. GTC is in the leadership role of enabling market growth by bringing the advantages of our innovative production platform to product development. In many cases our product candidates have the advantage of being targeted at known

indications where cost effective supply has been the principal constraint. Solving the very practical issues of expression and cost often determines whether a therapeutic protein can serve the unmet needs of patients, as well as become an attractive growth product for investors.

I wish to thank all of our investors for their continued support of GTC throughout the year. 2008 should prove to be a very exciting year as we continue the transformation of GTC as a commercial products company.

I invite you to learn more about us in our enclosed Annual Report on Form 10-K filed with the Securities and Exchange Commission. I also encourage you to keep current on our developments by periodically checking our web site, www.gtc-bio.com. I look forward to updating you on our progress over the coming months.

Sincerely,

A handwritten signature in black ink that reads "Geoffrey F. Cox". The signature is written in a cursive, flowing style.

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

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 30, 2007

or

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

For the transition period from _____ to _____

Commission File No. 0-21794

GTC BIOTHERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

MASSACHUSETTS
*(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:

Common Stock, par value \$0.01 per share
Rights to Purchase Series C Junior
Participating Cumulative

Preferred Stock, par value \$0.01 per share
Title of each class

Nasdaq Global Market
Name of each exchange on which registered

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

None

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

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

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

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

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

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

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

The aggregate market value of voting stock held by non-affiliates of the Registrant as of June 29, 2007, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$93,327,865, based on the closing sale price of the registrant's Common Stock as reported on the NASDAQ Global Market.

Number of shares of the registrant's Common Stock outstanding as of March 3, 2008: 85,192,748

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the Annual Meeting of Stockholders to be held on May 14, 2008 are incorporated by reference into Part III of this Form 10-K.

GTC Biotherapeutics, Inc.
Form 10-K
For the Fiscal Year Ended December 30, 2007
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PART I

In this Annual Report on Form 10-K, the words "we", "our", "ours" and "us" refer only to GTC Biotherapeutics, Inc., its wholly-owned subsidiaries and its joint venture. Unless indicated otherwise, references to the years 2007, 2006 and 2005 refer to our fiscal years ended December 30, 2007, December 31, 2006 and January 1, 2006, respectively.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements, including statements regarding future revenues, research and development programs, clinical trials and collaborations and our future cash requirements. The words or phrases "will", "will likely result", "are expected to", "will continue", "is anticipated", "estimate", "project", "potential", "believe", "plan", "anticipate", "expect", "intend", or similar expressions and variations of

such words are intended to identify forward-looking statements. 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 revenues, research and development programs, clinical trials and collaborations and our future cash requirements include, without limitation, continued operating losses, our ability to raise additional capital, technology risks to our transgenically produced products, the performance of our collaboration partners and continuation of our collaborations, our ability to enter into collaborations in the future and the terms of such collaborations, regulatory approval of our transgenically produced products, preclinical and clinical testing of our transgenically produced products, and those factors set forth in the Section entitled "Risk Factors" in Item 1A of this Form 10-K.

ITEM 1. BUSINESS

Overview

We are the leader in the development and production of human therapeutic proteins through transgenic technology that enables animals to produce what is known as a recombinant form of a specified human protein in their milk. Using this technology, we are developing a portfolio of recombinant blood proteins to treat a range of genetic and acquired blood deficiencies, including hemophilia and other blood coagulation disorders. These blood proteins, also known as plasma proteins, are difficult to produce in other manufacturing systems, and some are currently only available by extraction from human blood. We have also initiated the development of a portfolio of monoclonal antibodies, or MAb's, for use as potential follow-on biologics targeted at several large market products.

Our first product ATryn[®], our recombinant form of human antithrombin, validated our transgenic production technology's capability to meet the regulatory requirements for recombinant proteins. In 2006, ATryn[®] became the first transgenically produced therapeutic protein to be approved anywhere in the world when we obtained European Commission approval of the use of ATryn[®] as a prophylactic treatment for patients with hereditary antithrombin deficiency, or HD, undergoing surgical procedures. In February 2008, we announced that ATryn[®] had met the statistical requirements for the primary endpoint in our pivotal trial to support our filing of a Biologics License Application, or BLA, for the use of ATryn[®] in the United States in HD patients undergoing surgery or childbirth. We plan to complete the filing of the BLA in 2008.

We plan to develop ATryn[®] and many of our other recombinant proteins through strategic collaborations. Under our exclusive collaboration agreement entered into with LEO Pharma A/S in 2005, LEO is sponsoring the clinical development of ATryn[®] in Europe for a new indication of disseminated intravascular coagulation, or DIC, in severe sepsis. In September 2006, we entered into a collaboration agreement with LFB Biotechnologies, or LFB, to develop selected recombinant plasma proteins and MAb's. The first program in this collaboration is for the development of a recombinant form of human blood coagulation factor VIIa for the treatment of patients with hemophilia. We have subsequently added to the LFB collaboration a program to develop a recombinant form of human blood coagulation factor IX, as well as a program to develop an antibody to the CD20 immune system receptor, the same target as for the MAb marketed as Rituxan[®]. We are engaged in business development activities with the objective of adding additional collaborations.

The following summarizes our portfolio of proprietary products in development:

Recombinant Plasma Protein Products

We believe that our transgenic technology is able to offer well-characterized supplies of recombinant forms of therapeutic human plasma proteins. Therapeutic human plasma proteins are derived from either the liquid portion of human blood, or plasma, or are produced using recombinant DNA techniques. Plasma-derived proteins

are in many cases currently available only in limited quantities. Many plasma proteins are difficult to express in economically viable quantities in traditional recombinant production technologies such as mammalian cell culture or bacteria production. We believe that our transgenic recombinant production technology has:

- A greater capability to produce difficult-to-express recombinant plasma proteins in large quantities in a cost effective manner;
- the ability to expand the current markets for existing indications that are constrained by low production quantities and high production costs and prices; and
- the ability to create and support new markets based on the development of new indications due to a greater supply of these therapeutic proteins.

Our estimation of the potential market for recombinant forms of plasma proteins is based, in part, on the sales experience of recombinant forms of the blood coagulation proteins known as factors VIIa, VIII, and IX, which have generated \$3 billion of annual sales worldwide compared to the \$1 billion of annual sales worldwide for plasma-sourced coagulation factor products. These products have been developed for multiple indications which have expanded their markets. By increasing the number of approved indications for our proprietary recombinant plasma proteins, we believe we have the opportunity for similar success in expanded markets.

- **ATryn®:** We have established a collaboration agreement with LEO for further development and commercialization of ATryn® in Europe, Canada, and the Middle East. LEO has selected disseminated intravascular coagulation, or DIC, associated with severe sepsis as an acquired antithrombin deficiency indication for development in their territories. LEO has obtained scientific advice from the European Medicines Agency, or EMEA, on the design of a Phase II dose ranging study of approximately 200 patients and commenced enrollment in 2007. We will have the right to use the Phase II data in the U.S. and all other territories outside of LEO's territories. LEO plans to seek further advice from the EMEA for a potential Phase III study once the Phase II data is available. We will supply the product for these clinical studies and receive payment for delivery of the material to LEO. We will supply the product for commercial sales and LEO will pay us a transfer price and royalties on sales of ATryn®. ATryn® became available for sale for the HD indication in the United Kingdom in late 2007 and LEO will market in other European countries as they establish pricing on a country-by-country basis.

We have filed initial sections of our BLA seeking approval for the U.S. Food and Drug Administration, or FDA, to begin marketing ATryn® in the United States in HD patients undergoing surgery or childbirth. In September 2007, the FDA designated ATryn® as a "fast track product" and gave permission for a rolling BLA submission, where sections are submitted as they are completed. The FDA has also designated ATryn® an Orphan Drug, providing seven years of market exclusivity and waiver of the BLA submission fee.

We intend to commercially develop ATryn® in the U.S. either ourselves or with a partner. We estimate the market opportunity for DIC alone in the US is approximately \$2 -3 billion annually. We plan to develop ATryn® in Japan and the rest of the world through partnerships for one or more acquired antithrombin deficiency indications.

- **rhFVIIa:** We are developing a recombinant human coagulation factor VIIa, or rhFVIIa, a blood protein for the treatment of hemophilia as our first program in our strategic collaboration with LFB. We have begun developing the production system for rhFVIIa and we anticipate initiating clinical studies within two years to evaluate our rhFVIIa in treating hemophiliacs who have developed inhibitors to coagulation factors VIII or IX. An existing rhFVIIa product, marketed as NovoSeven® by Novo Nordisk, is commercially available today at a selling price of approximately \$1,000/mg. An independent analyst estimates that the total annual market size for NovoSeven® could be \$2 billion in five years. We believe our rhFVIIa product will cost less to produce and offer attractive profit margins at a lower selling price, which in turn may expand patient usage and broaden geographic distribution.

- **rhFIX:** In late 2007, we obtained a license from ProGenetics, LLC, granting exclusive rights in North America, Europe and Japan to commercially develop recombinant human factor IX, or rhFIX, a blood coagulation factor for the treatment of type B hemophilia. ProGenetics is responsible for the production of rhFIX in the milk of transgenic pigs. GTC is responsible for developing the downstream processing, conducting clinical programs and managing regulatory requirements. This program is now being developed as part of GTC's strategic collaboration with LFB.
- **rhAAT:** We have developed goats that produce a recombinant form of human alpha-1 antitrypsin, or rhAAT, an inhibitor of elastase. Scientists believe that uninhibited elastase activity in the lungs may be the cause of emphysema and several other respiratory disorders. Patients with hereditary deficiency of alpha-1 antitrypsin are likely to experience declining lung function throughout their lives. The genetic defect leading to hereditary deficiency is estimated to exist in over 3 million people worldwide, although the deficiency is significantly under-diagnosed and under-treated. If shown to be safe and efficacious, successful treatment will require chronic dosing. There are also potential therapeutic applications in other respiratory disorders such as chronic obstructive pulmonary disease. LFB has a first option to add rhAAT to the collaboration with us, which means that we cannot enter into an agreement with a third party with respect to this program without first offering to include it in the collaboration. Our intention is to offer rhAAT to the collaboration. Further commercial agreements with third parties could be pursued within the scope of the Joint Development and Commercialization Agreement between us and LFB.

Follow-on Biologics

We believe production of monoclonal antibodies, or MABs, using our transgenic production technology has economic advantages in large scale production compared to mammalian cell culture, including significantly lower capital investment and lower cost of goods. We are targeting several therapeutic MAB's which in total had worldwide sales of more than \$23 billion in 2006. Expiration of the patents for the first generation of therapeutic MAB's and the antibody-like proteins begin to expire in 2013, creating a significant opportunity for companies that are capable of producing biosimilar versions of the innovator products, which are also known as follow-on biologics. This market opportunity combines relatively low scientific risk with high returns from sales in large, established markets. Legislation to enable the approval of follow-on biologics by the FDA is currently under consideration by Congress. Our plan is to develop a portfolio of 4 to 5 MABs as potential follow-on biologics which have patents expiring from 2013 onwards. The first of these is a CD20 MAB produced transgenically, which we are developing in collaboration with LFB. We are seeking partnerships to support the development and commercialization of other follow-on MAB's.

- **CD20 MAB:** We are developing a MAB to the CD20 immune system receptor, which initiates an immune response, as a potential follow-on biologic. The resulting product is expected to have target specificity similar to Rituximab (Rituxan[®], Mabthera[®]) and to have a relatively higher immune response in which antibodies, by coating target cells, makes them vulnerable to attack by immune cells, this is known as Antibody Dependent Cell-mediated Cytotoxicity, or ADCC. Rituximab[®] is used as a single-agent treatment for relapsed or refractory indolent Non-Hodgkin Lymphoma, or NHL, and also in combination with chemotherapy for the treatment of aggressive NHL. Rituximab[®] has also received marketing approval in both the EU and the U.S. for indications in rheumatoid arthritis and is in trials for uses in Lupus and in Chronic Lymphocytic Leukemia and several auto-immune disorders. Sales of Rituximab[®] were \$3.9 billion in 2006.

External Programs

In addition to our proprietary programs, we have programs in which our collaboration partner owns the underlying product rights and we are producing the product through our transgenic technology. We refer to these as our external programs.

- **PharmAthene, Inc.:** We have provided PharmAthene, Inc. a license to our broad patent for the production of Protexia® in transgenic goats. Protexia® is a recombinant form of butylcholinesterase that is being developed by PharmAthene as a pre- and post-exposure therapy for casualties on the battlefield or civilian victims of nerve agent attacks. We are developing the downstream manufacturing and purification process under a development contract for this product. We are also manufacturing product for preclinical and clinical studies. PharmAthene's development of Protexia® as a biodefense product is funded by the United States Department of Defense, or DOD.
- **Merrimack Pharmaceuticals, Inc.:** Under a contract with Merrimack Pharmaceuticals, Inc. we produce in transgenic goats Merrimack's recombinant human alpha-fetoprotein, known as MM-093. This human plasma protein has been difficult to express in traditional recombinant protein production systems and is not available in significant quantities from plasma sources. Merrimack has used our transgenically produced version of MM-093 in its Phase IIb human clinical studies for rheumatoid arthritis and Phase IIa clinical studies for psoriasis.

Partnering Strategy

Until our initial product revenues grow large enough to result in positive operating cash flow, we are primarily dependent upon funding from equity financings, partnering programs and proceeds from short and long-term debt to finance our operations. With the validation of our production technology from our ATryn® approval and our broad patent in the U.S. for transgenic production in animal milk, our strategy is to seek partnering arrangements to expand the number of proprietary programs and support additional indications and territories for our existing programs.

Proprietary Product Programs

ATryn® (Recombinant Human Antithrombin)

Antithrombin is a protein found in the plasma of human blood that has anticoagulant and anti-inflammatory properties. Antithrombin, as is typical of many plasma proteins, is difficult to express in commercially viable quantities using traditional recombinant production methods. Scientists estimate that approximately 1 in 5,000 people has HD, which suggests that approximately 60,000 people in the U.S. and approximately 80,000 people in Europe have HD.

Patients with HD have low levels of antithrombin in their blood stream and are prone to develop thromboses spontaneously from puberty onwards. Once patients are aware that they have this disorder, they can normally be treated prophylactically with blood thinners such as warfarin or Coumadin®. The preferred course of treatment for HD patients undergoing high risk procedures is to take them off their blood thinners and bring their antithrombin to normal levels in order to prevent the occurrence of thromboembolisms during the course of such procedures. The use of antithrombin therefore is an acute treatment for this chronic disorder.

We have developed our transgenically produced recombinant form of antithrombin, known as ATryn®, which was approved for marketing in the EU by the European Commission in August 2006. We have completed enrollment in the pivotal trial for U.S. regulatory approval of ATryn® for HD patients undergoing surgery or childbirth. All patients recruited into the U.S. study were required to have had a previous thrombotic occurrence and therefore were considered to be high risk patients in these procedures. The results of this study are being compared with data collected from patients who have been treated previously with plasma-sourced antithrombin in similar procedures to demonstrate non-inferiority of ATryn®. The primary endpoint was the prevention of clinically significant deep vein thromboses or other thromboembolisms during high risk procedures in HD patients. In February 2008, we announced that ATryn® had met the statistical requirements for the primary endpoint in our pivotal trial to support our filing of a BLA in the United States. We have filed initial sections of our BLA seeking approval of the FDA to begin marketing ATryn® in the U.S. for a similar indication in HD patients undergoing surgery or childbirth. We plan to submit the last section of the BLA in 2008. In September 2007, the FDA designated ATryn® as a "fast track product" and gave permission for a rolling BLA submission, where sections are submitted as they are completed. The FDA also designated ATryn® an Orphan Drug, providing seven years of market exclusivity and waiver of submission fee.

We have a collaboration agreement with LEO for further development of ATryn® in Europe, Canada, and the Middle East for use in acquired antithrombin deficiencies, or AD, such as in DIC associated with severe sepsis. These deficiencies result when a medical condition leads to consumption or loss of native antithrombin in a patient's bloodstream at a rate significantly in excess of the body's ability to replace it. The AD may lead to subsequent complications that increase patient risk for morbidity. Other examples of AD conditions include severe burns, coronary artery bypass surgery, and bone marrow transplant procedures. LEO is a well established, vertically integrated private pharmaceutical company based in Denmark. LEO has selected DIC associated with severe sepsis as the first acquired antithrombin deficiency indication in which to conduct additional clinical studies. In DIC, the septic infection consumes the patient's native antithrombin faster than the body can replace it leading to clotting and inflammation problems that can cause death. Of the approximately 220,000 patients in the European Union and 250,000 patients in the U.S. with DIC in severe sepsis annually, approximately 50% die from the condition. We estimate that the annual market opportunity for DIC in the US alone is \$2 - 3 billion.

A subgroup analysis performed on a previous large study of plasma derived antithrombin in sepsis by Aventis showed a significant reduction in mortality for those patients who received antithrombin without concomitant heparin, an anticoagulant that is often used as part of the current standard of care for acute care patients. The patients who received both antithrombin and heparin did not show a survival benefit. LEO obtained scientific advice from the EMEA for a dose ranging Phase II study of antithrombin as a treatment for DIC in severe sepsis without the use of heparin. LEO has commenced recruitment into this study, which involves a comparison of the use of antithrombin alone against standard of care to establish optimum dosage for a subsequent Phase III study. In our collaboration with LEO we continue to be responsible for the production of ATryn® for which we receive payment. LEO will pay us a royalty on all commercial sales, as well as a transfer price for the supply of product. LEO pays us for all product used in clinical studies, based on our fully burdened costs subject to a maximum transfer price and is responsible for all other clinical study costs for approval in Europe. We will have the right to use all data generated from all studies up through the completion of Phase II trials in regulatory filings in territories outside of LEO's territories. We will be able to use the results of any Phase III studies in regulatory filings made outside the LEO territories if we participate in funding the Phase III studies. If we do not help fund the Phase III studies, we will also have the option to pay to use the data at a price to be determined.

Our strategy is to leverage the availability of ATryn® with easily scalable production capacity to support the development of additional clinical indications and the creation of markets significantly in excess of those supported by today's plasma-sourced products. We also plan to seek approval for acquired deficiency indications in the U.S. We intend to commercially develop ATryn® in the U.S. either ourselves or with a partner. We plan to develop ATryn® in Japan and the rest of the world through further partnerships.

We estimate that the existing worldwide annual sales for plasma-sourced antithrombin is approximately \$250 million, split principally between Japan and Europe with \$12 - \$15 million being sold in the U.S. from a single supplier. Historically there has been limited availability of plasma derived antithrombin in the U.S. and this product has not been developed in the broader acquired deficiency indications. Antithrombin products from European sourced plasma cannot be sold in the U.S.

Recombinant Factor VIIa (rhFVIIa)

We are developing rhFVIIa as the first program under our strategic collaboration with LFB to develop recombinant human plasma proteins and MAB's.

Factor VIIa is used in treating Type A and Type B hemophilia patients that have developed inhibitors to other blood coagulation products. Type A hemophilia is a genetic deficiency in the production of factor VIII. Type B hemophilia is a genetic deficiency in the production of factor IX. Both factors VIII and IX are involved in the body's production of blood clots. A deficiency in either factor can prevent normal blood coagulation resulting in abnormal and spontaneous bleeding. Patients develop inhibitors when their immune system incorrectly recognizes supplemental factors VIII or IX as foreign and generates antibodies to impede them. Providing supplemental factor VIIa, which is already present in blood, reduces the likelihood of initiating an immune

response and enables the formation of blood clots even with the existing factor VIII or IX deficiency. This is the indication that is anticipated to be developed initially. There are also potential indications of excessive bleeding where a factor VIIa product may have therapeutic value in establishing an effective blood clot.

Novo Nordisk, which sells a recombinant factor VIIa, has disclosed that sales of NovoSeven® were \$1.1 billion for 2007. An independent financial analyst report from Lehman Brothers has estimated that the annual market for rhVIIa may reach \$2 billion in 2012. Our transgenic production technology may support the pricing of our rhFVIIa at levels which would enable utilization in a broader range of indications and geographical territories.

The research program for rhFVIIa was initiated by LFB approximately four years ago. Under our collaboration, we will be responsible for developing a transgenic production system and will retain exclusive commercial rights in North America for all products developed in the collaboration. LFB will be responsible for clinical development and regulatory review of the rhFVIIa program and will have exclusive commercial rights in Europe. GTC and LFB will have co-exclusive commercial rights to all products of the collaboration in the rest of the world. The collaboration anticipates an equal sharing of costs and profits.

We anticipate an IND for rhFVIIa to be filed to initiate clinical development within the next two years.

Recombinant Factor IX (rhFIX)

In late 2007, we obtained a license from ProGenetics, LLC, granting exclusive rights in North America, Europe and Japan to commercially develop recombinant human factor IX, or rhFIX, a blood coagulation factor for the treatment of type B hemophilia. ProGenetics is responsible for the production of rhFIX in the milk of transgenic pigs. GTC is responsible for developing the downstream processing, conducting clinical programs and managing regulatory requirements. This program is now being developed as part of GTC's strategic collaboration with LFB. We also obtained exclusive rights from ProGenetics to commercially develop recombinant human factor VIII, a blood coagulation factor for the treatment of type A hemophilia, as well as fibrinogen, a component of blood clots. These two programs are not in commercial development at this time.

We anticipate an IND for rhFIX to be filed to initiate clinical development within the next two years.

Recombinant Alpha-1 Antitrypsin (rhAAT)

Alpha-1 antitrypsin, or AAT, is currently used to treat the congenital deficiency of this protein which can lead to emphysema. AAT supplementation using pulmonary delivery has also been considered as a therapeutic approach as a treatment for acute respiratory distress syndrome, chronic obstructive pulmonary disease, severe asthma and cystic fibrosis. Similar to many other plasma proteins, AAT is difficult to express in traditional recombinant production systems in economically viable quantities. Like antithrombin, AAT is a product that is currently sourced from fractionated human plasma.

We have begun development of a recombinant form of AAT, or rhAAT. We believe that we can provide a highly pure and unconstrained supply of rhAAT to the market using goats we have developed that produce it in significant quantities. We have also developed a bench scale purification process and are in the process of defining the clinical and regulatory program for this product, initially as an injected treatment of the congenital deficiency. Our goal over the next 18 months is to develop a preclinical program that will support initiation of clinical studies and to determine the partnership opportunities available for further development. The level and speed of development of this product will be dependent upon our financial resources and partnering opportunities. Under our collaboration agreement, LFB has been granted a right of first negotiation to partner with us for the development of rhAAT.

We estimate that plasma-sourced AAT products currently generate worldwide annual sales of approximately \$400 million. Similar to our other recombinant plasma protein programs, we believe the market for our product may be expanded significantly beyond the market for the current plasma-derived products as a result of its unconstrained production capacity. We also see further opportunities for multiple indications subject to the development of pulmonary delivery systems.

Follow-on Biologics or Biosimilars

We believe that the cost and large scale supply advantages of our transgenic production technology are ideally suited to developing cost-effective follow-on biologics, particularly MAb's that no longer have patent protection. MAbs are proteins that are generated by an immune system and bind to a specific target. MAbs typically express at reasonable levels in traditional recombinant production systems, but are often required in large quantities for their use in chronic disease indications. The patents for the first generation of therapeutic MAb's and other antibody-like proteins begin to expire in 2013, creating a significant opportunity for companies that are capable of producing biosimilar versions of the innovator products. The regulatory path for biosimilar products following patent expiration has been defined in Europe and the U.S. Congress is considering similar legislation. We anticipate that each follow-on product will generally require some level of clinical study, although not necessarily as extensive as that performed for the innovator antibody.

In addition, we believe that the glycosylation characteristics of MAb's produced in our transgenic system provide a more potent treatment for the targeting of tumor cells. Glycosylation refers to the natural process of adding sugars, or carbohydrates, to particular amino acids in the structure of a protein during secretion. We have shown that the glycosylation of our transgenically produced antibodies generates enhanced tumor cell toxicity through a process known as Antibody Dependent Cell-mediated Cytotoxicity, or ADCC, in which antibodies, by coating target cells, make them vulnerable to attack by immune cells. Enhanced cell toxicity may provide clinical advantages compared to the innovator product.

We have been granted several patents covering the production of MAbs in the milk of transgenic mammals, along with other transgenic process patents, which we believe establish a strong proprietary position in the field. This intellectual property position enables development and commercial production of MAbs without relying on patents normally associated with cell culture and bacterial production technologies.

The level and speed of development of follow-on biologics will be dependent upon our financial resources and new partnering arrangements as well as progress made in the legislative process.

CD20 Follow-On Antibody

Under our collaboration with LFB, we are developing a MAb to the CD20 immune system receptor which we anticipate will be a follow-on biologic. The resulting product is expected to have target specificity similar to Rituximab (Rituxan[®], Mabthera[®]). The existing relevant CD20 MAb patents will expire by 2014. Rituximab is used in the treatment of B-cell non-Hodgkin's lymphoma, B-cell leukemia and rheumatoid arthritis. It is also under investigation for a range of auto-immune conditions such as systemic lupus erythematosus, immune thrombocytopenic purpura (ITP), and type-1 diabetes. Rituximab had worldwide sales of nearly \$4 billion in 2006.

Other Programs

CD137 Antibody

We have developed animals that produce an antibody to CD137, also known as 4-1BB receptor, which is present on T-cells of the human immune system as well as some cancer cells. Our CD137 antibody may have therapeutic value primarily through the modulation of the immune system. As a result, we believe it has potential for use in multiple clinical applications including cancer and autoimmune diseases. We anticipate that the potential quantities of our CD137 antibody required for future treatment could be very large. We believe that the increase in production capacity necessary to merit this anticipated demand for a CD137 antibody can be achieved more economically by using our transgenic production technology rather than traditional cell culture and bacteria production methods.

We have obtained our patent rights to the CD137 antibody from the Mayo Clinic. These rights extend to any patents issued under its patent applications. The level and speed of development of a CD137 antibody product will be dependent upon our financial resources and our ability to partner this program. This program is currently funded by a Small Business Innovation Research, or SBIR, grant. Our initial goal, subject to financial resources, is to define the preclinical program to support the initiation of clinical studies and to seek a partner.

External Programs

Our external programs are ones in which the partner owns the underlying product rights. We believe that the advantages to an external partner of using our transgenic production technology include enabling the development of proteins that are difficult to produce in traditional recombinant production systems, requiring significantly lower capital investment, assuring lower cost of goods, and providing for flexibility in production capacity expansion. To date, we have typically developed a transgenically produced version of an external partner's protein on a service contract basis.

PharmAthene, Inc.

We entered a license and services agreement with PharmAthene, Inc. for their Protexia® product. Protexia® is a recombinant form of human butylcholinesterase produced by PharmAthene in the milk of their transgenic goats. PharmAthene is developing Protexia® as a pre- and post-exposure therapy for military or civilian victims of a chemical nerve agent attack. The development of Protexia® is funded by the DOD. The agreement includes rights to utilize GTC's transgenic technology in the worldwide development and commercialization of Protexia® for all uses. GTC is providing PharmAthene clinical supply and manufacturing services for Protexia®.

Merrimack Pharmaceuticals, Inc.

We are working with Merrimack Pharmaceuticals on their MM-093 product, a recombinant form of human alpha-fetoprotein, or rhAFP. Alpha-fetoprotein is a human plasma protein normally produced during pregnancy and, therefore, is not commercially available from human plasma. MM-093 has been difficult to express in traditional recombinant systems. We have developed goats for Merrimack that express this protein in their milk and we have successfully produced MM-093 for Merrimack's clinical trials. If MM-093 is found to be safe and efficacious in Merrimack's clinical program, there is a potential for us to earn significant additional revenue for production of MM-093 to supply further clinical trials and product for commercialization. We also own 661,726 shares of Merrimack preferred stock that were valued at \$1.25 million when issued in December 2003 in partial payment for services we had provided.

Transgenic Production Technology

Overview

Applying our transgenic production technology, we insert human protein-specific DNA into the genetic structure of an animal to enable it to produce what is known as a recombinant form of the corresponding human protein in the animal's milk. We then purify the protein from the milk to obtain the therapeutic product, which is typically administered to patients by injection. Our transgenic technology is protected by our leading patent position, which includes a U.S. patent, issued in 2006 and expiring in 2021, that covers the production of all therapeutic proteins in the milk of transgenic mammals.

Our transgenic production technology capabilities include the molecular biology expertise and intellectual property to generate transgenic animals, primarily goats, and, in some cases, rabbits, pigs, and cattle, that express a specific recombinant protein in their milk and to collect and purify the proteins once produced. We also have the necessary regulatory and clinical development experience required to navigate clinical trials and engage in commercial activities.

Our technology is well suited to large volume applications, particularly 100 kilograms or more per year, in comparison to traditional recombinant protein production systems. These advantages include significantly reduced capital expenditures, greater flexibility in expanding production capacity and lower unit production costs. In the case of certain complex proteins that do not express well in traditional systems, transgenic production may represent the only technologically and economically feasible method of commercial production. Many human plasma proteins are examples of recombinant proteins that may not express at economically viable levels in traditional systems.

We conduct our husbandry, breeding, milking and initial purification operations at our production facilities in central Massachusetts, where we have approximately 1,500 goats in a closed herd. Our goat husbandry operations include providing on site veterinary care. We have a biosecurity program that controls access to our site and includes barriers to provide separation of our animals from wildlife and the public. We also specify and carefully monitor feed quality. Milking is typically performed using modern milking and processing equipment. Filtration and purification are performed at our facilities, the facilities of our partners, or in contracted facilities. We have also established capacity in our Framingham, Massachusetts facilities for the purification of recombinant proteins suitable for clinical studies.

While we have both the technical capability and the patent protection to work with a wide range of mammals, we typically utilize goats in our development programs. The species selected for a particular program will depend on a variety of factors, including the expected market size, desired herd size, and anticipated production level of the desired protein by the animal's mammary gland. We take great pride in the health and welfare of our animals. Our animal operations are subject to the review of our Institutional Animal Care and Use Committee and are accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care International, or AAALAC, and we are registered with the U.S. Department of Agriculture, or USDA and the Office of Laboratory Animal Welfare of the National Institutes of Health, or OLAW.

We use microinjection and nuclear transfer technology to develop our transgenic animals. Microinjection involves injecting the desired DNA into a fertilized single cell embryo using a needle. In a number of our programs, including our lead program, ATryn®, we used microinjection to generate the initial transgenic animal, which we refer to as the founder animal. Nuclear transfer technology involves generating cells that have the specific DNA for expression of the target protein in milk and inserting the cell's DNA in an animal's ovum in place of the ovum's DNA. Once the ovum is activated, the embryo is implanted in the womb of a surrogate female animal. Nuclear transfer technology may offer rapid development of large scale production capacity by producing a larger number of transgenic animals in one generation.

Advantages of Transgenic Production Technology

We believe our transgenic production technology provides significant advantages over traditional recombinant methods of therapeutic protein production, such as mammalian cell culture and bacterial systems, including:

- ***Commercial Scale Production.*** Transgenic production offers the ability to commercially produce therapeutic proteins for large volume indications while achieving consistent expression rates with complex molecules.
- ***Lower Capital Investment.*** Developing transgenic animals and maintaining appropriate production facilities can be accomplished with substantially lower capital investment than building a cell culture bioreactor production facility.
- ***Lower Cost of Goods.*** Lower amortization from reduced capital investment, lower cost of consumable materials used in production and high productivity levels in protein production we believe will provide an assured lower cost of goods.
- ***Flexible Production Capacity.*** Transgenic production of recombinant proteins offers the ability to match production capacity to market demand once the first applicable transgenic animal is developed. If a product's market is larger than originally planned, the incremental investment to breed additional animals and collect and purify the related proteins is relatively small. In contrast, increasing production capacity of traditional cell culture and bacteria production networks requires the construction or acquisition of additional bioreactor space with unit costs similar to the original capital investment and with typical construction times of three to five years.

- *Glycosylation and ADCC Benefits.* Glycosylation refers to the process or result of adding sugars, or carbohydrates, to the amino acid structure of a protein during protein secretion. Glycosylation of therapeutic proteins produced in the mammary gland may have beneficial characteristics compared to those expressed in traditional cell culture and bacteria based technologies. Our production technology in many instances produces proteins with low fucose sugars which scientists believe can create enhanced cell toxicity, also known as Antibody Dependent Cell-mediated Cytotoxicity, or ADCC, in which there is an immune response whereby antibodies, by coating target cells, makes them vulnerable to attack by immune cells. ADCC appears to be an important characteristic in the efficacy of many MAb's where targeted cell death is a desired outcome.

Collaborations

LEO Pharma

In November 2005, we entered into a collaboration agreement with LEO to develop and market ATryn[®], for markets in LEO's territories of Europe, the Middle East, and Canada. Our agreement with LEO includes up to \$73 million in potential milestone payments from LEO to us for meeting regulatory, clinical and sales goals. These payments include a total of \$5 million in non-refundable payments that we received upon entering the collaboration agreement and for achieving approval of ATryn[®] for the HD indication in Europe.

In our collaboration with LEO we are responsible for the production of ATryn[®]. We will supply the product for clinical studies and receive payment for delivery of material to LEO. We will also supply the product for commercial sales and LEO will pay us a transfer price and royalties on sales of ATryn[®]. We are paid by LEO for clinical material based on our fully burdened costs subject to a maximum price per unit, which is currently less than our costs to produce the material. LEO has exclusive rights for sales and marketing of ATryn[®] in all indications in LEO's territories. We retain all rights to ATryn[®] in all other territories, including the United States and Japan.

LFB Biotechnologies

In September 2006, we entered into a collaboration agreement with LFB to develop selected recombinant plasma proteins and MAb's using our transgenic production platform. LFB is a subsidiary of LFB S.A., a vertically integrated plasma fractionation company based in Paris, France that currently markets 19 plasma-derived products in the areas of hemostasis, anesthesia-intensive care and immunology. LFB S.A. is a for-profit company currently 100% owned by the French government. The first program in this collaboration is for the development of rhFVIIa. We have subsequently added to the LFB collaboration a program to develop a recombinant form of human factor IX as well as a program to develop an antibody to the CD20 immune system receptor. Under this agreement, we will share equally with LFB in the cost of the development and commercialization of each product and will be entitled to 50% of any profits derived from products developed through the collaboration provided we each contribute equally to the costs of their development. In the event that contributions to development are not equal, the profit allocation will be adjusted based on development costs incurred. Under the agreement, a joint steering committee of each company's representatives will determine product development and commercialization plans. We will be responsible for development of the production system for the products and will retain exclusive commercial rights to the products in North America. LFB will be responsible for clinical development and regulatory review of the programs in this collaboration, and will have exclusive commercial rights in Europe. We will hold co-exclusive rights with LFB in the rest of the world to any products developed through the collaboration. The initial term of the agreement is fifteen years, subject to extension or termination by mutual consent, and the terms for any product developed through the collaboration will continue until the later of the initial term or ten years beyond regulatory approval of that product.

Also in September 2006, LFB agreed to purchase \$25 million of our securities (see Note 3 to the Notes to Consolidated Financial Statements included in Item 8 of this Report). LFB's equity ownership is limited to a maximum of 19.9% of our common stock outstanding.

Patents and Proprietary Rights

We currently hold 23 issued or allowed U.S. patents and 180 corresponding foreign patents. We have received a U.S. patent, with claim coverage for the production of therapeutic proteins in the mammary glands of transgenic mammals. This patent has an expiration date of 2021. Our other patents generally expire between 2008 and 2023. In accordance with ongoing research and development efforts, we have 40 pending U.S. patent applications and 116 corresponding foreign applications covering relevant and newly developed portions of our transgenic technology. Several of these pending applications are included in various cross-licensing or out-licensing arrangements with other companies that in turn provide us access to their proprietary technologies. We have granted limited access to our technology to Pharming Group, N.V., or Pharming, and to PharmAthene, Inc. Recently issued U.S. patents provide us with claim coverage for protein purification from the milk of transgenic animals, the production of monoclonal and assembled antibodies at commercial levels in the milk of transgenic mammals, the production of recombinant antithrombin in the milk of transgenic goats and the production of prolactin in the milk of transgenic animals.

In addition, we hold exclusive and non-exclusive licenses from Genzyme Corporation, Biogen-Idec, Inc., and other individuals and corporations to rights under a number of issued patents and patent applications in the U.S. and the corresponding cases abroad for a variety of technologies enabling the transgenic production of proteins in the milk of non-human animals. We hold licenses to 23 issued U.S. patents and 40 pending U.S. applications. On an international basis, we hold licenses to 180 issued patents and have 116 pending applications. Our principal in-licensed intellectual property surrounding our microinjection technology expired at the end of 2006, after which no royalties or other payments are due to the licensor. However, we will continue to have freedom to practice microinjection.

We have exclusive and nonexclusive licenses to specific technologies owned by other parties. Some of the licenses require us to pay royalties on sales of products which may be derived from or produced using the licensed technology. These licenses generally extend for the life of any applicable patent. We have concluded an extensive cross-licensing arrangement with Pharming providing broad access to the transgenic cattle platform as well as some additional nuclear transfer technology. We have also obtained a non-exclusive license to nuclear transfer technology from Start Licensing Inc.

We obtained a license from ProGenetics, LLC, granting exclusive rights for North America, Europe and Japan to commercially develop recombinant human factor VIII, recombinant human factor IX, and recombinant human fibrinogen. We granted ProGenetics a non-exclusive license to our patent for the transgenic expression of therapeutic proteins in milk in the United States to enable the commercial development of these products outside of our territories of North America, Europe and Japan.

We rely upon certain proprietary trade secrets, know-how and continuing technological advances to develop and maintain our competitive position. In an effort to maintain the confidentiality and ownership of trade secrets and proprietary information, we generally require employees, consultants and collaborators to execute confidentiality and invention assignment agreements upon commencement of a relationship with us.

Competition

Competition in the biotechnology and pharmaceutical industries is intense and comes from many and varied sources. We experience significant competition from specialized biotechnology firms and large pharmaceutical companies in the U.S., Europe and elsewhere. Some of our competitors have substantially greater financial, marketing, research and development and human resources than we have. Most large pharmaceutical and biotechnology companies have considerable experience in undertaking clinical trials and in obtaining regulatory approval to market pharmaceutical products. In addition to company and industry level competition, our proprietary programs face particular competitive challenges.

Competition for our lead product candidate ATryn® comes from a number of companies internationally producing and marketing human antithrombin sourced from the fractionation of human plasma. CSL Behring's antithrombin has a significant share of this market worldwide, but is not approved in the U.S. Talecris BioTherapeutics, or Talecris, is the only company that has commercially available fractionated antithrombin that is approved for sale

in the U.S. Talecris' U.S. sales are a small portion of the worldwide antithrombin market. There are a number of providers of plasma-derived antithrombin in Europe, including Octopharma, Grifols, Baxter International, Pfizer, Inc., CSL Behring, LFB, Kedrion and BioProducts Laboratory. A Grifols plasma-derived antithrombin product is in clinical studies to support a planned request for approval with the FDA.

Asahi Kasei Pharma Corporation has developed ART-123, a soluble human recombinant thrombomodulin, which binds thrombin and serves as a factor in the body's regulation of blood coagulation. ART-123 has recently been approved in Japan for the treatment of DIC. Artisan is developing ART-123 in the U.S. and the EU and has recently initiated an 800-patient Phase 2b trial in DIC in the U.S.

In 2007 Talecris had approximately \$225 million of worldwide sales of its plasma sourced alpha-1 antitrypsin product, Prolastin®. Including the sales of a number of other providers of plasma-sourced alpha-1 antitrypsin, Talecris estimates that 2007 worldwide sales for treatment of AAT deficiency were approximately \$400 million.

Novo Nordisk is the manufacturer of the only available recombinant form of factor VIIa, NovoSeven®, which is approved for the treatment of hemophilia patients with inhibitors to factors VIII and IX. There are insignificant sales of various plasma-derived factor VIIa products for the treatment of these hemophilia patients. The NovoSeven® patents expire in 2012.

There are many companies, including biotechnology and pharmaceutical companies, which are actively engaged in seeking efficient methods of producing proteins for therapeutic applications. These include companies that are developing transgenic technology using various mammalian, plant and avian systems, as well as many companies that are building their own cell-culture-based production systems or other recombinant protein production methods, and contract manufacturers who are using those systems to produce proteins for others. Any of these companies could become competitors in the development of follow-on biologics.

Government Regulation

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

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. We believe that our programs satisfactorily address the topics identified in these documents and generally view these publications as positive milestones in the acceptance of the transgenic form of production. Nonetheless, obtaining further regulatory approvals for our transgenically produced products may take several years to complete and is expensive and uncertain. To our knowledge, no therapeutic protein produced in the milk of a transgenic animal, other than ATryn®, has been submitted to the FDA for final regulatory approval or to any other regulatory agency outside of Europe for final regulatory approval.

Legal requirements for the investigation and commercialization of drug products and medical devices are set forth in the Federal Food, Drug and Cosmetic Act and regulations issued thereunder. While similar in many respects, legal requirements for the development and licensure of biological products, including transgenic products, are set forth in the Public Health Service Act, or PHSA, and regulations issued under that statute. As with drug products, these regulations require FDA approval prior to marketing. This approval is based on the manufacturer's demonstration that the product is safe and effective for its labeled or indicated uses. The demonstration of safety and efficacy, is subject to a thorough review by FDA and consists of both preclinical laboratory and animal studies, which must demonstrate that the drug or biological product is sufficiently safe to be tested in humans, and extensive human clinical trials, which establish the product's safety and efficacy in humans at the doses it will be administered and for the uses for which it will be labeled and marketed. This testing is both lengthy and expensive, and its outcome is frequently uncertain. In general, following testing in animals to establish that the drug is sufficiently safe for human testing, manufacturers apply for permission to

study the drug in humans through the filing of an IND application which contains both the results of the animal testing as well as the plan or protocol for testing the drug in humans. Testing in humans usually encompasses three phases (I, II and III). Phase I studies, frequently conducted in healthy subjects, establish preliminary safety and kinetics in humans; Phase II studies are usually controlled and provide preliminary findings of efficacy and safety, while Phase III studies consist of much larger controlled trials and are used to establish the necessary proof of efficacy to support marketing. All testing in humans is subject to FDA oversight, and may be suspended or delayed if the agency determines that subjects may experience any unanticipated or unreasonable risks.

Following a manufacturer's conclusion of the testing paradigm, the details of which may differ depending on the type of drug, the medical need for it, and the seriousness of the condition it is intended to treat, the data are compiled by the manufacturer into either a New Drug Application, or NDA, for new drugs, or a BLA for biological products, in accordance with the classification for the molecule determined by the FDA, and submitted for review. In addition, manufacturers are required to include extensive data regarding the composition and manufacture of the product to assure its purity, potency and quality. The FDA may request additional information or data from the manufacturer, and following its review will either approve or disapprove the application. As part of a decision to approve the drug, the FDA will approve product labeling, setting forth the use or uses which have been shown to be safe and efficacious, summaries of the clinical studies, dosing information, and extensive information presented hierarchically about potential risks. It may also require further testing as a condition of approval (referred to as Phase IV) as well as inform the manufacturer of certain limitations it believes are appropriate for product promotion. The approval process is comparable in Western Europe and other modern countries, such as Japan, with respect to the need for both safety and efficacy to be demonstrated through rigorous clinical trials.

Following marketing approval, the FDA continues to regulate drug and biological products extensively. Manufacturers are required to supply the agency with reports of all adverse events submitted to them, to report product defects, to submit to routine facility inspections, and to notify the agency of any planned product changes, many of which may also require prior approval. The failure to meet continuing regulatory requirements can result in administrative and legal sanctions, such as products recalls, requests to issue new information to medical practitioners, and in severe cases, product withdrawals, seizures, injunctions, and criminal prosecutions. All marketing is also subject to continuing FDA monitoring which, if found deficient or in violation of requirements, may result in demands for corrective measures as well as potential imposition of the same sanctions. More recently, pharmaceutical marketing violations by several companies have been subject to extensive and serious sanctions of the Food and Drug Control Administration, or FDCA, the Medicare/Medicaid anti-kickback legislation and the False Claims Act by the federal and various state attorneys general and the Health and Human Services Office of Inspector General, including the imposition of both civil and criminal fines, the application of corporate integrity agreements, and in the most serious cases, potential disqualification from providing product to the agencies of the federal government.

Research and Development Costs

During 2007, 2006 and 2005, we incurred development expenses of \$28.9 million, \$25.4 million and \$21.1 million, respectively, including preclinical and clinical development expenses related to our proprietary programs. Of the total spent on research and development, \$20.5 million, \$20.3 million and \$12.6 million, was for costs spent on the ATryn[®] development program in fiscal years 2007, 2006 and 2005, respectively, which included manufacturing costs for our U.S. clinical trial, manufacturing costs of clinical material in excess of the maximum selling price to LEO as well as process development and validation costs for scale up of the ATryn[®] manufacturing process. These costs include labor, materials, supplies and overhead, as well as certain subcontracted service costs. Also included are the costs of operating the transgenic production facility such as feed and bedding, veterinary costs and utilities.

Employees

As of December 30, 2007, we employed 167 people, including 11 part-time and temporary employees. Of our total employees, 88 were engaged in farm operations, clarification processes, quality assurance and control, 15 were engaged in research and development and 64 were engaged in administration, business development and marketing. Of our employees, approximately 15 have Ph.D. degrees and 3 have D.V.M. degrees. None of our employees are covered by collective bargaining agreements. We believe our employee relations are satisfactory.

Executive Officers

Our executive officers and their respective ages and positions as of March 1, 2008 are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Geoffrey F. Cox, Ph.D.	64	Chairman of the Board, President and Chief Executive Officer
John B. Green	53	Senior Vice President, Chief Financial Officer and Treasurer
Gregory F. Liposky.....	53	Senior Vice President, Operations
Harry M. Meade, Ph.D.	61	Senior Vice President, Research and Development
Richard A. Scotland.....	52	Senior Vice President, Regulatory
Daniel S. Woloshen.....	60	Senior Vice President and General Counsel

Dr. Cox was appointed Chairman of the Board, President and Chief Executive Officer in July 2001. From 1997 to 2001, Dr. Cox was Chairman and Chief Executive Officer of Aronex Pharmaceuticals, Inc., a biotechnology company. From 1984 to 1997, Dr. Cox was employed by Genzyme Corporation, where he most recently served as Executive Vice President, responsible for operations and the pharmaceutical, diagnostic and genetics business units. Prior to joining Genzyme, Dr. Cox was General Manager of the UK manufacturing operations for Gist-Brocades. Dr. Cox also serves as non-executive Chairman of the Board for Nabi Biopharmaceuticals, and serves on the Board of the Biotechnology Industry Organization and the Board of the Massachusetts Biotechnology Council. Dr. Cox received a Ph.D. in Biochemistry from the University of East Anglia U.K. and a BSc (Hons) in Biochemistry from the University of Birmingham U.K.

Mr. Green was appointed Senior Vice President in May 2002, having previously served as Vice President since 1994. Mr. Green has also served as our Chief Financial Officer since December 1994 and Treasurer since August 1997. Prior to joining us, Mr. Green was Vice President and Assistant Treasurer of TSI Corporation from December 1989 until our acquisition of TSI in 1994. Mr. Green is a Certified Public Accountant (CPA) with over 25 years of financial experience, including 18 within the biotechnology industry as Chief Financial Officer of GTC and Vice President and Assistant Treasurer for TSI Corporation. Mr. Green received a Master's degree in Business Administration from Boston University Graduate School of Management and a Bachelor's degree from the College of the Holy Cross.

Mr. Liposky was appointed Senior Vice President, Operations in May 2002, having previously served as Vice President, Operations since January 1999. Prior to joining us, Mr. Liposky served as Vice President, Contract Manufacturing for Creative Biomolecules, Inc. from 1992 through 1998 and Vice President, Bioprocessing and Operations and Projects Manager for Verax Corporation from 1987 to 1991. Mr. Liposky received his Master's degree in Business Administration from Monmouth University and a Bachelor's degree in Biology from Belmont Abbey College.

Dr. Meade was appointed Senior Vice President of Research and Development in May 2002. From 1994 to 2002, Dr. Meade was our Vice President of Transgenics Research, having served as Research Director since May 1993. Prior to joining us, Dr. Meade was a Scientific Fellow at Genzyme, where he was responsible for directing the transgenic molecular biology program. From 1981 to March 1990, Dr. Meade was a Senior Scientist at Biogen, Inc., where he helped develop the technology used for protein production in milk and was a named inventor on the first issued patent covering the related protein production process. Dr. Meade received his Ph.D. in Biology from the Massachusetts Institute of Technology and completed his post-doctoral studies at Harvard University. He holds Bachelor's degrees in Chemistry and Electrical Engineering from Union College.

Mr. Scotland joined GTC Biotherapeutics in 2002 and holds the position of Senior Vice President, Regulatory Affairs. Mr. Scotland is responsible for directing worldwide regulatory activities pertaining to the development of therapeutic proteins derived from the milk of transgenic animals. Mr. Scotland has over 25 years of regulatory affairs experience with various biotechnology and pharmaceutical companies including Serono Laboratories, Genzyme Corporation and Astra Pharmaceuticals. Mr. Scotland holds a Bachelor's degree in Biology from St. Joseph's College in North Windham, Maine.

Mr. Woloshen was appointed Senior Vice President and General Counsel in May 2002, having previously served as Vice President and General Counsel since August 1999. Prior to joining us, Mr. Woloshen served as Vice President and General Counsel of Philips Medical Systems North America from April 1989 to July 1999. Mr. Woloshen received a Juris Doctor degree from Boston College Law School and holds a Bachelor's degree from Colby College.

Available Information

Our internet website is www.gtc-bio.com and through the "Investor Information" portion of the website, investors may access, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements on Schedule 14A and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. Information on our Investor Information page and on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein by reference.

ITEM 1A. RISK FACTORS

The following are certain factors that could affect our future results. They should be considered in connection with evaluating forward-looking statements made by us because these factors could cause actual outcomes and results to differ materially from the outcomes and results as expressed in those forward-looking statements.

RISKS RELATED TO OUR BUSINESS

We expect to continue to incur significant operating losses for the next several years and we may never become profitable.

We have had operating losses since our inception, and we expect losses to continue for the next several years. From our inception in 1993 to December 30, 2007, we have incurred cumulative losses of approximately \$281 million. These losses have resulted principally from the costs of our research and development activities. Our net losses for fiscal years 2007, 2006 and 2005 have been \$36.3 million, \$35.3 million, and \$30.1 million, respectively. We expect to continue incurring significant operating losses for at least the next several years. We may never receive material revenues from product sales or become profitable.

Our current resources are only sufficient to fund our operations in the short term, which raises substantial doubt about our ability to continue as a going concern.

Based on our cash balance as of December 30, 2007, as well as potential cash receipts from existing programs and the \$5.5 million in net proceeds from our registered direct offering in February 2008, we believe our resources will be sufficient to fund operations into the second half of 2008. We have received an audit report from our independent registered public accounting firm containing an explanatory paragraph stating that our historical recurring losses from operations and limited funds raise substantial doubt about our ability to continue as a going concern. We will have to obtain additional equity or debt financing or payments from new and existing partnering collaborations, or a combination of these sources, to fund our clinical development plans through to regulatory approval, when we could begin to earn any product revenues.

We may be unable to raise the additional capital needed to develop and commercialize our product programs successfully.

As of December 30, 2007, we had \$9.1 million in cash and cash equivalents and \$6.7 million in marketable securities, which were offset by our \$18.7 million in current liabilities. Including the proceeds from our registered direct offering of common stock and warrants in February 2008, which raised approximately \$5.5 million, net of expenses, we expect our current cash resources and potential future cash payments from existing collaboration and licensing programs to be sufficient to fund operations into the second half of 2008. We will need additional capital to fund our operations, including research and development, manufacturing and commercialization. In order to develop and bring our transgenically produced products to market, we and our collaboration partners must commit substantial resources to costly and time-consuming research, preclinical testing and clinical trials. We will need additional capital to fund our operations, including our research and development, manufacturing and commercialization activities. If we do not have or cannot raise additional capital when needed, we would be forced to delay, scale back or eliminate one or more of our research and development programs.

Our drug development programs and the further development of ATryn® for approvals in the United States will require substantial additional cash to fund expenses that we will incur in connection with preclinical studies and clinical trials, regulatory review, manufacturing and sales and marketing efforts. Our cash requirements may vary materially from those now planned, depending upon the results of our research and development programs, competitive and technological advances, the terms of future collaborations, regulatory requirements and other factors. We expect we will need to obtain additional financing, through public or private sources, including debt or equity financing, in addition to any funding obtained through collaborative or other arrangements with corporate partners. Depending on the state of the capital markets, interest rates, our financial profile and other factors at that time, we may not be able to obtain adequate funds on acceptable terms when needed. If we raise capital through the sale of equity, or securities convertible into equity, existing shareholders' proportionate ownership in us will be reduced.

Our transgenically produced products may be subject to technology risks that may restrict or prevent their development and commercialization.

Developing products based on transgenic technology is subject to significant development risks. Each DNA construct is unique and it is possible that it might not be expressed in the transgenic animal's milk at a level that is commercially viable. Purifying the recombinant protein out of the milk to use as a biotherapeutic may be too difficult to be commercially feasible. In addition, production of the recombinant protein may have negative effects on the health of either the mammary gland or more systematically on the animal as a whole. This would compromise the ability of the animal to produce the recombinant protein. Directing the mammary gland to produce additional proteins in the milk could negatively affect lactation, thereby shutting down milk production. The mammary gland may also modify a protein in such a manner that it is non-functional or harmful in humans. It is also possible that there may be disease agents present in the animals that would prevent the use of products derived from these animals. If an as yet unknown disease was identified that could not be effectively mitigated, government agencies may confiscate or destroy the animals, or prevent the utilization of their milk. Any of these governmental actions would prevent the use of the recombinant proteins.

Our collaboration partners may fail to perform satisfactorily or may terminate our collaboration agreements.

We are dependent on our collaboration partners for the development and commercialization of our approved product and our lead product candidates. We do not have adequate resources to develop our products and product candidates on our own. We also have neither the experience nor capabilities to sell, market or distribute products. We currently have a collaboration agreement with LEO to develop and market ATryn® and a collaboration agreement with LFB to develop selected recombinant plasma proteins and MAb's. We also plan to enter into additional collaborations with other partners to develop and commercialize current and future products and product candidates. The performance of our collaboration partners is not within our control. For example,

- we may not be able to ensure that our collaboration partners dedicate sufficient time and resources to successfully meet their obligations under our collaboration agreements;
- disputes may arise between us and our partners that may result in the delay or termination of the development or commercialization of products or product candidates or that may subject us to costly litigation or arbitration;
- our collaboration partners may experience financial difficulties or undergo business combinations or significant changes in corporate strategy that may adversely affect their ability or willingness to meet their obligations under our collaboration agreements; and
- our collaboration partners may not adequately maintain and protect, or may improperly use, our proprietary information which could jeopardize our intellectual property rights or subject us to costly litigation or arbitration.

We depend on collaboration agreements for our current revenue.

Our revenues and business strategy depend largely on our entering into additional development and marketing agreements with third parties as well as existing agreements for our own therapeutic compounds. We may not be able to establish these agreements on commercially acceptable terms, if at all, depending on the market position of our technology and our compounds. The willingness of potential collaborators to enter into agreements with us depends on factors such as the perceived technological or economic advantages of transgenic production and our ability to structure a mutually acceptable collaboration arrangement. For existing and future development agreements, the collaborations may ultimately be unsuccessful, our partners could terminate the agreements or the agreements could expire before meaningful developmental milestones are reached. Depending upon the terms of any future collaborations, our role in the collaboration will often be limited to the production aspects of the proteins. As a result, we may also be dependent on collaborators for other aspects of the development of any transgenically produced product, including preclinical and clinical testing and regulatory approval, and marketing and distribution.

The majority of our collaborations to date have been external programs that involve proteins proprietary to our partners. Much of the continuing revenue, if any, that we may receive under these collaborations will depend upon our partners' willingness and ability to successfully develop and commercially introduce, market and sell the version of the collaborator's product derived from our transgenic production systems. Our partners may choose competitive production technologies or competitive products outside of their collaborations with us, which could have a material adverse effect on our business. The failure of any external collaboration could have a material adverse effect on our business.

We may fail to obtain the necessary regulatory approval to market and sell our transgenically produced products in the United States or in other countries.

Before we can market or sell any transgenically produced drug or biological products that we or our collaborators develop, we must receive regulatory approvals from federal, state and local governmental authorities, including the FDA and corresponding agencies in other countries, such as the European Medicines Agency, or EMEA, in Europe. We received our only regulatory approval of any of our transgenically produced products in August 2006 from the European Commission for use of ATryn[®] as a prophylactic treatment of patients with hereditary antithrombin deficiency undergoing surgical procedures. Our Marketing Authorization Application for ATryn[®] was approved by the European Commission under exceptional circumstances, meaning that the license must be renewed on an annual basis as opposed to every five years, with certain post approval obligations that must be fulfilled to maintain approval. In addition, continuing marketing authorization approval must be obtained on an annual basis. Moreover, to our knowledge, no application for final regulatory approval of any therapeutic protein produced in the milk of a transgenic animal has been submitted to the FDA, other than our own in-process application for ATryn[®]. The required regulatory approvals process for our transgenically produced products may take several years to complete and is expensive and uncertain. It is possible that the FDA or any other regulatory authority may not act quickly or favorably on our requests for approval or may require us to provide additional data that we may not have then available. For example, the FDA may impose restrictions and demands on our clinical trials that require additional resources and result in unexpected delays. In addition, the FDA may require us to conduct further clinical trials and post-marketing testing and surveillance to monitor the effects of approved products. The FDA or other regulatory authorities may also place conditions on approval that could restrict the commercial applications of such products.

Failure to comply with extensive FDA or similar regulations may result in delay, suspension or cancellation of a trial or a regulatory authority's refusal to accept test results. Regulatory authorities may have varying interpretations of our pre-clinical and clinical trial data, which could delay, limit or prevent regulatory approval or clearance. Because transgenically produced products represent novel therapeutic products, the process for regulatory approval is unproven. There may be additional delays in regulatory approval due to issues arising from the breeding of transgenic animals and the use of proteins derived from them. Any delays or difficulties in obtaining regulatory approval or clearance for transgenically produced products may:

- adversely affect the marketing of any transgenically produced products we or our collaborators develop;
- impose significant additional costs on us or our collaborators;
- diminish any competitive advantages that we or our collaborators may attain; and
- limit our ability to receive royalties and generate revenue and profits.

If we do not receive regulatory approvals for our transgenically produced products in a timely manner, we will not be able to commercialize our products, or their commercialization may be limited or delayed and, therefore, our business and stock price will suffer.

Even if we receive regulatory approval for our transgenically produced products, the FDA or similar agencies in other countries may impose limitations on the indicated uses for which our products may be marketed and sold. These limitations could reduce the size of the potential market for a product. Failure to comply with applicable FDA and other regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to renew our marketing applications and criminal prosecution.

We filed an Investigational New Drug application, or IND, with the FDA in 2003 for clinical development of ATryn® in the HD indication. In April 2005, we received authorization from the FDA to begin a further clinical trial of ATryn® under an amended version of our IND. This trial, which was completed in February 2008 when the final patient was treated, had been delayed by difficulties in identifying and recruiting patients. Further, delays in completing our current ATryn® trial data review or in obtaining FDA approval of ATryn® could cause substantial delays in the commercialization of ATryn® in the United States and adversely affect our business and stock price.

Our clinical trials of our transgenically produced products may be unsuccessful or delayed, which may prevent us from meeting our anticipated development timeline.

We and our collaborators must demonstrate through preclinical and clinical trials that our transgenically produced products are safe and effective for use in humans. Clinical trials are expensive and may take several years. Several factors could prevent or delay completion of these trials, including an inability to enroll the required number of patients or demonstrate adequately the safety or efficacy of the product for humans. If safety concerns develop, regulatory authorities could stop or delay our trials. Furthermore, the results from early clinical trials are often not predictive of results in later clinical trials.

To our knowledge, Pharming is the only other entity to have completed human clinical trials of a transgenically produced product. Until we have completed the submission of our BLA to the FDA for ATryn®, we will not have confirmation that our ATryn® trials are sufficient for approval in the United States. If we are unable to complete all clinical trials and to satisfy other requirements that may be required by the FDA, or the EMEA for expanded indications of ATryn®, or if any of our other transgenically produced proteins in development are not proved to be safe or effective to the satisfaction of regulatory authorities, it would have a material adverse effect on our business and operations.

Any transgenically produced products for which we obtain regulatory approval will be subject to continuing review and extensive regulatory requirements, which could affect their manufacture and marketing.

If and when the FDA or other foreign agencies approve any of our transgenically produced products under development, the manufacture and marketing of these products will be subject to continuing regulation and product approvals may be withdrawn if problems occur after initial approval. Post-approval regulation includes compliance with current Quality Systems Regulations and Good Manufacturing Practices, known as QSR/GMP, adverse event reporting requirements and prohibitions on promoting a product for unapproved uses. We will also be required to obtain additional approvals for any significant alterations in the product's labeling or manufacturing process. Enforcement actions resulting from failure to comply with QSR/GMP requirements could result in fines, suspensions of approvals, recalls of products, operating restrictions and criminal prosecutions, and affect the manufacture and marketing of our transgenically produced products. The FDA or other regulatory agencies

could withdraw a previously approved product from the market upon receipt of newly discovered information, including a failure to comply with regulatory requirements and the occurrence of unanticipated problems with products following approval. Any of these withdrawals could adversely affect our operating results.

We have limited manufacturing capability and may be required to rely on third party contract manufacturers to purify and formulate our transgenically produced products.

We currently have the capability to purify pre-clinical and clinical trial quantities of our transgenically produced products up to and including Phase II trials. We also rely upon third party manufacturers to purify and formulate significant pre-clinical, clinical and commercial quantities of our transgenically produced products. We depend on these third party manufacturers to perform their obligations in a timely manner and in accordance with applicable government regulations in order to conduct our clinical trials or commercialize any of our products. For example, we had to write off \$2.9 million of ATryn® inventory in 2007 which was rendered unusable as a result of the fill/finish process conducted at a U.S.-based fill/finish contractor. We have terminated our contract with that contractor and now are only using MedImmune (Holland) for these services. There are very few third party manufacturers that have sufficient production capacity to manufacture all of our products either for our clinical trials or on a commercial scale. Our third party manufacturers may encounter difficulties, including problems involving:

- inconsistent production yields;
- poor quality control and assurance or inadequate process controls;
- lack of compliance with FDA, EMEA and other regulations; and
- high production costs.

These contract manufacturers may not be able to manufacture our products at a cost or in quantities necessary to make them commercially viable. If we are unable to enter into agreements with additional manufacturers on commercially reasonable terms, or if there is poor performance on the part of our third party manufacturers, we may not be able to complete development of, or market, our transgenically produced products.

We have contracted with Cambrex Bio Science Hopkinton, recently acquired by Lonza Biologics, for large scale purification and with Medimmune (Holland) for fill/finish services of our lead product, ATryn®. Although we have identified possible alternative suppliers with respect to these services for this product, interruptions in these services and the process of changing to an alternative manufacturer could have a material adverse effect on our timely ability to manufacture bulk delivery of ATryn® for delivery to our collaborators or to market distribution after regulatory approval.

Transgenically produced products may never become commercially successful.

Even if our transgenically produced products are successfully developed and approved by the FDA and foreign regulatory agencies, they may not enjoy commercial acceptance or success, which would adversely affect our business and results of operations. Several factors could limit our success, including:

- limited market acceptance among patients, physicians, medical centers and third party payors, including acceptance of products transgenically produced from animals;
- our inability to access a sales force capable of marketing the product, either through a third party contract sales force or by establishing our own internal sales force;
- our inability to supply a sufficient amount of product to meet market demand;
- the number and relative efficacy of competitive products that may subsequently enter the market; and
- for a transgenically produced product designed to replace or supplement currently marketed non-transgenically produced products, the relative risk-benefit profile and cost-effectiveness of the transgenically produced product.

In addition, it is possible that we or our collaborative partners will be unsuccessful in developing, marketing or implementing a commercialization strategy for any transgenically produced products.

Our business may fail due to intense competition in our industry.

The industry in which we operate is highly competitive and may become even more so. Some of our competitors have greater financial and human resources and more experience in research and development than we have. We will need to continue to devote substantial efforts and expense in research and development to maintain a competitive position for our transgenic production technology and potential product offerings. It is also possible that others will develop alternative technologies or products that will render our proposed products or technologies obsolete. We may encounter significant competition for our protein development and production capabilities from other companies. In addition, our potential transgenic production capabilities may face significant competition from biological products manufactured in cell culture or by other traditional protein production methods. Our business will also compete against other companies whose business is dedicated to offering transgenic production and with prospective customers or collaborators who decide to pursue such transgenic production internally. Competitors that complete clinical trials, obtain regulatory approvals and begin commercial sales of their products before us will enjoy a significant competitive advantage. We anticipate that we will face increased competition in the future as new companies enter the market and alternative technologies become available.

For ATryn®, a number of companies internationally produce and market antithrombin derived from human plasma. CSL Behring's product has a significant share of the worldwide market, but is not yet approved for sale in the U.S. Talecris, which purchased Bayer's plasma business, has a commercially available fractionated antithrombin product that is approved for sale in the U.S. Other companies, including Octapharma, CSL Behring, Grifols, Kedrion, Baxter International, LFB and BioProducts Laboratory supply the European market with plasma-derived antithrombin products, none of which have yet been approved throughout the European Union. Like antithrombin, the alpha-1 antitrypsin sold today is derived from human plasma. Talecris has a significant presence in the U.S. with an alpha-1 antitrypsin product called Prolastin® which is approved for chronic use in patients with a genetic deficiency of alpha-1 antitrypsin who are prone to pulmonary disorders such as emphysema.

Novo Nordisk is the manufacturer of the only available recombinant form of factor VIIa, NovoSeven®, which is approved for the treatment of hemophilia patients with inhibitors to factors VIII and IX. There are insignificant sales of various plasma-derived factor VIIa products for the treatment of these hemophilia patients. The NovoSeven patents expire in 2012.

To the extent that a market develops for transgenically produced therapeutic products generally, we may compete with other transgenic technology companies. Pharming and BioProtein Technologies are other companies known to us that are extensively engaged in the application of transgenic technology in mammals for the production of proteins for therapeutic use in humans. Pharming, based in the Netherlands, is primarily engaged in the development of recombinant proteins in the milk of transgenic cows and rabbits. Pharming reports that it has one product that has been submitted for review by the EMEA. Pharming has also submitted a request to the FDA to recognize their lactoferrin product as being safe for nutritional applications. BioProtein Technologies is a contract manufacturing organization specializing in the production of human therapeutic proteins and vaccines in the milk of transgenic rabbits also under a technology license agreement. There are also other companies seeking to develop transgenic technology in animals and in plants, which may be competitive with our technology with respect to our patents and proprietary rights as discussed further below. In addition, it is possible that research and discoveries by others could render our transgenic technology obsolete or noncompetitive as a method of production for protein-based therapeutic products.

We may face public concerns about genetic engineering in animals.

Our activities involve genetic engineering in animals. The success of our potential commercial products will depend in part on public acceptance of the use of genetic engineering. Public attitudes may be influenced by claims and perceptions that these types of activities are unsafe and our products may not gain the acceptance of the public or the medical community. Negative public reaction to genetic engineering activities in general could result in greater restrictive legislation and regulations involving nuclear transfer and other methodologies which could impede our ability to conduct our business efficiently, delay preclinical studies or future clinical trials, or prevent us or our partners from obtaining regulatory approvals or commercializing transgenically produced products.

We depend on patents and proprietary rights that may fail to protect our business.

Our success will partly depend on our ability to obtain and maintain patent or other proprietary protection for our technologies, products and processes such as:

- compositions of matter or processes;
- processes developed by our employees; or
- uses of compositions of matter discovered through our technology.

We may not be able to obtain the necessary proprietary protection. Our success will also depend on our ability to operate without infringing the proprietary rights of other parties. Legal standards relating to the validity of patents covering pharmaceutical and biotechnological inventions and the scope of claims made under these patents are still developing. There is no consistent policy regarding the breadth of claims allowed in biotechnology patents. The patent position of a biotechnology company is susceptible to uncertainty and involves complex legal and factual questions.

We hold 23 issued or allowed U.S. patents and 180 corresponding foreign patents. Our patents generally expire between 2013 and 2015, with the exception being a recently issued patent in the United States, which expires in 2021. This patent provides us with claim coverage for the production of therapeutic proteins in the mammary glands of transgenic mammals. One in-licensed European patent, pertaining to transgenic animals secreting proteins in milk, expired in 2006. In accordance with ongoing research and development efforts, we have 40 pending U.S. patent applications and 116 corresponding foreign applications covering relevant and newly developed portions of our transgenic technology. Several of these pending applications are included in various cross-licensing or out-licensing arrangements with other companies that in turn provide access to their proprietary technologies. Specifically we have cross-licensed our proprietary technology for the production of proteins in milk to Pharming. Other technologies for which we hold existing patents include: protein purification from the milk of transgenic animals, the production of monoclonal and assembled antibodies at commercial levels in the milk of transgenic mammals and the production of recombinant antithrombin in the milk of transgenic goats. We cannot be certain that we will receive issued patents based on pending or future applications. Our issued patents may not contain claims sufficiently broad to protect us against competitors with similar technology. Additionally, our patents, our partners' patents and patents for which we have license rights may be challenged, narrowed, invalidated or circumvented. Furthermore, rights granted under patents may not provide us with any competitive advantage.

We may have to initiate arbitration or litigation to enforce our patent and license rights. If our competitors file patent applications that claim technology also claimed by us, we may have to participate in interference or opposition proceedings to determine the priority of invention. An adverse outcome could subject us to significant liabilities to third parties and require us to cease using the technology or to license the disputed rights from third parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all.

The cost to us of any litigation or proceeding relating to patent rights, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of any pending patent or related litigation could have a material adverse effect on our ability to compete in the marketplace. An unfavorable result could subject us to significant liabilities to third parties, require us to cease using the affected processes or require us to license the disputed rights from third parties. For example, a key nuclear transfer patent that we licensed from a third party was recently invalidated in favor of a patent application now licensed to Start Licensing, Inc. In response to the ultimate resolution of that invalidation, we recently obtained a non-exclusive license from Start Licensing, Inc. for patents and patent applications developed to apply nuclear transfer to the production of therapeutic proteins in the milk of transgenic animals. If, unlike the Start Licensing example, we could not obtain a license to patented technology we need, or could only obtain a license on terms we consider to be unacceptable, or if we were unable to design our products or processes to avoid infringement of such patented technology, our business would be harmed.

We rely on certain proprietary trade secrets and know-how that are not patentable. We have taken measures to protect our unpatented trade secrets and know-how, including having our employees, consultants and some contractors execute confidentiality agreements. These agreements could be breached. If so, it is possible that our remedies for a given breach might be inadequate. It is also possible that competitors emerge who could independently develop or discover our trade secrets or that the trade secrets could otherwise become known.

We may not be able to recover from any catastrophic event affecting our animals or facilities.

While we have measures in place to minimize and recover from catastrophic events that may substantially destroy our animal herd(s), these measures may not be adequate to recover our production processes quickly enough to support critical timelines, collaborator needs or market demands. These catastrophic events may include animal diseases that breach our biosecurity measures or weather events such as tornadoes, earthquakes or fires. In addition, these catastrophic events may render some or all of the products at the affected facilities unusable.

Successful commercialization of our products will depend on obtaining coverage and reimbursement for use of the products from third-party payors.

Sales of pharmaceutical products depend largely on the reimbursement of patients' medical expenses by government health care programs and private health insurers. It is possible that third party payors will not reimburse sales of our transgenically produced products. Reimbursement by third party payors depends on a number of factors, including the payor's determination that use of the product is safe and effective, not experimental or investigational, medically necessary, appropriate for the specific patient and cost-effective. Reimbursement in the United States or foreign countries may not be available or maintained for any of our products. If we do not obtain approvals for adequate third party reimbursements, we may not be able to establish or maintain price levels sufficient to realize an appropriate return on our or our partners' investment in product development. Any limits on reimbursement available from third party payors may reduce the demand for, or negatively affect the price of, our or our partners' products. Without the financial support of the government or third party insurers, the market for transgenically produced products will be limited.

The U.S. federal government and private insurers are continually working on ways to contain health care costs, particularly by limiting both coverage and the level of reimbursement for new therapeutic products. The government or private insurers may institute future price controls and other cost-containment measures on Medicare, Medicaid and other health care insurance spending. These controls and limits could affect the payments we collect from sales of our products. Internationally, medical reimbursement systems vary significantly, with some medical centers having fixed budgets, regardless of levels of patient treatment, and other countries requiring application for, and approval of, government or third party reimbursement. Even if we or our partners succeed in bringing transgenically produced products to market, uncertainties regarding future health care policy, legislation and regulation, as well as private market practices, could affect our ability to sell our products in commercially acceptable quantities at profitable prices.

Our ability to negotiate with potential marketing partners for ATryn® may be limited by existing obligations.

If we choose to commercialize ATryn® with an additional marketing partner outside of Asia, Genzyme Corporation has an exclusive first right of negotiation for commercialization rights. This right is triggered on product-by-product and market-by-market basis at such time as we make a submission to a regulatory authority for marketing approval in a given market. This right may delay our ability to negotiate a favorable agreement with a potential partner. This right does not apply if we have already entered into a collaboration or other agreement with a prospective research, development and exclusive marketing partner prior to such regulatory submission. The right does not apply to commercialization rights in Europe, Canada or the Middle East for any indication for ATryn® so long as those rights are subject to our licensing and supply agreement entered into with LEO Pharma in October 2005.

The manufacture and sale of our products may expose us to product liability claims for which we could have substantial liability.

We face an inherent risk of product liability exposure related to testing of our transgenically produced products in human clinical trials and will face even greater risks when we commercialize our products. An individual may bring a product liability claim against us if one of our products causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use, even if the product involved is granted regulatory authorization for commercial sale. We have obtained product liability coverage for the clinical trials to be conducted to support a filing for marketing approval of ATryn® with the FDA through our own policies. Product liability insurance for commercial sales of ATryn® has been established by LEO. It is possible that our insurance coverage will not be sufficient to cover any claim. Any product liability claim brought against us, with or without merit, could result in:

- liabilities that substantially exceed our product liability insurance, which we would then be required to pay from other sources, if available;
- an increase of our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms or at all;
- damage to our reputation and the reputation of our products, resulting in lower sales;
- regulatory investigations that could require costly recalls or product modifications; and
- the diversion of management's attention from managing our business.

We may be unable to attract and retain qualified managerial and scientific personnel which could adversely affect our business and operations.

We are highly dependent on the principal members of our scientific and management staff. Our success will depend in part on our ability to identify, attract and retain qualified managerial and scientific personnel. There is intense competition for qualified personnel in our industry. We may not be able to continue to attract and retain personnel with the advanced technical qualifications or managerial expertise necessary for the development of our business. If we fail to attract and retain key personnel, it could have a material adverse effect on our business, financial condition and results of operations. We have employment agreements with our executive officers, but these agreements do not guarantee that they will remain employed with us in the future. If we lose an executive officer, or a significant number of our staff, or are unable to hire and retain qualified personnel, then our ability to develop and commercialize our products and processes may be delayed or impaired. We do not carry key personnel insurance.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud. As a result, investors may lose confidence in our financial reporting.

The Sarbanes-Oxley Act of 2002 requires that we report annually on the effectiveness of our internal controls over financial reporting. Among other things, we must perform systems and process evaluation and testing. We must also conduct an assessment of our internal controls to allow management to report on our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. These requirements were effective for the first time for 2004. In connection with our Section 404 compliance efforts, we have incurred or expended, and expect to continue to incur or expend, substantial accounting and other expenses and significant management time and resources. Any subsequent assessment by us or our independent registered public accounting firm may reveal significant deficiencies or material weaknesses in our internal controls, which may need to be disclosed in subsequent periodic reports filed with the Securities and Exchange Commission, or SEC and could result in a restatement of previously issued financial information. Disclosures of this type could cause investors to lose confidence in our financial reporting and may negatively affect the price of our common stock. Moreover, effective internal controls are necessary to produce reliable financial reports and to prevent fraud. If we have deficiencies in our internal controls over financial reporting, these deficiencies may negatively impact our business and operations.

RISKS RELATED TO OUR COMMON STOCK

Our common stock is at risk for delisting from the Nasdaq Global Market.

Our common stock is currently listed on the Nasdaq Global Market. Nasdaq has requirements that a company must meet in order to remain listed on the Nasdaq Global Market. These requirements include maintaining a minimum closing bid price of \$1.00 per share. On January 17, 2008, we received a notice from The Nasdaq Stock Market, or Nasdaq, that for the previous 30 business days our common stock had not met the \$1.00 minimum closing bid price requirement for continued listing on the Nasdaq Global Market, as specified by Marketplace Rule 4450(a)(5). Although the notification of non-compliance has no effect on the listing of our common stock at this time and we have 180 calendar days, or until July 15, 2008, to regain compliance by having the closing bid price of our common stock equal or exceed \$1.00 per share for a minimum of 10 consecutive trading days, there is no guarantee that we will be able to regain compliance. Additionally, Nasdaq may, in its discretion, require us to maintain a bid price of at least \$1.00 per share for a period in excess of ten consecutive business days before determining that we have demonstrated an ability to maintain long-term compliance.

If we do not regain compliance with the minimum bid price requirement by July 15, 2008, Nasdaq will provide us written notification that our common stock is subject to delisting. Although we may elect to apply to transfer our common stock from the Nasdaq Global Market to the Nasdaq Capital Market, there is no guarantee that we will satisfy all requirements for initial inclusion in that market. Such a transfer application is also subject to approval by Nasdaq, and we would once again be required to regain compliance with the minimum closing bid price requirement until 180 days after the end of the first 180-day period. If, at the conclusion of either or both of the 180-day periods, we have not achieved compliance, we may appeal Nasdaq's determination to delist our common stock to the Nasdaq Hearing Panel, but there is no guarantee that such an appeal would be successful.

If we fail to meet the continued listing requirements of the Nasdaq Global Market and our common stock is delisted, trading in our common stock, if any, could be conducted on the OTC Bulletin Board as long as we continue to file reports required by the Securities and Exchange Commission. The OTC Bulletin Board is generally considered to be a less efficient market than the Nasdaq Global Market, and our stock price, as well as the liquidity of our common stock, would be adversely affected as a result. Delisting would also negatively impact our ability to sell our common stock and secure additional financing.

We have obligations to issue shares of common stock in the future that will dilute your ownership interest.

Sales of substantial amounts of our common stock in the public market, or the perception that such sales may occur, could adversely affect our common stock's market price. As of December 30, 2007, there were (i) 78.3 million shares of our common stock outstanding(ii) options to purchase an aggregate of 5.9 million shares of common stock at varying exercise prices were outstanding, of which total, options to purchase 4.3 million shares were immediately exercisable and the underlying shares could be immediately resold into the public market; and (iii) outstanding warrants to purchase an aggregate of 14.6 million shares of our common stock at exercise prices ranging from \$1.41 to \$8.75 per share, which were issued to investors in various prior financings. In February 2008, we also sold 6.9 million shares of our common stock at \$0.87 per share and issued 7-year warrants to purchase an aggregate of 6.9 million shares of our common stock at an exercise price of \$0.87 per share.

The warrants to purchase an aggregate of 1,828,573 of shares of our common stock, which we issued in our August 2005 private placement had an initial exercise price of \$2.68 per share. The exercise price of these warrants is subject to adjustment upon the occurrence of a dilutive issuance, that is, an issuance of any shares of our common stock or common stock equivalents at an exercise price lower than the then-effective exercise price per share. Upon a dilutive issuance the exercise price of the unexercised portion of these warrants shall be reduced by multiplying the then-effective exercise price by a fraction, the numerator of which is the number of shares of common stock outstanding immediately prior to the dilutive issuance plus the number of shares of common stock which the aggregate consideration received or deemed to be received by the company in connection with the dilutive issuance would purchase at the exercise price, and the denominator of which is the number of shares of common stock and common stock equivalents issued and outstanding immediately following such dilutive issuance. As adjusted for all dilutive issuances through February 12, 2008, the exercise price of the August 2005 warrants has been reduced to approximately \$2.05 per share.

We have 14,615 shares of Series D convertible preferred stock outstanding as of December 30, 2007, which are convertible into a total of 14,615,000 shares of common stock at the option of the preferred stock holder any time.

We have a convertible note in the amount of \$2.6 million dollars to LFB as of December 30, 2007, which automatically converts into shares of our common stock in conjunction with any future common stock offerings at the per share offering price of the respective offering but only to the extent that any conversion does not result in LFB's holdings exceeding 19.9% of our common stock on an as-converted basis. In connection with the closing of our February 2008 registered direct offering, \$1.7 million of the principal amount of this note and approximately \$40,000 of accrued interest on that principal amount were converted into 2 million shares of our common stock at a rate of \$0.87 per share, which was the closing sale price of our common stock as reported on The NASDAQ Global Market on February 7, 2008.

Our capital raising efforts will dilute shareholder interests.

If we raise additional capital by issuing equity securities, the issuance will result in a reduction of the percentage of ownership for our existing shareholders, a result commonly referred to as dilution. The extent of such dilution will vary based upon the amount of capital raised.

Our common stock may continue to have a volatile public trading price.

Historically, the market price of our common stock has been highly volatile and the market for our common stock has experienced significant price and volume fluctuations, some of which are unrelated to our company's operating performance. Since January 1, 2003, the trading price of our stock has fluctuated from a high of \$4.47 to a low of \$0.84. It is likely that the market price of our common stock will continue to fluctuate in the future. Factors which may have a significant adverse effect on our common stock's market price include:

- actual or potential clinical or regulatory events relating to our products or compounds under development;
- other regulatory developments in Europe or the United States;
- announcements by us or our competitors of technological innovations or new commercial products;
- an unexpected termination of one of our partnerships;
- developments concerning our proprietary rights, including patent and litigation matters;
- general market conditions; and
- quarterly fluctuations in our cash position, revenues and other financial results.

The average daily trading volume of our common stock for the twelve-month period ending December 30, 2007 was approximately 350,000 shares.

Anti-takeover provisions in our charter and by-laws and Massachusetts law may result in management entrenchment and adversely affect our stock price.

Anti-takeover provisions in our charter, our by-laws and Massachusetts statutes could delay or make more difficult a merger, tender offer or proxy contest involving us. These provisions may delay or prevent a change of control without action by the shareholders, and may resist important changes shareholders seek to make if they are dissatisfied with the conduct of our management. Therefore, these provisions could result in the entrenchment of our management and adversely affect the price of our common stock.

Our charter grants authority to the board of directors to issue series of preferred stock with certain rights and privileges, including voting rights, as it deems appropriate. This authority may enable our board of directors to deter or delay a change in control despite a shift in stock ownership, as a result of an increase in the number of shares needed to gain voting control. This may have the effect of discouraging tender offers and proxy contests, and give management the power to reject certain transactions which might be desired by shareholders. This provision could also be deemed to benefit incumbent management to the extent it deters offers by persons who would wish to make changes in management or exercise control over management.

In addition, our by-laws may have the effect of preventing changes in our management because shareholders are required to give us written notice of any proposal or director nomination within a specified period of time before the annual meeting of shareholders, certain qualifications for a person to be elected to the board of directors must be established, and shareholders are prohibited from calling a special meeting of shareholders, unless the shareholder owns 90% of our outstanding voting stock.

Our shareholder rights plan is another anti-takeover device. It involves a distribution to our shareholders of certain rights to acquire shares of our capital stock in the event of an acquisition of a predetermined number of shares by an investor. The shareholder rights plan is designed to deter coercive takeover tactics and to encourage a party interested in acquiring the corporation to negotiate with the board of directors.

Certain Massachusetts corporate statutes provide anti-takeover protections. Our charter gives effect to a provision of Massachusetts law that places directors of publicly-held Massachusetts corporations into three classes of nearly equal sizes with staggered terms, thereby permitting only one-third of the board of directors to be elected at once. In addition, with certain exceptions, Massachusetts law prohibits a publicly-held Massachusetts corporation from engaging in a business combination transaction with an "interested stockholder" for a period of three years. An "interested stockholder" is a person who owns 5% or more of the outstanding voting stock of the corporation. Finally, our by-laws include a provision excluding us from the applicability of a Massachusetts statute that denies voting rights to any person acquiring 20% or more of the outstanding voting stock of a corporation, unless such voting rights are approved by a majority of the corporation's disinterested shareholders. Our by-laws may be amended at any time to subject us to this statute prospectively.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

All of our facilities are located in Massachusetts. We lease approximately 32,356 square feet of office and laboratory space which expires in September 2010. In February 2007, we signed a lease amendment to lease an additional 8,188 square feet of office space which also expires in September 2010.

We own a 383-acre facility in central Massachusetts. This facility contains 106,793 square feet of production, laboratory and administrative space and currently houses more than 1,500 goats. We believe that our owned and leased facilities are adequate for significant further development of commercial transgenic products. In March 2005, we completed the sale of 135 acres of farm land located in eastern New York State.

ITEM 3. LEGAL PROCEEDINGS

We are not party to any material pending legal proceedings, other than ordinary routine litigation incidental to our business.

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

During the fourth quarter of 2007, no matter was submitted to a vote of our security holders.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our Common Stock is traded on the NASDAQ Global Market under the symbol GTCB. Quarterly high and low sales prices for the Common Stock as reported by the NASDAQ Global Market are shown below:

	<u>High</u>	<u>Low</u>
2006:		
1st Quarter (ended April 2).....	\$ 2.41	\$ 0.93
2nd Quarter (ended July 2).....	1.96	0.87
3rd Quarter (ended October 1).....	1.57	1.16
4th Quarter (ended December 31).....	1.36	1.01
2007:		
1st Quarter (ended April 1).....	\$ 1.21	\$ 0.96
2nd Quarter (ended July 1).....	1.25	1.03
3rd Quarter (ended September 30).....	1.23	0.98
4th Quarter (ended December 30).....	1.12	0.84

On March 3, 2008, the closing price of our Common Stock was \$0.70 per share as reported on the NASDAQ Global Market.

As of March 3, 2008, we had approximately 1,430 shareholders of record.

We have never paid a cash dividend on our Common Stock and do not expect to do so for the foreseeable future.

ITEM 6. SELECTED FINANCIAL DATA

The selected financial data set forth below as of December 30, 2007 and December 31, 2006 and for each of the three fiscal years in the period ended December 30, 2007 are derived from our consolidated financial statements included elsewhere in this Report, which have been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm. The report of PricewaterhouseCoopers LLP included in this report contains an explanatory paragraph relating to our ability to continue as a going concern, as described in Note 1 to the consolidated financial statements. The selected financial data set forth below as of January 1, 2006, January 2, 2005 and December 28, 2003 and for the years ended January 2, 2005 and December 28, 2003 are derived from audited consolidated financial statements not included in this Report.

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

SELECTED FINANCIAL DATA
(Dollars in thousands except per share data)

	<u>December 30, 2007</u>	<u>December 31, 2006</u>	<u>January 1, 2006</u>	<u>January 2, 2005</u>	<u>December 28, 2003</u>
Statement of Operations Data:					
Revenue	\$ 13,896	\$ 6,128	\$ 4,152	\$ 6,626	\$ 9,764
Costs of revenue and operating expenses:					
Cost of revenue.....	11,561	6,651	4,344	6,107	11,116
Research and development.....	28,925	25,401	21,145	20,002	18,277
Selling, general and administrative	9,834	9,723	8,428	9,710	10,688
	<u>50,320</u>	<u>41,775</u>	<u>33,917</u>	<u>35,819</u>	<u>40,081</u>
Operating loss from continuing operations.....	(36,424)	(35,647)	(29,765)	(29,193)	(30,317)
Other income and (expenses):					
Interest income	1,443	1,237	547	312	1,103
Interest expense	(1,329)	(1,001)	(1,140)	(951)	(508)
Other income (expense).....	(11)	66	246	339	185
	<u>(36,321)</u>	<u>(35,345)</u>	<u>(30,112)</u>	<u>(29,493)</u>	<u>(29,537)</u>
Net loss	<u>(36,321)</u>	<u>(35,345)</u>	<u>(30,112)</u>	<u>(29,493)</u>	<u>(29,537)</u>
Net loss per common share (basic and diluted).....	<u>\$ (0.47)</u>	<u>\$ (0.53)</u>	<u>\$ (0.62)</u>	<u>\$ (0.79)</u>	<u>\$ (1.00)</u>
Weighted average number of shares outstanding (basic and diluted)	77,863,008	66,860,345	48,658,143	37,360,758	29,562,152
	<u>December 30, 2007</u>	<u>December 31, 2006</u>	<u>January 1, 2006</u>	<u>January 2, 2005</u>	<u>December 28, 2003</u>
Balance Sheet Data:					
Cash, cash equivalents and marketable securities.....	\$ 15,765	\$ 43,385	\$ 36,169	\$ 22,281	\$ 31,091
Working capital	(1,740)	29,382	18,601	10,639	23,967
Total assets.....	40,713	73,235	66,719	57,301	71,072
Long-term liabilities.....	13,970	16,443	9,688	9,336	12,582
Shareholders' equity.....	8,024	37,956	36,709	33,653	48,161

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

Overview

We are the leader in the development and production of human therapeutic proteins through transgenic technology that enables animals to produce what is known as a recombinant form of a specified human protein in their milk. Using this technology, we are developing a portfolio of recombinant blood proteins to treat a range of genetic and acquired blood deficiencies, including hemophilia and other blood coagulation disorders. These blood proteins, also known as plasma proteins, are difficult to produce in other manufacturing systems, and some are currently only available by extraction from human blood. We have also initiated the development of a portfolio of monoclonal antibodies, or MAb's, for use as potential follow-on biologics are targeted at several large market products.

Our first product ATryn[®], our recombinant form of human antithrombin, validated our transgenic production technology's capability to meet the regulatory requirements for recombinant proteins. In 2006, ATryn[®] became the first transgenically produced therapeutic protein to be approved anywhere in the world when we obtained European Commission approval of the use of ATryn[®] as a prophylactic treatment for patients with hereditary antithrombin deficiency, or HD, undergoing surgical procedures. In February 2008, we announced that ATryn[®] had met the statistical requirements for the primary endpoint in our pivotal trial to support our filing of a Biologics License Application, or BLA, for the use of ATryn[®] in the United States in HD patients undergoing surgery or childbirth. We plan to complete the filing of the BLA in mid-2008.

We plan to develop ATryn[®] and many of our other recombinant proteins through strategic collaborations. Under our exclusive collaboration agreement entered into with LEO Pharma A/S in 2005, LEO is sponsoring the clinical development of ATryn[®] in Europe for a new indication of disseminated intravascular coagulation, or DIC, in severe sepsis. In September 2006, we entered into a collaboration agreement with LFB Biotechnologies, or LFB, to develop selected recombinant plasma proteins and MAb's. The first program in this collaboration is for the development of a recombinant form of human blood coagulation factor VIIa for the treatment of patients with hemophilia. We have subsequently added to the LFB collaboration a program to develop a recombinant form of human blood coagulation factor IX, as well as a program to develop an antibody to the CD20 immune system receptor, the same target as for the MAb marketed as Rituxan[®]. We are engaged in business development activities with the objective of adding additional collaborations.

We have also used our transgenic technology in external programs to produce therapeutic products for our partners. For our external programs, we enter into licensing and development agreements with partners to use our transgenic technology to develop, produce and purify recombinant forms of therapeutic proteins. Historically, we operated on a service contract basis, generally receiving fees for the development of the production platform and production and purification of the proteins. We currently have two active external programs with Merrimack Pharmaceuticals and PharmAthene. Most of our fiscal 2007 revenues were derived from our external programs.

We have operated at a net loss since our inception in 1993 and we used \$29.9 million of cash in operating cash flows in 2007. We are entirely dependent upon funding from equity financings, partnering programs and proceeds from short and long-term debt to finance our operations until we achieve commercial success in selling and licensing our products and positive cash flow from operations. Based on our cash balance as of December 30, 2007, as well as potential cash receipts from existing programs and our receipt of approximately \$5.5 million in net proceeds from our registered direct offering in February 2008, we believe our resources will be sufficient to fund operations into the second half of 2008. We expect that future sources of funding may include new or expanded collaboration arrangements and sales of equity or debt securities. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our planned commercialization efforts, or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialized independently. Additionally, any future equity funding may dilute ownership of our equity investors.

Our key value drivers include the following:

ATryn®

Our lead product is a recombinant form of human antithrombin known as ATryn®, which has been approved for marketing in the EU by the European Commission for use in patients with HD who are undergoing surgical procedures. In February 2008, we announced that ATryn® had met the statistical requirements for the primary endpoint in our pivotal trial to support our filing of a Biologics License Application, or BLA, in the United States. We have filed initial sections of our BLA seeking approval of the U.S. Food and Drug Administration, or FDA, to begin marketing ATryn® in the United States for a similar indication in HD patients undergoing surgery or childbirth. We plan to submit the last section of the BLA to complete the filing in 2008. In September 2007, the FDA designated ATryn® as a “fast track product”, which enabled us to request priority review by the FDA when we initiated our BLA filing. If priority review is granted, the FDA will complete its review 6 months after the final section of our BLA is submitted. Following fast track designation, the FDA gave us permission for a rolling BLA submission, where sections are submitted as they are completed. The FDA has also designated ATryn® an Orphan Drug, providing seven years of market exclusivity and waiver of the BLA submission fee. While we expect any commercial activity relating to the HD indication to be limited, we believe that ATryn® presents a significant commercial opportunity if its use can be expanded into additional indications that result from acquired deficiencies.

Our agreement with LEO includes up to \$73 million in potential milestone payments from LEO to us for meeting regulatory, clinical and sales goals. These payments include a total of \$5 million in non-refundable payments that we received upon entering the collaboration agreement and for achieving approval of ATryn® for the HD indication in Europe. These milestone revenues are being recognized over the life of the agreement on a straight-line basis beginning with the first delivery of ATryn® material to LEO, which occurred in the fourth quarter of 2006. As of December 30, 2007, \$4.7 million of the total amount received from LEO was accounted for as deferred revenue.

In our collaboration with LEO we are responsible for the production of ATryn®. We will supply the product for clinical studies and receive payment for delivery of material to LEO. We will also supply the product for commercial sales and LEO will pay us a transfer price and royalties on sales of ATryn®. We are paid by LEO for clinical material based on our fully burdened costs subject to a maximum price per unit, which is currently than our costs to produce the material. LEO has exclusive rights for sales and marketing of ATryn® in all indications in LEO's territories. We retain all rights to ATryn® in all other territories, including the United States and Japan.

LEO has selected disseminated intravascular coagulation, or DIC, associated with severe sepsis as an acquired antithrombin deficiency indication for development in Europe. LEO has obtained scientific advice from the European Medicines Agency, or EMEA, on the design of a Phase II dose ranging study of approximately 200 patients and commenced enrollment in 2007.

LFB Collaboration Agreement

The first program under our collaboration agreement with LFB for the development of selected recombinant plasma proteins and MAb's is recombinant factor VIIa, or rhFVIIa. We have subsequently added to the LFB collaboration a program to develop a recombinant form of human factor IX as well as a program to develop an antibody to the CD20 immune system receptor. Under this agreement, we will share equally with LFB in the cost of the development and commercialization of each product and will be entitled to 50% of any profits derived from products developed through the collaboration provided we each contribute equally to the costs of their development. In the event that contributions to development are not equal, the profit allocation will be adjusted based on development costs incurred. Under the agreement, a joint steering committee of each company's representatives will determine product development and commercialization plans. Our activities under this program in 2008 will be primarily focused on development of the production and purification system. We anticipate that the rhFVIIa product will enter clinical studies in approximately two years to evaluate its use in treating hemophiliacs that have developed inhibitors to coagulation factors VIII or IX. During 2007, we received approximately \$1.2 million in funding from LFB as reimbursement for an agreed portion of our costs incurred in these programs which was recorded against the program costs in research and development.

CD20

The CD20 MAb is being developed as a follow-on biologic under the collaboration with LFB. The resulting product is expected to have target specificity similar to Rituximab (Rituxan[®], Mabthera[®]) and to have a relatively higher immune response in which antibodies, by coating target cells, makes them vulnerable to attack by immune cells, this is known as Antibody Dependent Cell-mediated Cytotoxicity, or ADCC. The existing relevant CD20 antibody patents will expire by 2014. The transgenically produced CD20 antibody is anticipated to be commercially developed for oncology and auto-immune indications. Rituximab is used in the treatment of B-cell non-Hodgkin's lymphoma, B-cell leukemia and rheumatoid arthritis. It is also under investigation for a range of auto-immune conditions such as systemic lupus erythematosus, immune thrombocytopenic purpura (ITP), and type-1 diabetes. Rituximab had worldwide sales of nearly \$4 billion in 2006 and is projected to have an \$8.1 billion market by 2014.

rhAAT

We have begun development of a recombinant form of human alpha-1 antitrypsin, or rhAAT, which, like antithrombin, is a product that is currently sourced from fractionated human plasma. We believe that we can provide a highly pure and unconstrained supply of rhAAT to the market using goats we have developed that produce it in significant quantities. We have also developed a bench scale purification process and are in the process of defining the clinical and regulatory program for this product, initially as an injected treatment of the congenital deficiency. Our goal over the next 18 months is to develop a preclinical program that will support initiation of clinical studies and to determine the partnership opportunities available for further development. The level and speed of development of this product will be dependent upon our financial resources and partnering opportunities. Under our collaboration agreement, LFB has been granted a right of first negotiation to partner with us for the development of rhAAT.

External Program Portfolio

We believe the advantages to external partners of using our transgenic production technology include enabling the development of proteins that are difficult to produce in traditional recombinant production systems, requiring significantly lower capital investment, assuring lower cost of goods, and providing for flexibility in capacity expansion. To date we have typically developed a transgenically produced version of an external partner's protein on a service contract basis. We are in the process of transitioning that model into a portfolio of programs where we obtain benefits beyond the margin of a service contract, such as fees for successful downstream partnering with third parties, royalties, or some other relationship with the partner beyond fees or milestones collected for development of the production platform.

The following table summarizes our significant external program revenues as a percent of total revenue in the last three years:

	2007	2006	2005
Merrimack	29%	54%	29%
PharmAthene	28%	—	—
Centocor	—	1%	7%
Elan (Tysabri [®] - formerly Antegren [®])	—	—	35%

In 2005, the Merrimack revenue was a result of the processing of rhAFP for clinical studies while the revenue in 2006 and 2007 was related to breeding and material production.

During 2007, we signed an agreement to provide product development and purification services to PharmAthene[®] for their Protexia[®] product which is funded by the United States Department of Defense, or DOD.

During 2005, the revenue derived from the Centocor program was a result of work related to breeding, semen collection and animal maintenance. During 2004, the revenue derived from the Centocor program was a result of work related to material processing. The program with Centocor was concluded in the fourth quarter of 2005.

We successfully completed our transgenic development work in December 2004 on the Elan program. Under a new agreement with Elan in 2005, the program was scaled down and then concluded in the third quarter of 2005.

Critical Accounting Policies and Estimates

The preparation of consolidated financial statements requires that we make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. Our critical accounting policies are summarized in Note 2 in the Notes to Consolidated Financial Statements included in Item 8 of this Report. On an on-going basis, we evaluate our estimates, including those related to revenue recognition, investments, intangible and long-lived assets, income taxes, accrued expenses, financing operations, and contingencies and litigation. We base our estimates on historical experience and on various other assumptions that we believe 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. Our actual results may differ from these estimates under different assumptions or conditions.

We believe that our application of the following accounting policies involve the most significant judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

We enter into licensing and development agreements with collaborative partners for the development, production and purification of our internally developed recombinant protein candidates or for a transgenically produced version of the partner's therapeutic recombinant proteins. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon the achievement of certain milestones and royalties on future product sales, if any. In September 2005, we entered into a manufacturing services agreement with Merrimack Pharmaceuticals for the production of therapeutic recombinant proteins produced in the milk of transgenic animals. The terms of the agreement include payments for maintenance services, manufacturing suite time and the cost to scale up the production herd. In addition, we have entered into a license and supply agreement with LEO for the production of ATryn®. The terms of the supply agreement with LEO include non-refundable license fees, transfer price for product delivered, royalties on future net sales and potential milestone payments to us for meeting regulatory, clinical and sales goals.

We recognize revenue in accordance with Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" (SAB No. 101), as amended by Staff Accounting Bulletin No. 104, "Revenue Recognition" (SAB No. 104), and Emerging Issues Task Force Issue No. 00-21, "Revenue Agreements with Multiple Deliverables" (EITF No. 00-21).

Revenues from the sale of products and services are recognized when persuasive evidence of an agreement exists, delivery has occurred or services have been rendered, the fees are fixed and determinable, and collectibility is reasonably assured. Revenues from royalties on third-party sales of licensed technologies will be generally recognized in accordance with the contract terms when the royalties can be reliably determined and collectibility is reasonably assured.

We assess multiple element revenue arrangements involving upfront payments, license fees, manufacturing services and milestone payments received for the delivery of rights or services. The following criteria must be met for an element to represent a separate unit of accounting:

- a) The delivered items have value to a customer on a standalone basis;
- b) There is objective and reliable evidence of the fair value of the undelivered items; and
- c) Delivery or performance is probable and within our control for any delivered items that have a right of return.

If these criteria are met, we apply the appropriate revenue recognition model as described above to each separate unit of accounting. If these criteria are not met, elements are combined into a single unit of accounting and revenue is not recognized until we have verifiable objective evidence of the undelivered element. Upfront

payments and license fees are recognized ratably over the longer of the contractual term or expected relationship period. Payments for the achievement of substantive milestones are recognized when the milestone is achieved. Payments for milestones which are not the result of the achievement of a substantive milestone, are recognized ratably over the longer of the remaining contractual term or expected relationship period.

Revenue is also recognized in accordance with SAB 101 FAQ 13 (EITF 91-6). Under that model, revenue is recognized using the lesser of non-refundable cash received and milestones met or the result achieved using level-of-efforts accounting. The estimated costs to complete each program are based on the contract terms, detailed program plans, including cost projections, and each program under review. All revenue recognition estimates are made based upon the current facts and circumstances and are reassessed on at least a quarterly basis. There are a number of factors which could cause the need for a revision to these estimates, which in turn may have the effect of increasing or decreasing revenue in the current period as they become known. These factors include unforeseen additional costs, delay in a program, efficiencies or decisions at the partner's discretion.

Deferred revenue arises from payments received in advance of the culmination of the earnings process. Deferred revenue expected to be recognized within the next twelve months is classified as a current liability. Deferred revenue will be recognized as revenue in future periods when the applicable revenue recognition criteria have been met.

Inventory

All of our inventory on hand as of December 30, 2007 was work in process inventory. The net book value of this inventory as of December 30, 2007 was zero because our estimated cost to complete current orders from LEO exceeds the agreed upon maximum transfer price. All of the inventory on hand for the prior fiscal year ended December 31, 2006, relates to ATryn[®], which we capitalized after completion of the clinical trials in anticipation of marketing approval for commercial sale in Europe and was subsequently sold to LEO in 2007. We expect that any inventory which we capitalize will be sold to LEO for clinical trials and commercial sale. If at any time we believe that the sale of inventory to LEO is no longer probable, we will charge the inventory to expense. We analyze our inventory levels and estimate demand for commercial sale and clinical trials on a quarterly basis. The assessment of the expected use of the inventory is highly judgmental and is based on our best estimate for demand related to both commercial sale and clinical trial usage. We also review the appropriate carrying value of the inventory based on the estimated selling price of the material taking into account inventory obsolescence and inventory expiration dates. We project our current cost of production to exceed the agreed upon maximum transfer price for clinical studies until we reach larger production volumes, and we will expense all costs above the agreed upon maximum transfer price.

Validation Costs

The costs that we have capitalized to date are those costs that are related to seeking FDA or EMEA approval of the manufacturing equipment to be used for the bulk production of ATryn[®], which are being depreciated over the expected useful life of the facility. They include the costs of employees and third parties directly involved in the approval process, direct material consumed in the validation process and incremental fixed overhead. Costs that are excluded from capitalization include maintenance costs, process development/improvement and fixed overhead. As of December 30, 2007, December 31, 2006 and January 1, 2006, we had approximately \$1.8 million, \$2.1 million and \$2.4 million, respectively, of capitalized validation costs, net of accumulated amortization, included in property, plant and equipment. The capitalized validation costs are being depreciated over five years.

Valuation of Intangible and Long Lived Assets

Management's policy regarding long-lived assets is to evaluate the recoverability of our 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 undiscounted net operating cash flow over the remaining life of the asset. If an impairment exists it is measured by the excess of the carrying value over the discounted cash flows. Any write-downs are to be treated as permanent reductions in the carrying amount of the assets.

Share-Based Compensation

Effective January 2, 2006, we adopted SFAS 123(R) Share-Based Payment (or SFAF 123(R)), which requires companies to measure and recognize compensation expense for all share-based payments at fair value. SFAS 123(R) is being applied on the modified prospective basis. Prior to the adoption of SFAS 123(R), we accounted for our share-based compensation plans under the recognition and measurement principles of Accounting Principles Board, or APB, Opinion 25, Accounting for Stock Issued to Employees, and related interpretations. We did not recognize compensation expense related to the share-based plans because the options were granted with an exercise price equal to the fair market value on the date of the grant.

Under the modified prospective approach, SFAS 123(R) applies to new awards and to awards that were outstanding on January 2, 2006. Under the modified prospective approach, compensation expense recognized during fiscal 2006 includes compensation expense for all share-based payments granted prior to, but not yet vested on, January 2, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R), and compensation expense for all share-based payments granted subsequent to January 2, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R). Prior periods were not restated to reflect the impact of adopting the new standard.

Changes in the inputs and assumptions can materially affect the measure of the estimated fair value of our employee equity awards. Also, the accounting estimate of share-based compensation expense is reasonably likely to change from period to period as further equity awards are granted and adjustments are made for equity award forfeitures and cancellations.

Included within the statements of operations are the following charges for share-based compensation:

	(dollars in thousands)	
	December 30, 2007	December 31, 2006
Research and development expense	\$ 359	\$ 312
Selling, general and administrative expense.....	488	254
Total share-based compensation.....	<u>\$ 847</u>	<u>\$ 566</u>

Results of Operations

The key components to our losses are revenue, cost of revenue, research and development expenses, and selling, general and administrative expenses.

2007 as Compared to 2006

	(\$ in thousands)			
	2007	2006	\$ Change	% Change
Revenue.....	\$ 13,896	\$ 6,128	\$ 7,768	127%
Cost of revenue	\$ 11,561	\$ 6,651	\$ 4,910	74%
Research and development	\$ 28,925	\$ 25,401	\$ 3,524	14%
Selling, general and administrative.....	\$ 9,834	\$ 9,723	\$ 111	1%

Revenue. During 2007, we derived \$9 million of our revenue from external programs, primarily with Merrimack and PharmAthene, as a result of the timing of milestones met on the programs during 2007, and \$4 million from sales to LEO. During 2006, we derived \$4 million of our revenue from external programs, primarily with Merrimack, as a result of the timing of milestones met on the program during 2006, and \$2 million from sales to LEO. We expect revenues to continue to vary on a year-to-year basis.

Cost of revenue. The increase in cost of revenue was primarily the result of a \$3 million increase in cost of goods sold associated with the sale of ATryn[®] product to LEO as compared to 2006 as well as a \$2.9 million write-off of ATryn[®] inventory which was rendered unusable during the second quarter 2007 as a result of the fill/finish process conducted at a U.S. based third party fill/finish contractor and a write off of \$469,000 of in-process inventory which was determined not to meet specifications during release testing for commercial

use. These increases were partially offset by a net reduction in costs on our external programs due to the stage of development of those programs. Even excluding the impact of these write-offs, the level of expenses for our external programs will fluctuate from period to period depending upon the stage of development of individual programs as they progress.

Research and development expense. The 2007 research and development expense included \$20.5 million related to the ATryn[®] program, an increase of \$200,000 over the \$20.3 million in 2006. The increase was primarily due to ATryn[®] manufacturing costs which include manufacturing costs of clinical material in excess of the maximum selling price to LEO as well as process development and revalidation costs for scale up of the ATryn[®] manufacturing process. Details of expenses for the ATryn[®] program for the respective years are as follows:

	(dollars in millions)	
	<u>2007</u>	<u>2006</u>
ATryn [®] manufacturing expenses.....	\$ 12.3	\$ 11.6
EMEA regulatory process expenses	2.7	3.4
U.S. clinical trial expenses	5.1	3.8
Write down of prior year inventory	—	1.3
Other	<u>0.3</u>	<u>0.2</u>
Total	\$ 20.5	\$ 20.3

Manufacturing costs included costs of producing clinical material in excess of the maximum transfer price to LEO as well as process development and validation costs for scale up of the ATryn[®] manufacturing process and costs associated with establishment of a second fill site.

During 2007, we also incurred approximately \$3.9 million of expense in support of the programs in our LFB collaboration (FVIIa \$3.3 million, FIX \$600,000; CD20 \$70,000) which were offset by approximately \$1.2 million in funding from LFB in 2007 as reimbursement for an agreed portion of our costs incurred in these programs. During 2006, we incurred approximately \$200,000 of expense in support of the programs in our LFB collaboration.

We cannot estimate the costs to complete our ongoing research and development programs due to significant variability in clinical trial costs and the regulatory approval process.

Selling, General and Administrative Expense. The increase in SG&A expenses was primarily a result of increased costs related to FAS 123R expense of approximately \$160,000, and increased legal costs related to patents and partnering/financing transactions as well as costs of approximately \$463,000 related to senior management hires, which were partially offset by lower professional fees and director and officer insurance. Our 2006 SG&A expenses included \$225,000 related to the settlement of the litigation (see Note 5 to the Notes to Consolidated Financial Statements included in Item 8 of this Report).

2006 as Compared to 2005

	(\$ in thousands)			
	<u>2006</u>	<u>2005</u>	<u>\$ Change</u>	<u>% Change</u>
Revenue.....	\$ 6,128	\$ 4,152	\$ 1,976	48%
Cost of revenue	\$ 6,651	\$ 4,344	\$ 2,307	53%
Research and development	\$ 25,401	\$ 21,145	\$ 4,256	20%
Selling, general and administrative.....	\$ 9,723	\$ 8,428	\$ 1,295	15%

Revenue. During 2006, we derived \$4 million of our revenue from external programs, primarily with Merrimack, as a result of the timing of milestones met on the program during 2006, and \$2 million from sales to LEO. During 2005, we derived \$3.7 million of our revenue from external programs, primarily with Merrimack and Elan, and \$489,000 from proprietary programs, specifically, \$237,000 from the CD137 program and \$252,000 from the malaria program. The Tysabri[®] program with Elan was completed in early 2005 and the NIAID ended

its funding of the malaria program in August 2005 due to budgetary constraints. The program with Centocor was concluded in the fourth quarter of 2005. We expect revenues to continue to vary on a year-to-year basis. Deferred contract revenue, which is not included in the statement of operations but is reflected on the balance sheet, increased by \$3.7 million in 2006 over 2005. As of December 31, 2006, we had approximately \$9.3 million in deferred revenue on our balance sheet, including \$4.9 million from LEO and \$3.3 million from Merrimack, due to cash received for which revenue had not yet been recognized pursuant to our revenue recognition policy. The deferred revenue will be recognized in future periods over the terms of the agreements.

Cost of revenue. The increase in cost of revenue is primarily the result of the costs associated with our external programs, as well as approximately \$1.4 million of costs of manufacturing product on our internal program with LEO. The increase was partially offset by the completion of the Tysabri[®] program with Elan in early 2005 and the completion of the Centocor program in the fourth quarter of 2005. The level of expenses on our external programs will fluctuate from period to period depending upon the stage of development of individual programs and their progress.

Research and development expense. The 2006 research and development expense included \$20.3 million related to the ATryn[®] program, an increase of \$7.7 million over the \$12.6 million in 2005. The increase was primarily due to the expense of ATryn[®] manufacturing costs, which included manufacturing costs of clinical material in excess of the maximum selling price to LEO as well as process development and validation costs for scale up of the ATryn[®] manufacturing process. Details of expenses for the ATryn[®] program for the respective years are as follows:

	(dollars in millions)	
	2006	2005
ATryn [®] manufacturing expenses	\$ 11.6	\$ 3.9
EMEA regulatory process expenses	3.4	6.0
U.S. clinical trial expenses	3.8	2.2
Write down of prior year inventory	1.3	0.5
Other	0.2	—
Total	\$ 20.3	\$ 12.6

The increase in ATryn[®] related expenses during 2006 was partially offset by a decrease in spending of approximately \$1.4 million on the CD137 development program during 2006 as well as a net decrease in other research and development programs as a result of the reallocation of resources to the ATryn[®] program. Research and development expenses in 2006 also included a charge of \$497,000 for the write off of the Advanced Cell Technology, Inc., or ACT, intangible asset (see Note 6 to the Notes to Consolidated Financial Statements included in Item 8 of this Report).

Selling, General and Administrative Expense. The increase in SG&A expenses was primarily a result of increased legal costs related to patents and partnering transactions of approximately \$900,000 as well as approximately \$225,000 related to the settlement of the litigation (see Note 5 to the Notes to Consolidated Financial Statements included in Item 8 of this Report), increased public company costs related to an increase in authorized shares of approximately \$100,000, and expenses related to the implementation of SFAS 123(R) of approximately \$250,000.

Liquidity and Capital Resources

Overview

Our objective is to finance our business appropriately through a mix of equity financings, partnering payments, receipts from contracts for external programs, grant proceeds, debt financings and interest income earned on our cash and cash equivalents, until such time as product sales and royalties occur and we achieve positive cash flow from operations. We expect that our ability to raise future funds will be affected by our ability to enter into new or expanded partnering arrangements or contracts for external programs, the terms of such arrangements and contracts, the regulatory review of ATryn[®] in the U.S. for HD, the progress of initial clinical trials for DIC in the EU, the results of research and development and preclinical testing of our other proprietary product candidates, and advances in competing products and technologies, as well as general market conditions.

We use our cash primarily to pay salaries, wages and benefits, facility and facility-related costs of office, farm and laboratory space and other outside direct costs such as manufacturing and clinical trial expenses. During 2007 we had a net decrease in cash and marketable securities of \$28 million, which reflects \$4.5 million received in proceeds from the LFB financing, \$29.9 million used in operations, and \$1.6 million used for capital expenditures. We are currently in discussions for potential new partnering arrangements with a plan to bring in further financial resources. In addition, we may sell additional equity or debt securities. However, there can be no assurance that we will be able to enter into anticipated partnering arrangements, or raise additional capital, on terms that are acceptable to us, or at all. Based on additional partnering arrangements that we expect to enter into during 2008, we estimate the net use of cash in operations for 2008 to be between \$24 million and \$28 million.

At December 30, 2007, we had cash, cash equivalents and marketable securities of \$15.8 million compared to \$43.8 million at December 31, 2006, and at December 30, 2007, we had negative working capital of \$1.7 million compared to working capital of \$29.4 million at December 31, 2006.

Our consolidated financial statements have been presented on the basis that we are a going concern, which contemplates the continuity of business, realization of assets and the satisfaction of liabilities in the ordinary course of business. We have incurred losses from operations and negative operating cash flow in each of 2007, 2006 and 2005 and have an accumulated deficit of approximately \$281 million at December 30, 2007. The primary sources of additional capital raised in 2007, 2006 and 2005 have been equity financings and debt financings under our credit facility. Based on our cash balance as of December 30, 2007, as well as potential cash receipts from existing programs and our receipt of approximately \$5.5 million in net proceeds from our registered direct offering in February 2008, we believe our resources will be sufficient to fund operations into the second half of 2008. We expect that future sources of funding may include new or expanded collaboration arrangements and sales of equity or debt securities. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our planned commercialization efforts, or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialized independently. Additionally, any future equity funding may dilute ownership of our equity investors.

Cash Flows from Financing Activities

Equity Financing Activities

In July 2006, in a registered direct offering to institutional investors, we sold 12 million shares of our Common Stock at \$1.38 per share (market price on the date of closing) and 10-year warrants to purchase an aggregate of 7.8 million shares of our Common Stock at an exercise price of \$1.4145 per share. We received approximately \$16.1 million in proceeds from this sale, net of approximately \$1.4 million in offering costs and fees. The shares and warrants (including the shares issuable upon exercise of the warrants) were issued under a shelf registration statement.

In the fourth quarter of 2006, we sold LFB 14,615 shares of our newly designated Series D preferred stock at a purchase price of \$1.23 per Common Stock equivalent (market price on the date of the agreement), representing 14.6 million common share equivalents. We received approximately \$18 million in proceeds from this sale.

In January 2007, we sold LFB 3.6 million shares of our Common Stock at a purchase price of \$1.23 (the market closing price on the date of the agreement) in connection with the third tranche under the purchase agreement with LFB. We received approximately \$4.5 million in proceeds from the sale.

Offering costs and fees in conjunction with the two Series D preferred stock placements to LFB were approximately \$270,000.

In February 2008, we received approximately \$5.5 million in proceeds from a registered direct offering, net of approximately \$500,000 in offering costs and fees. In the offering, we sold 6.9 million shares of our common stock at \$0.87 per share (rounded price on the date of closing) and 7-year warrants to purchase an aggregate of 6.9 million shares of our common stock at an exercise price of \$0.87 per share.

Credit Facilities

In December 2006, we refinanced our term loan with GE Capital in the amount of \$10 million, of which \$7.1 million was used to pay off an existing loan with GE Capital. There are two separate amortization schedules, the first in the amount of \$8 million carries a fixed 10.8% annual interest rate and monthly payments of principal and interest of approximately \$109,000 through December 2011 with a balloon payment of approximately \$5.2 million in January 2012. The second in the amount of \$2 million carries a fixed 10.84% annual interest rate and monthly payments of principal and interest of approximately \$65,000 through January 2010. Collateral for the loan includes all of our existing and future acquired assets, excluding intellectual property.

In December 2006, as part of the second investment tranche related to the LFB agreement, we received \$2.6 million in exchange for a five-year convertible note issued to LFB. The note accrues interest at a rate of 2% per annum and will automatically convert into shares of our common stock in conjunction with any future common stock offerings at the per share offering price of the respective offering, but only to the extent that any conversion does not result in LFB's holdings exceeding 19.9% of our common stock on an as converted basis. In connection with the closing of our February 2008 registered direct offering, \$1.7 million of the principal amount of this note and approximately \$40,000 of accrued interest on that principal amount were converted into 2 million shares of our common stock at the rate of \$0.87 per share. Based on our effective borrowing rate of 10.8%, we recorded a debt discount of approximately \$1.1 million for the difference between the stated interest rate and the effective borrowing rate. The debt discount is being amortized over the five-year term of the note, resulting in additional interest expense of approximately \$225,000 and \$10,000 during fiscal year 2007 and 2006, respectively.

Cash Flows used in Operating Activities

Cash flows used in operating activities were \$29.9 million and \$24.6 million for fiscal 2007 and 2006, respectively. The increase of \$5.3 million is primarily a result of a cash inflow in 2006 from LEO of approximately \$3 million which was recorded as deferred revenue and is being recognized in future periods over the term of the agreement.

Cash Flows from Investing Activities

Cash flows provided by investing activities include \$11.7 million in net redemptions of marketable securities in our portfolio, all of which was used to fund operations; \$200,000 was used for the purchase of a technology license and \$1.6 million was used for purchases of capital equipment. We anticipate a similar level of capital expenditures company-wide in 2008 as compared to 2007.

Contractual Obligations

The following summarizes our contractual obligations at December 30, 2007, and the effect such obligations are expected to have on our liquidity and cash flow in future periods.

	<u>Less than 1 Year</u>	<u>1 to 3 Years</u>	<u>3 to 5 Years</u>	<u>More than 5 Years</u>	<u>Total</u>
Contractual Obligations:					
Long-term debt obligations, including					
current portion ⁽¹⁾	\$ 1,177	\$ 4,404	\$ 5,113	\$ —	\$ 10,694
Operating lease obligations.....	1,834	3,190	3	—	5,027
Service and sublease agreement with Genzyme.....	478	—	—	—	478
Total contractual cash obligations	<u>\$ 3,489</u>	<u>\$ 7,594</u>	<u>\$ 5,116</u>	<u>\$ —</u>	<u>\$ 16,199</u>

⁽¹⁾ Our 10.7 million of outstanding long-term debt at December 30, 2007 includes \$9 million owed to GE Capital and \$1.7 million in convertible debt to LFB net of approximately \$900,000 of unamortized debt discount that is also payable on the LFB debt. Of the \$10.7 million, approximately \$1.2 million was classified as current. The current portion reflects the amount due through December 2008 on our GE Capital term loan.

We are party to license agreements for certain technologies (see Note 11 to the Notes to Consolidated Financial Statements included in Item 8 of this Report). In July 2001, we reacquired Genzyme's ownership interest in the ATIII LLC joint venture in exchange for a royalty to Genzyme based on our sales of ATryn[®], if any, commencing three years after the first commercial sale, up to a cumulative maximum of \$30 million. Certain of these other agreements contain provisions for future royalties to be paid on commercial sales of products developed from the licensed technologies. Currently, the amounts payable under these other agreements and any resulting commitments on our behalf are unknown and are not able to be estimated because the level of future sales, if any, is uncertain. Accordingly, they are not included in the preceding table.

New Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ("SFAS 157"), which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 applies under other existing accounting pronouncements that require or permit fair value measurements, the FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, SFAS 157 does not require any new fair value measurements. However, the application of this statement may change our current practice for fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. We are currently evaluating the impact this statement will have on our financial position and results of operations.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities—Including an Amendment of FASB Statement No. 115* ("SFAS 159"). SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. SFAS 159 permits all entities to choose, at specified election dates, to measure eligible items at fair value (the "fair value option"). A business entity shall report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. Upfront costs and fees related to items for which the fair value option is elected shall be recognized in earnings as incurred and not deferred. SFAS 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between entities that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. We are currently evaluating the impact this statement will have on our financial position and results of operations, if any.

In June 2007, the Emerging Issues Task Force ("EITF") reached a final consensus on EITF Issue No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities" ("EITF 07-3"). EITF 07-3 is effective for fiscal years beginning after December 15, 2007. EITF 07-3 requires that non-refundable advance payments for future research and development activities should be capitalized until the goods have been delivered or related services have been performed. Adoption is on a prospective basis and could impact the timing of expense recognition for agreements entered into after December 31, 2007. We do not expect the adoption of EITF 07-3 to have a significant impact on our consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We have certain fixed rate financial instruments at December 30, 2007, including a term loan, a convertible promissory note payable and a stand-by letter of credit which are not sensitive to changes in interest rates. Our term loan has a carrying value of \$10.7 million, which approximates its fair value. Our stand-by letters of credit of \$449,360 are required under a facility lease. At December 30, 2007, nothing has been drawn down on the stand-by letters of credit. Our five-year convertible note payable to LFB had a principal balance of \$2.6 million at December 30, 2007. In connection with the closing of our February 2008 registered direct offering, \$1.7 million of the principal amount of this note, and approximately \$40,000 of accrued interest on that principal amount were converted into 2 million shares of our common stock. These instruments are not leveraged and are held for purposes other than trading.

Substantially all of our marketable securities were settled by February 4, 2008 and there were no significant losses upon settlement of these marketable securities.

For the term loan and the remaining LFB convertible promissory note outstanding, the table below presents the principal cash payments that exist by maturity date as of December 30, 2007.

	(\$ in 000's)						
	2008	2009	2010	2011	2012	Thereafter	Total
Term Loan.....	\$ 1,177	\$ 1,311	\$ 708	\$ 717	\$ 5,113	\$ —	\$ 9,026
LFB Convertible Note Payable ⁽¹⁾	—	—	—	2,558	—	—	2,558
Total	<u>\$ 1,177</u>	<u>\$ 1,311</u>	<u>\$ 708</u>	<u>\$ 3,275</u>	<u>\$ 5,113</u>	<u>\$ —</u>	<u>\$ 11,584</u>

The interest rate on the term loan varies between 10.8% and 10.84% at December 30, 2007 and the interest rate on the LFB convertible note payable was 2% at December 30, 2007.

⁽¹⁾ Based on our effective borrowing rate of 10.8%, we recorded a debt discount of approximately \$1.1 million for the difference between the stated interest rate and the effective borrowing rate. The debt discount is being amortized over the five-year term of the note.

Interest Rate Risk

We do not engage in trading market risk sensitive instruments or purchasing hedging instruments or “other than trading” instruments that are likely to expose us to market risk, whether interest rate, foreign currency exchange, commodity price or equity price risk. We have not purchased options or entered into swaps, or forward or future contracts. Our primary market risk is interest rate risk on our investment portfolio. We estimate that the hypothetical loss in earnings for one year of investments held at December 30, 2007, resulting from a hypothetical 10% increase in interest rates, would not have materially affected net loss or materially affected the fair value of rate sensitive instruments. The hypothetical loss was based on financial instruments we held at December 30, 2007 with variable and fixed interest rates.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Financial Statements

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

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this annual report.

Changes in Internal Controls

There were no changes in our internal control over financial reporting that occurred during the our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control – Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 30, 2007.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS OF THE REGISTRANT AND CORPORATE GOVERNANCE

The names, ages, titles and biographies of our executive officers are provided under “Executive Officers” in Part I, Item 1 of this Form 10-K, and are incorporated herein by reference. Additional information regarding our directors and executive officers is set forth in our Proxy Statement for the Annual Meeting of Stockholders to be held on May 21, 2008 (the “2008 Proxy Statement”) under “Election of Directors” and “Section 16(a) Beneficial Ownership Reporting and Compliance.” We have adopted a Code of Business Conduct and Ethics that applies to all of our directors, officers and employees, including our chief executive officer, chief financial officer, and controllers. The Code is available on our website at <http://www.gtc-bio.com/investorinfo/corporategovernance.html>. A copy of the Code is also available without charge upon request from the Chief Financial Officer at GTC Biotherapeutics, Inc., 175 Crossing Boulevard, Framingham, MA 01702. If we make any substantive amendments to the Code or grant any waiver from a provision of it, we will disclose the nature of such amendment or waiver on our website at www.gtc-bio.com or in a Current Report on Form 8-K.

ITEM 11. EXECUTIVE COMPENSATION

Information regarding executive compensation is set forth under the Sections entitled “Executive Officer and Director Compensation and Board of Directors Committees” in our 2008 Proxy Statement and is incorporated herein by reference.

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

Information regarding security ownership of certain beneficial owners, directors and executive officers is set forth under the Section entitled “Security Ownership of Certain Beneficial Owners and Management” in our 2008 Proxy Statement and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, DIRECTOR INDEPENDENCE

Information regarding certain relationships and related transactions is set forth under the Section entitled “Transactions with Related Persons” in our 2008 Proxy Statement and is incorporated herein by reference. See also Note 11 to the Consolidated Financial Statements included in Item 8 of this Form 10-K.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information regarding auditor fees and services is set forth under the Section entitled “Independent Registered Public Accounting Firm” in our 2008 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

(1) Financial Statements

	<u>Page #</u>
Report of PricewaterhouseCoopers LLP—Independent Registered Public Accounting Firm.....	F-2
Consolidated Balance Sheets—December 30, 2007 and December 31, 2006.....	F-3
Consolidated Statements of Operations and Comprehensive Loss—For the fiscal years ended December 30, 2007, December 31, 2006 and January 1, 2006.....	F-4
Consolidated Statements of Shareholders' Equity—For the fiscal years ended December 30, 2007, December 31, 2006 and January 1, 2006.....	F-5
Consolidated Statements of Cash Flows—For the fiscal years ended December 30, 2007, December 31, 2006 and January 1, 2006.....	F-6
Notes to Consolidated Financial Statements.....	F-7

(2) Financial Statement Schedules

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

(3) Exhibits We hereby file and incorporate by reference the exhibits listed in the Exhibit Index immediately following the signature page of this Form 10-K.

Report of Independent Registered Public Accounting Firm

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

In our opinion, the consolidated financial statements listed in the index appearing under Item 15(a)(1) present fairly, in all material respects, the financial position of GTC Biotherapeutics, Inc. and its subsidiaries at December 30, 2007 and December 31, 2006, and the results of their operations and their cash flows for each of the three years in the period ended December 30, 2007 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 30, 2007, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements, and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for share-based compensation in 2006.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

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

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 6, 2008

GTC BIOTHERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(Dollars in thousands except share amounts)

	<u>December 30,</u> <u>2007</u>	<u>December 31,</u> <u>2006</u>
Current assets:		
Cash and cash equivalents	\$ 9,075	\$ 25,356
Marketable securities	6,690	18,479
Accounts receivable and unbilled contract revenue.....	240	285
Inventory.....	—	3,092
Other current assets.....	974	1,006
Total current assets.....	16,979	48,218
Property, plant, and equipment, net.....	14,449	15,336
Intangible assets, net.....	7,151	7,539
Other assets.....	1,684	1,692
Restricted cash.....	450	450
Total assets.....	<u>\$ 40,713</u>	<u>\$ 73,235</u>
Current liabilities:		
Accounts payable.....	\$ 9,904	\$ 9,367
Accrued liabilities.....	4,571	5,195
Short-term deferred contract revenue	3,067	3,301
Current portion of long-term debt.....	1,177	973
Total current liabilities.....	18,719	18,836
Long-term deferred contract revenue.....	4,433	5,953
Long-term debt, net of current portion	7,850	9,027
Long-term convertible note to LFB, net of debt discount	1,667	1,443
Other long-term liabilities.....	20	20
Total liabilities.....	32,689	35,279
Commitments and contingencies (see Notes 5 and 7).....		
Shareholders' equity:		
Preferred stock, \$.01 par value; 5,000,000 shares authorized: 15,000 shares designated as Series D convertible preferred stock, \$.01 par value; 14,615 shares were issued and outstanding at December 30, 2007 and December 31, 2006.....	—	—
Common stock, \$.01 par value; 200,000,000 shares authorized; 78,269,186 shares and 73,620,477 shares issued and outstanding at December 30, 2007 and December 31, 2006, respectively	783	736
Additional paid-in capital	288,688	282,343
Accumulated deficit.....	(281,450)	(245,129)
Accumulated other comprehensive income.....	3	6
Total shareholders' equity.....	8,024	37,956
Total liabilities and shareholders' equity.....	<u>\$ 40,713</u>	<u>\$ 73,235</u>

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

GTC BIOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Dollars in thousands except share and per share amounts)

	For the Fiscal Years Ended		
	December 30, 2007	December 31, 2006	January 1, 2006
Revenues:			
Revenue	\$ 13,896	\$ 6,128	\$ 4,152
Costs of revenue and operating expenses:			
Cost of revenue	11,561	6,651	4,344
Research and development	28,925	25,401	21,145
Selling, general and administrative.....	9,834	9,723	8,428
Total cost of revenue and operating expenses.....	<u>50,320</u>	<u>41,775</u>	<u>33,917</u>
Operating loss	<u>(36,424)</u>	<u>(35,647)</u>	<u>(29,765)</u>
Other income (expense):			
Interest income.....	1,443	1,237	547
Interest expense.....	(1,329)	(1,001)	(1,140)
Other income (expense).....	<u>(11)</u>	<u>66</u>	<u>246</u>
Net loss.....	<u>\$ (36,321)</u>	<u>\$ (35,345)</u>	<u>\$ (30,112)</u>
Net loss per common share (basic and diluted).....	<u>\$ (0.47)</u>	<u>\$ (0.53)</u>	<u>\$ (0.62)</u>
Weighted average number of common shares outstanding (basic and diluted).....	<u>77,863,008</u>	<u>66,860,345</u>	<u>48,658,143</u>
Comprehensive loss:			
Net loss	\$ (36,321)	\$ (35,345)	\$ (30,112)
Other comprehensive gain (loss):			
Unrealized holding gain (loss) on available for sale securities.....	<u>(3)</u>	<u>49</u>	<u>93</u>
Total other comprehensive gain (loss).....	<u>(3)</u>	<u>49</u>	<u>93</u>
Comprehensive loss	<u>\$ (36,324)</u>	<u>\$ (35,296)</u>	<u>\$ (30,019)</u>

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

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

	Preferred Stock		Common Stock		Additional	Accumulated	Accumulated		Total
	Shares	Amount	Shares	Amount	Paid-in Capital Amount		Deficit	Other Comprehensive Income (Loss)	
Balance, January 2, 2005	—	\$ —	38,800	\$ 388	\$ —	\$ 213,073	\$ (179,672)	\$ (136)	\$ 33,653
Net loss							(30,112)		(30,112)
Common stock sold under Employee Stock Purchase Plan			213	2		261			263
Common stock issuance to the GTC Savings and Retirement Plan			130	1		192			193
Common stock issued under GTC Bonus Plan			81	1		138			139
Proceeds from the exercise of stock options			10			11			11
Proceeds from the issuance of common stock, net of offering costs of \$2,637			21,414	214		32,255			32,469
Unrealized gain on investment							93		93
Balance, January 1, 2006	—	\$ —	60,648	\$ 606	\$ —	\$ 245,930	\$ (209,784)	\$ (43)	\$ 36,709
Net loss							(35,345)		(35,345)
Common stock sold under Employee Stock Purchase Plan			133	2		118			120
Common stock issuance to the GTC Savings and Retirement Plan			165	2		182			184
Common stock issued under GTC Bonus Plan			543	5		554			559
Common stock issued under GTC Director Compensation Plan			6			7			7
Proceeds from the exercise of stock options			5			5			5
Proceeds from the issuance of preferred stock, net of offering costs of \$270	15					18,832			18,832
Proceeds from the issuance of common stock, net of offering costs of \$1,410			12,000	120		16,005			16,125
Stock grant to employees			120	1		146			147
Stock based compensation						564			564
Unrealized gain on investment							49		49
Balance, December 31, 2006	15	\$ —	73,620	\$ 736	\$ —	\$ 282,343	\$ (245,129)	\$ 6	\$ 37,956
Net loss							(36,321)		(36,321)
Common stock sold under Employee Stock Purchase Plan			176	2		166			168
Common stock issuance to the GTC Savings and Retirement Plan			279	4		307			311
Common stock issued under GTC Director Compensation Plan			52			55			55
Proceeds from the exercise of stock options			5			4			4
Proceeds from the issuance of common stock			3,630	36		4,446			4,482
Stock based compensation						847			847
Unrealized (loss) on investment							(3)		(3)
Common stock issued for Technology License			278	3		297			300
Common stock issued for legal settlement			225	2		223			225
Balance, December 30, 2007	15	\$ —	78,264	\$ 783	\$ —	\$ 288,688	\$ (281,450)	\$ 3	\$ 8,024

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

GTC BIOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Dollars in thousands)

	For the Fiscal Years Ended		
	December 30, 2007	December 31, 2006	January 1, 2006
Cash flows for operating activities:			
Net loss from operations.....	\$ (36,321)	\$ (35,345)	\$ (30,112)
Adjustments to reconcile net loss from operations to net cash used in operating activities:			
Depreciation and amortization.....	3,320	3,488	3,904
Stock based compensation.....	902	718	—
Amortization of premium (discount) on marketable securities.....	57	(369)	(304)
Common stock issuance to GTC savings and retirement plan.....	311	184	193
Inventory write off.....	3,412	1,343	419
Write off of intangible assets.....	—	497	147
Loss (gain) on disposal of fixed assets.....	22	—	(28)
Non-cash interest expense.....	225	10	—
Changes in assets and liabilities:			
Accounts receivable and unbilled contract revenue.....	45	(81)	521
Inventory.....	(320)	(3,092)	(1,296)
Other assets and liabilities.....	40	96	244
Accounts payable.....	537	1,932	2,238
Accrued liabilities.....	(399)	2,275	249
Deferred contract revenue.....	(1,754)	3,714	4,807
Net cash used in operating activities.....	(29,923)	(24,630)	(19,018)
Cash flows from investing activities:			
Purchase of property, plant and equipment.....	(1,567)	(1,101)	(671)
Purchase of intangible asset.....	(200)	—	—
Sale of property, plant and equipment.....	—	—	834
Purchase of marketable securities.....	(16,987)	(33,538)	(10,027)
Redemption of marketable securities.....	28,716	25,295	21,052
Net cash provided by (used in) investing activities.....	9,962	(9,344)	11,188
Cash flows from financing activities:			
Proceeds from the LFB financing, net of offering costs.....	4,482	20,265	—
Proceeds from the issuance of common stock, net of offering costs.....	—	16,125	32,469
Net proceeds from employee stock purchase plan.....	168	120	263
Net proceeds from the exercise of stock options.....	4	5	11
Proceeds from long-term debt, net of financing costs.....	—	9,760	4,800
Repayment of long-term debt.....	(974)	(13,296)	(5,197)
Net cash provided by financing activities.....	3,680	32,979	32,346
Net increase (decrease) in cash and cash equivalents.....	(16,281)	(995)	24,516
Cash and cash equivalents at beginning of the period.....	25,356	26,351	1,835
Cash and cash equivalents at end of the period.....	<u>\$ 9,075</u>	<u>\$ 25,356</u>	<u>\$ 26,351</u>
Supplemental disclosure of cash flow information:			
Cash paid during the period for interest.....	\$ 961	\$ 976	\$ 1,115
Common stock issuance for Technology License.....	300	—	—
Common stock issuance for legal settlement.....	225	—	—

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Fiscal years ended December 30, 2007, December 31, 2006 and January 1, 2006 (fiscal 2005) (all tabular \$ in thousands, except per share data).

NOTE 1. NATURE OF BUSINESS

We are the leader in the development and production of human therapeutic proteins through transgenic technology that enables animals to produce what is known as a recombinant form of a specified human protein in their milk. Using this technology, we are developing a portfolio of recombinant blood proteins to treat a range of genetic and acquired blood deficiencies, including hemophilia and other blood coagulation disorders. These blood proteins, also known as plasma proteins, are difficult to produce in other manufacturing systems, and some are currently only available by extraction from human blood. We have also initiated the development of a portfolio of monoclonal antibodies, or MAb's, for use as potential follow-on biologics targeted at several large market products.

Our first product ATryn[®], our recombinant form of human antithrombin, validated our transgenic production technology's capability to meet the regulatory requirements for recombinant proteins. In 2006, ATryn[®] became the first transgenically produced therapeutic protein to be approved anywhere in the world when we obtained European Commission approval of the use of ATryn[®] as a prophylactic treatment for patients with hereditary antithrombin deficiency, or HD, undergoing surgical procedures. In February 2008, we announced that ATryn[®] had met the statistical requirements for the primary endpoint in our pivotal trial to support our filing of a Biologics License Application, or BLA, for the use of ATryn[®] in the United States in HD patients undergoing surgery or childbirth. We plan to complete the filing of the BLA in mid-2008.

We plan to develop ATryn[®] and many of our other recombinant proteins through strategic collaborations. Under our exclusive collaboration agreement entered into with LEO Pharma A/S in 2005, LEO is sponsoring the clinical development of ATryn[®] in Europe for a new indication of disseminated intravascular coagulation, or DIC, in severe sepsis. In September 2006, we entered into a collaboration agreement with LFB Biotechnologies, or LFB, to develop selected recombinant plasma proteins and MAb's. The first program in this collaboration is for the development of a recombinant form of human blood coagulation factor VIIa for the treatment of patients with hemophilia. We have subsequently added to the LFB collaboration a program to develop a recombinant form of human blood coagulation factor IX, as well as a program to develop an antibody to the CD20 immune system receptor, the same target as for the MAb marketed as Rituxan[®]. We are engaged in business development activities with the objective of adding additional collaborations.

We are subject to risks common to companies in the biotechnology industry, including, but not limited to, the uncertainties of clinical trials and regulatory requirements for approval of therapeutic compounds, the need for additional capital, competitive new technologies, dependence on key personnel, protection of proprietary technology, and compliance with the FDA and other United States and foreign government regulations. Our consolidated financial statements have been presented on the basis that we are a going concern, which contemplates the continuity of business, realization of assets and the satisfaction of liabilities in the ordinary course of business. We have incurred losses from operations and negative operating cash flow in each fiscal year 2007, 2006 and 2005 and have an accumulated deficit of approximately \$281 million at December 30, 2007. Based on our cash balance as of December 30, 2007, as well as potential cash receipts from existing programs and our receipt of approximately \$5.5 million in net proceeds from our registered direct offering in February 2008, we believe our resources will be sufficient to fund operations into the second half of 2008. Our recurring losses from operations and limited funds raise substantial doubt about our ability to continue as a going concern. Our plans with regard to these matters include seeking additional financing arrangements and seeking collaboration arrangements with corporate sources. The financial statements do not include any adjustments relating to the recoverability and classification of recorded assets or the amount of reclassification of liabilities, or any adjustments that might be necessary should we be unable to continue as a going concern. The primary sources of additional capital raised in 2007, 2006 and 2005 have been equity financings and debt financings under our credit facility. Management expects that future sources of funding may include new or expanded partnering

arrangements and sales of equity or debt securities. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. We may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our planned commercialization efforts, or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialized independently. Additionally, any future equity funding may dilute ownership of our equity investors.

NOTE 2. SIGNIFICANT ACCOUNTING POLICIES

Basis of Consolidation

The consolidated financial statements include our results, the results of our wholly-owned subsidiaries and our Taurus hSA LLC joint venture. We consolidate the Taurus hSA LLC joint venture for financial reporting purposes (see Note 12). All significant inter-company transactions have been eliminated and we operate in one business segment.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The significant estimates and assumptions in these financial statements include revenue recognition, collectibility of accounts receivable and unbilled revenues, estimates of accrued expenses, valuation of inventory and tax valuation reserves. Actual results could differ materially from those estimates.

Cash and Cash Equivalents

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

Marketable Securities

Marketable securities have been classified as available for sale and are stated at market value based on quoted market prices. Gains and losses on sales of securities are calculated using the specific identification method. Marketable securities at December 30, 2007 and December 31, 2006 can be summarized as follows:

	December 30, 2007		December 31, 2006	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Government backed obligations	\$ —	\$ —	\$ 2,983	\$ 2,984
Corporate obligations	6,688	6,690	15,496	15,496
Total marketable securities	<u>\$ 6,688</u>	<u>\$ 6,690</u>	<u>\$ 18,479</u>	<u>\$ 18,480</u>

Maturities of our marketable securities at December 30, 2007 and December 31, 2006 are less than one year.

At December 30, 2007, December 31, 2006 and January 1, 2006 the change in unrealized gain (loss) on marketable securities included in other accumulated comprehensive income and equity was \$(3,000), \$49,000 and \$93,000, respectively. All realized gains (losses) on available for sale securities in 2007, 2006 and 2005, were immaterial. At December 30, 2007, the contractual maturities of our investments available for sale range from 1 month to 3 months. All of our investments are classified as short-term, which is consistent with their intended use and maturity dates. There were no unrealized losses on marketable securities at December 30, 2007 or December 31, 2006.

Concentration of Credit Risk

Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash, cash equivalents, marketable securities and trade accounts receivable. At December 30, 2007 and December 31, 2006, approximately 100% of cash, cash equivalents and marketable securities were held by one United States financial institution and exceed federally insured limits.

We perform ongoing credit evaluations of our customers' financial conditions and maintain reserves for potential credit losses. There were no reserves required for 2007, 2006 or 2005, nor were there any write-offs for fiscal 2007, 2006 and 2005.

At December 30, 2007, there were no accounts receivable. At December 31, 2006 and January 1, 2006, one customer and four customers, respectively, accounted for 100% of accounts receivable.

The following table summarizes our revenues by customer / partner as a percent of revenue in the last three years:

	<u>2007</u>	<u>2006</u>	<u>2005</u>
Merrimack	29%	54%	29%
LEO.....	32%	32%	—
PharmAthene.....	28%	—	—
Centocor.....	—	1%	7%
Elan (Tysabri® - formerly Antegren®)	—	—	35%
Other	11%	13%	29%
	<u>100%</u>	<u>100%</u>	<u>100%</u>

Property, Plant and Equipment

Property, plant and equipment are stated at cost and are 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 purchase of the New Zealand goats ("Livestock (NZ)") are capitalized and amortized using the straight-line method over their estimated useful lives of five years.

We capitalize those incremental costs that are incurred in obtaining approval from the FDA or EMEA for manufacturing assets and the related processes for bulk drug production. Under Statement of Financial Accounting Standards (SFAS) No. 34, "Capitalization of Interest Costs," the historical cost of acquiring an asset includes the costs necessarily incurred to bring it to the condition and location necessary for its intended use. The capitalization period begins when expenditures for the asset have been made and activities that are necessary to get the asset ready for its intended use are in progress. Pursuant to regulations of the FDA or the EMEA, a facility and its related manufacturing assets must achieve "process qualification" in order for it to be approved, or "validated," for commercial production. Without approval from the FDA or the EMEA, the facility cannot be placed into service for commercial production; accordingly, the incremental validation costs we incur are an essential part of preparing the related assets for their intended use. Approval by the FDA will allow us to market products for sale in the U.S. We received approval for ATryn® from the EMEA in 2006, which will allow us to market that product in Europe through our collaboration with LEO.

The costs that we have capitalized to date are those costs that are related to FDA or EMEA approval of the manufacturing equipment to be used for the bulk production of ATryn® and are being depreciated over the expected life of the facility. These include the costs of employees and third parties directly involved in the process, direct material consumed in the validation process, and incremental fixed overhead. Costs that are excluded from capitalization include costs of maintenance, process development/improvement and fixed overhead. As of December 30, 2007 and December 31, 2006, we had approximately \$1.8 million and \$2.1 million, respectively, of capitalized validation costs, net of accumulated amortization, included in property, plant and equipment. The capitalized validation costs are being depreciated over five years.

The following is the summary of property, plant and equipment and related accumulated amortization and depreciation as of December 30, 2007 and December 31, 2006.

	Years of Life	December 30, 2007	December 31, 2006
Land	—	\$ 909	\$ 909
Buildings.....	20-30	14,132	14,146
Livestock (NZ).....	3-5	2,842	2,842
Leasehold improvements.....	leaselif	2,341	2,085
Laboratory, manufacturing and office equipment	3-10	13,576	12,619
Laboratory, manufacturing and office equipment—capital lease	3-10	1,143	1,143
		<u>34,943</u>	<u>33,744</u>
Less accumulated amortization and depreciation		<u>(20,494)</u>	<u>(18,408)</u>
Net property, plant and equipment		<u>\$ 14,449</u>	<u>\$ 15,336</u>

Depreciation and amortization expense was \$2,432,000, \$2,500,000 and \$2,869,000, for the fiscal years ended December 30, 2007, December 31, 2006 and January 1, 2006, respectively. Accumulated amortization for equipment under capital lease was \$1,127,000, \$1,118,000 and \$1,106,000 at December 30, 2007, December 31, 2006 and January 1, 2006, respectively.

In March 2005, we completed the sale of 135 acres of farm land located in eastern New York State. As a result of the sale, we received net proceeds of approximately \$534,000 and recorded a gain of approximately \$29,000. Also during 2005, we purchased \$300,000 of fixed assets and financed these additions with operating lease obligations.

Long-Lived Assets

Management's policy regarding long-lived assets is to evaluate the recoverability of our 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 undiscounted net operating cash flow over the remaining life of the asset. If an impairment exists, it is measured by the excess of the carrying value over the discounted cash flows. Any write-downs are to be treated as permanent reductions in the carrying amount of the assets.

Share-Based Compensation

Effective January 2, 2006, we adopted SFAS 123(R) Share-Based Payment (or SFAS 123(R)), which requires companies to measure and recognize compensation expense for all share-based payments at fair value. SFAS 123(R) is being applied on the modified prospective basis. Prior to the adoption of SFAS 123(R), we accounted for our share-based compensation plans under the recognition and measurement principles of Accounting Principles Board, or APB, Opinion 25, Accounting for Stock Issued to Employees, and related interpretations. We did not recognize compensation expense related to the share-based plans because the options were granted with an exercise price equal to the fair market value on the date of the grant.

Under the modified prospective approach, SFAS 123(R) applies to new awards and to awards that were outstanding on January 2, 2006. Under the modified prospective approach, compensation expense recognized during fiscal 2006 includes compensation expense for all share-based payments granted prior to, but not yet vested on, January 2, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123, and compensation expense for all share-based payments granted subsequent to January 2, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R). Prior periods were not restated to reflect the impact of adopting the new standard.

Revenue Recognition and Contract Accounting

We enter into licensing and development agreements with collaborative partners for the development, production and purification of our internally developed recombinant protein candidates or for a transgenically produced version of the partner's therapeutic recombinant proteins. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon the achievement of certain milestones and royalties on future product sales, if any. In September 2005, we entered into a manufacturing service agreement with Merrimack Pharmaceuticals for the production of a therapeutic recombinant protein of Merrimack that we produce in the milk of transgenic animals. The terms of the agreement include payments for maintenance services, manufacturing suite time and cost to scale up the production herd. In addition, we have entered into a license and supply agreement with LEO for the production of ATryn[®]. The terms of the supply agreement with LEO includes non-refundable license fees, transfer price for products delivered, royalties on future net sales and potential milestone payments to us for meeting regulatory, clinical and sales goals.

We recognize revenue in accordance with Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" (SAB No. 101), as amended by Staff Accounting Bulletin No. 104, "Revenue Recognition" (SAB No. 104), and Emerging Issues Task Force Issue No. 00-21, "Revenue Agreements with Multiple Deliverables" (EITF No. 00-21).

Revenues from the sale of products and services are recognized when persuasive evidence of an agreement exists, delivery has occurred or services have been rendered, the fees are fixed and determinable, and collectibility is reasonably assured. Revenues from royalties on third-party sales of licensed technologies are generally recognized in accordance with the contract terms when the royalties can be reliably determined and collectibility is reasonably assured.

We assess multiple element revenue arrangements involving upfront payments, license fees, manufacturing services and milestone payments received for the delivery of rights or services. The following criteria must be met for an element to represent a separate unit of accounting:

- a) The delivered items have value to a customer on a standalone basis;
- b) There is objective and reliable evidence of the fair value of the undelivered items; and
- c) Delivery or performance is probable and within our control for any delivered items that have a right of return.

If these criteria are met, we apply the appropriate revenue recognition model as described above to each separate unit of accounting. If these criteria are not met, elements are combined into a single unit of accounting and revenue is not recognized until we have verifiable objective evidence of the undelivered element. Upfront payments and license fees are recognized ratably over the longer of the contractual term or expected relationship period. Payments for the achievement of substantive milestones are recognized when the milestone is achieved. Payments for milestones which are not the result of the achievement of a substantive milestone, are recognized ratably over the longer of the remaining contractual term or expected relationship period.

Revenue is also recognized in accordance with SAB 101 FAQ 13 (EITF 91-6). Under that model, revenue is recognized using the lesser of non-refundable cash received and milestones met or the result achieved using level-of-efforts accounting. The estimated costs to complete each program are based on the contract terms and detailed program plans, including cost projections, of each program under review. All revenue recognition estimates are made based upon the current facts and circumstances and are reassessed on at least a quarterly basis. There are a number of factors which could cause the need for a revision to these estimates, which in turn may have the effect of increasing or decreasing revenue in the current period as they become known. These factors include unforeseen additional costs, delay in a program, efficiencies or decisions at the partner's discretion.

Deferred revenue arises from payments received in advance of the culmination of the earnings process. Deferred revenue expected to be recognized within the next twelve months is classified as a current liability. Deferred revenue will be recognized as revenue in future periods when the applicable revenue recognition criteria have been met.

Inventory

All of our inventory on hand as of December 30, 2007 was work in process inventory. The net book value of our inventory as of December 30, 2007 was zero because our estimated cost to complete current orders from LEO exceeds the agreed upon maximum transfer price. All of the inventory on hand at December 31, 2006 was work in progress.

We carry inventory at the lower of cost or market using the first-in, first-out method. Inventories on hand at December 31, 2006 were related to ATryn[®], which we capitalized after completion of the clinical trials in anticipation of marketing approval for commercial sale in Europe. We expect that all inventory which we capitalize will be sold to LEO for clinical trials and commercial use. If at any time we believe that the sale of inventory to LEO is no longer probable, we will charge the inventory to expense. Because our current cost of production exceeds our agreed upon maximum price, we are expensing these excess costs as incurred. Once our cost of production falls below the agreed upon maximum price, we will capitalize all those costs. We anticipate our cost of production will be substantially reduced as we move to larger production volumes to support clinical and commercial requirements.

During 2006 and 2005, following delays in regulatory approvals, we wrote off to research and development expense portions of the ATryn[®] inventory that were designated for clinical trials as well as inventory that was used for development purposes or expected to expire prior to sale.

During 2007 we wrote off in-process inventory which was rendered unusable as a result of the fill/finish process at the facility of our U.S. based third party fill/finish contractor. We recorded a charge of approximately \$2,943,000 to cost of sales in connection with the write off. None of this material had been released for clinical or commercial use. In addition, we wrote off in-process inventory which was determined not to meet specifications during release testing for commercial use. We recorded a charge of \$469,000 to cost of sales in connection with this write-off.

We analyze our inventory levels quarterly and will write down inventory that is expected to expire prior to sale, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements. Expired inventory will be disposed of and the related costs will be written off. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required. Also, if we should need to use a portion of the capitalized inventory for clinical trials, we would expense the inventory when it was designated for use in such clinical trial.

Research and Development Costs

All research and development costs are expensed as incurred. During our fiscal years ended December 30, 2007, December 31, 2006 and January 1, 2006, we incurred development expenses of \$28.9 million, \$25.4 million and \$21.1 million, respectively, related to proprietary programs. Of the total spent on research and development, \$20.5 million, \$20.3 million and \$12.6 million, was spent on the ATryn[®] development program in fiscal years 2007, 2006 and 2005, respectively, which included manufacturing costs for our U.S. clinical trial, manufacturing costs of clinical material in excess of the maximum selling price to LEO, as well as process development and validation costs for scale up of the ATryn[®] manufacturing process. These costs include labor, materials, supplies and overhead, as well as certain subcontracted research projects. Also included are the costs of operating the transgenic production facility such as feed and bedding, veterinary costs and utilities.

Net Loss per Common Share

We apply Statement of Financial Accounting Standards No. 128 ("SFAS 128"), *Earnings Per Share* in calculating earnings per share. Potential common shares consist of warrants (see Note 8), stock options (see Note 9) and stock to be issued under the defined contribution retirement plan (see Note 9). We were in a net loss position in 2007, 2006 and 2005, and, therefore, 35.4 million, 35.6 million and 13.3 million of potential common shares, respectively, were not used to compute diluted loss per share, as the effect was antidilutive. We also have a convertible note in the original principal amount of approximately \$2.6 million to LFB, which automatically converts into shares of our common stock in conjunction with any future common stock offerings at the per share offering price of the respective offering but only to the extent that any conversion does not result in LFB's holdings exceeding 19.9% of our common stock on an as-converted basis. In connection with the closing of our

February 2008 registered direct offering, \$1.7 million of the principal amount of this note and approximately \$40,000 of accrued interest on that principal amount were converted into 2 million shares of our common stock at a rate of \$0.87 per share. LFB's ownership remained at 19.9% after the conversion.

Income Taxes

We account 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 Pronouncements

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ("SFAS 157"), which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 applies under other existing accounting pronouncements that require or permit fair value measurements, the FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, SFAS 157 does not require any new fair value measurements. However, the application of this statement may change our current practice for fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. We are currently evaluating the impact this statement will have on our financial position and results of operations.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities—Including an Amendment of FASB Statement No. 115* ("SFAS 159"). SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. SFAS 159 permits all entities to choose, at specified election dates, to measure eligible items at fair value (the "fair value option"). A business entity shall report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. Upfront costs and fees related to items for which the fair value option is elected shall be recognized in earnings as incurred and not deferred. SFAS 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between entities that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. We are currently evaluating the impact this statement will have on our financial position and results of operations, if any.

In June 2007, the Emerging Issues Task Force ("EITF") reached a final consensus on EITF Issue No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities" ("EITF 07-3"). EITF 07-3 is effective for fiscal years beginning after December 15, 2007. EITF 07-3 requires that non-refundable advance payments for future research and development activities should be capitalized until the goods have been delivered or related services have been performed. Adoption is on a prospective basis and could impact the timing of expense recognition for agreements entered into after December 31, 2007. We do not expect the adoption of EITF 07-3 to have a significant impact on our consolidated financial statements.

NOTE 3. SIGNIFICANT AGREEMENTS

LEO Pharma A/S ("LEO")

In November 2005, we entered into a collaboration agreement with LEO to develop and market ATryn[®], for markets in LEO's territories of Europe, the Middle East, and Canada. Our agreement with LEO includes up to \$73 million in potential milestone payments from LEO to us for meeting regulatory, clinical and sales goals.

These payments include a total of \$5 million in non-refundable payments that we received upon entering the collaboration agreement and for achieving approval of ATryn[®] for the HD indication in Europe. These milestone revenues are being recognized over the life of the agreement on a straight-line basis beginning with the first delivery of ATryn[®] material to LEO, which occurred in the fourth quarter of 2006. As of December 30, 2007, \$4.7 million of the total amount received from LEO was accounted for as deferred revenue.

In our collaboration with LEO we are responsible for the production of ATryn[®]. LEO pays for all product used in clinical studies as well as for commercial sale. For product sold for approved therapeutic use, LEO will pay us a royalty on all commercial sales, as well as a transfer price. We are paid by LEO for clinical material based on our fully burdened costs subject to a maximum price per unit, which is currently less than our costs to produce the material. LEO has exclusive rights for sales and marketing of ATryn[®] in all indications in LEO's territories. We retain all rights to ATryn[®] in all other territories, including the United States and Japan.

LFB Biotechnologies ("LFB")

In September 2006, we entered into a collaboration agreement with LFB, a related party, to develop selected recombinant plasma proteins and MAb's using our transgenic production platform. LFB is a subsidiary of LFB S.A., a vertically integrated plasma fractionation company based in Paris, France that currently markets 19 plasma-derived products in the areas of hemostasis, anesthesia-intensive care and immunology. LFB S.A. is a for-profit company currently 100% owned by the French government. The first program in this collaboration is for the development of rhFVIIa. We have subsequently added to the LFB collaboration a program to develop a recombinant form of human factor IX as well as a program to develop an antibody to the CD20 immune system receptor. Under this agreement, we will share equally with LFB in the cost of the development and commercialization of each product and will be entitled to 50% of any profits derived from products developed through the collaboration, provided we each contribute equally to the costs of their development. During 2007, we received approximately \$1.2 million in funding from LFB as reimbursement for an agreed portion of our costs incurred in the programs in the collaboration which was recorded against research and development expenses. In the event that contributions to development are not equal, the profit allocation will be adjusted based on development costs incurred. Under the agreement, a joint steering committee of each company's representatives will determine product development and commercialization plans. We will be responsible for development of the production system for the products and will retain exclusive commercial rights to the products in North America. LFB will be responsible for clinical development and regulatory review of the programs in this collaboration, and will have exclusive commercial rights in Europe. We will hold co-exclusive rights with LFB in the rest of the world to any products developed through the collaboration. The initial term of the agreement is fifteen years, subject to extension or termination by mutual consent, and the terms for any product developed through the collaboration will continue until the later of the initial term or ten years beyond regulatory approval of that product.

In connection with the collaboration agreement, we entered into a purchase agreement with LFB pursuant to which LFB committed to purchase up to an aggregate of \$25 million of shares of convertible preferred stock, shares of common stock and a subordinated convertible note. Each preferred stock is convertible into 1,000 shares of common stock at the option of the preferred stock holder any time subsequent to the issuance. The purchase price of the shares of stock is \$1.23 per common share equivalent, which was the market value of our common stock on the date of the agreement. These securities were issued and sold in three tranches, or installments, the first of which involved LFB's purchase on October 4, 2006 of 5,000 shares of our newly designated Series D preferred stock representing 5 million common share equivalents at an aggregate purchase price of \$6.15 million. In the second tranche, LFB purchased an additional 9,615 shares of Series D preferred stock at an as converted per share price of \$1.23 and a subordinated convertible note in the principal amount of approximately \$2.56 million, for an aggregate purchase price of approximately \$14.39 million. The convertible note has a term of five years, accrues interest at a rate of 2.0% per annum and will automatically convert into shares of our common stock in conjunction with any future common stock offerings at the per share offering price of the respective offering, but only to the extent that any conversion does not result in LFB's holdings to exceed 19.9% of our common stock on an as converted basis. As sole holder of the Series D preferred stock, LFB became entitled to designate a director to serve on our board. In the third tranche, which closed on January 3, 2007, LFB purchased 3,630,000 shares of common stock at a price of \$1.23 per share, for an aggregate purchase price of approximately \$4.46 million. Completion of the second and third tranches was subject to our receipt of certain shareholder

approvals, which were obtained on December 5, 2006. As of December 30, 2007 and December 31, 2006, LFB held, on an as converted basis, approximately 19.6% and 19.9% of our common stock, respectively. In connection with the closing of our February 2008 registered direct offering, \$1.7 million of the principal amount of the note and approximately \$40,000 of accrued interest on that note were converted into 2 million shares of our common stock at a rate of \$0.87 per share. LFB's ownership remained at 19.9% after the conversion.

Merrimack Pharmaceuticals, Inc. ("Merrimack")

In September 2005, we entered into a three year agreement for further production of MM-093 for Merrimack. Under a Master Agreement, the parties acknowledged that the work done under the earlier agreements had been successfully completed and that the parties intend to enter into new agreements to continue the production of transgenic rhAFP exclusively by us.

Our primary responsibilities include maintaining facilities, staffing, equipment and quality systems. For the detailed services, Merrimack pays us for a combination of fees for equivalent full time employees and fixed charges for suite usage and material testing and release. In addition, Merrimack is required to pay royalties to us based on Merrimack's net revenues and net partner sales.

As of December 30, 2007, we had approximately \$2.2 million of deferred revenue related to these agreements.

PharmAthene, Inc. ("PharmAthene")

In March 2007, we entered into a process and development and clinical supply manufacturing services agreement with PharmAthene for Protexia[®] as well as an agreement providing PharmAthene an expanded license to our patent rights, which will support the further development, manufacturing, regulatory approval and commercialization process for PharmAthene's Protexia[®] program. The development of Protexia[®] is funded by the United States Department of Defense.

NOTE 4. ACCRUED LIABILITIES

Accrued liabilities included the following:

	<u>At December 30, 2007</u>	<u>At December 31, 2006</u>
Accrued payroll and benefits.....	\$ 1,922	\$ 1,740
Accrued bonuses.....	814	1,167
Amounts owed to third party manufacturer.....	1,532	535
Other	303	1,753
Total accrued expenses	<u>\$ 4,571</u>	<u>\$ 5,195</u>

NOTE 5. COMMITMENTS AND CONTINGENCIES

We lease equipment and facilities under various operating leases. Rent expense for the fiscal years ended December 30, 2007, December 31, 2006 and January 1, 2006 was approximately \$2,540,000, \$1,868,000 and \$1,891,000, respectively.

At December 30, 2007, our future minimum payments required under these leases were as follows:

	<u>Operating</u>
2008	\$ 1,834
2009	1,673
2010.....	1,289
2011	228
2012 and thereafter	<u>3</u>
Total	<u>\$ 5,027</u>

In February 2007, we signed a lease amendment to lease an additional 8,188 square feet of office space which expires in September 2010.

We are a party to license agreements for certain technologies (see Note 3). Several 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 our behalf are unknown and cannot be practically estimated since the level of future sales, if any, is uncertain.

Under a Sublease Agreement with Genzyme (see Note 11), we committed to make a minimum annual payment of approximately \$478,000 in 2008 which is not included in the above table.

On November 13, 2001, two employees of one of our former subsidiaries filed an action against us in the Court of Common Pleas for Philadelphia County in Pennsylvania seeking damages, declaratory relief and certification of a class action relating primarily to their GTC stock options. On February 15, 2007, the parties agreed to settle these claims under terms which provide that our insurer will pay \$175,000 in cash and we will deliver \$225,000 of our Common Stock. We accrued this settlement as of December 31, 2006. We issued 225,000 shares of Common Stock in the settlement at \$1.00 per share in 2007. The number of shares of Common Stock which were issued was determined based on the per share market value of the Common Stock on the date of issue after the Court concluded a fairness hearing regarding the settlement.

We maintain our herd of cattle for the Taurus hSA LLC at TransOva Genetics in Iowa under an agreement signed in December 2002. As part of the agreement, TransOva agreed to be compensated partially in equity of Taurus only when, and if, Taurus receives outside third party financing. The amount of equity would be valued under the same terms as such outside financing. Any issuance of Taurus equity to TransOva under the agreement is not expected to result in any material expense to us.

NOTE 6. INTANGIBLE ASSETS

In 1990, we established the SMIG JV joint venture with Sumitomo Metal Industries Group to develop proteins transgenically for Asian markets. In September 2000, we acquired full ownership of the SMIG JV from Sumitomo in exchange for shares of our Common Stock valued at approximately \$11.2 million. As a result, we hold the marketing rights to transgenic technology in 18 Asian countries, including Japan. The entire purchase price of \$11.2 million was allocated to the value of the marketing rights (SMIG marketing rights), the sole assets of SMIG. These costs are being amortized over the estimated 15-year economic useful life of these rights from the date of purchase. These rights relate to our current business as they allow us to sell transgenic proteins in Asia. Without these rights, we would have been severely limited in our ability to pursue key Asian markets, primarily Japan, and would have had a substantial royalty obligation for any revenues derived from Asia and Europe. We are pursuing opportunities in these markets for our transgenic products in development.

In June 2002, we obtained licenses to technology relative to transgenic milk expression, transgenic cattle technology and nuclear transfer technology from Pharming Group N.V., or Pharming. The license provided for a payment of 1.5 million Euro, or approximately \$1.5 million, which was paid in July of 2002. These licenses relate to technology, some of which is currently being used in our ongoing activities and, therefore, their associated costs are reported as an intangible asset at December 30, 2007 and are being amortized over a 15-year period, the remaining life of the underlying patents.

In November 2006 the Management Committee of the Taurus Joint Venture, a joint venture between GTC and Fresenius-Kabi to develop hSA in cattle, agreed that neither GTC nor Fresenius-Kabi would fund the recombinant albumin program during the next 12 months. As a result of prioritizing our resources to other development programs, we are minimizing further investment in this program at this time. We determined that this was an event that triggered an impairment review of our Pharming intangible asset. The Pharming technology includes significant general animal development technology as well as bovine technology. It supports our overall animal transgenic platform including basic promoter technology which is a key component to our transgenic technology platform. We concluded that the estimated value of our intangibles was greater than its net book value at December 31, 2006. Judgments used during the analysis included the estimation of the value of revenues to be achieved from our overall business plan for all products produced transgenically.

In April 2007, we obtained a non-exclusive license from Start Licensing, Inc., or Start, for the patents and patent applications developed by the Roslin Institute to apply nuclear transfer to the production of therapeutic proteins in the milk of transgenic animals. Financial terms include an upfront payment of \$500,000, of which \$200,000 was paid in cash to Start, and a total of 278,370 shares of our common stock, with an aggregate value of approximately \$300,000, were issued, divided equally between Start and Exeter. The license agreement remains in place through the last patent to expire, which is expected to occur in 2016 for the currently issued patents. Accordingly, the \$500,000 license fee was recorded as an intangible asset in 2007 and is being amortized using the straight-line method over approximately 9 years. There will also be a royalty payable to Start for the commercialization of any products developed with the patented nuclear transfer technology. Our ATryn[®] product was not developed using this technology.

Intangible assets consist of:

	<u>Amortization Life</u>	<u>December 30, 2007</u>	<u>December 31, 2006</u>
Marketing rights	15 years	\$ 11,210	\$ 11,210
Accumulated amortization—marketing rights		<u>(5,480)</u>	<u>(4,733)</u>
Net.....		<u>5,730</u>	<u>6,477</u>
Technology licenses (see Note 3).....	10 years to 15 years	2,017	1,517
Accumulated amortization—technology licenses		<u>(596)</u>	<u>(455)</u>
Net.....		<u>1,421</u>	<u>1,062</u>
Total intangible assets, net.....		<u>\$ 7,151</u>	<u>\$ 7,539</u>

Amortization expense was \$888,000, \$988,000 and \$1,035,000 in 2007, 2006 and 2005, respectively.

At December 30, 2007, the estimated aggregate amortization expense was as follows:

2008	\$ 902
2009	\$ 902
2010.....	\$ 902
2011	\$ 902
2012.....	\$ 902
2013 and thereafter	\$ 2,643

NOTE 7. BORROWINGS

On April 4, 2002, we repurchased 2.82 million shares of our Common Stock from Genzyme, which was recorded as treasury stock. We purchased the shares for an aggregate consideration of approximately \$9.6 million, consisting of approximately \$4.8 million in cash and a promissory note to Genzyme for the remaining \$4.8 million. The principal was payable in two installments: \$2.4 million, due and paid on April 4, 2005, and \$2.4 million due on April 4, 2006 and paid in January 2006.

In May 2004, we entered into a four year loan agreement with General Electric Capital Corporation, or GE Capital, in the amount of \$10 million, which was used to repay an outstanding loan from Silicon Valley Bank. Also in connection with the refinancing, we were required to provide \$450,000 of cash collateral for our two outstanding stand-by letters of credit, which appears as restricted cash on the balance sheet. In February 2005, we increased the term loan with GE Capital to allow us to draw down an additional \$2.4 million which was used to pay down the note due to Genzyme in April 2005. In December 2005, we further increased the term loan with GE Capital to allow us to refinance the final \$2.4 million payment on the note payable to Genzyme due in 2006. The term loans were refinanced in December 2006.

In December 2006, we entered into a new term loan with GE Capital in the amount of \$10 million, of which \$7.1 million was used to pay off the existing loans from GE Capital. There are two separate amortization schedules, the first in the amount of \$8 million carries a fixed 10.8% annual interest rate and monthly payments of principal and interest of approximately \$109,000 through December 2011 with a balloon payment of approximately \$5.2

million in January 2012. The second in the amount of \$2 million carries a fixed 10.84% annual interest rate and monthly payments of principal and interest of approximately \$65,000 through January 2010. Collateral for the loan includes all of our existing and future acquired assets, excluding intellectual property.

In December 2006, as part of the second tranche under the LFB agreement, we issued to LFB a \$2.6 million, five-year convertible note. The note accrues interest at a rate of 2% per annum and will automatically convert into shares of our common stock in conjunction with any future common stock offerings at the per share offering price of the respective offering, but only to the extent that any conversion does not result in LFB's holdings exceeding 19.9% of our common stock on an as converted basis. In connection with the closing of our February 2008 registered direct offering, \$1.7 million of the principal amount of this note and approximately \$40,000 of accrued interest on that principal amount were converted into 2 million shares of our common stock at the rate of \$0.87 per share. Based on our effective borrowing rate of 10.8%, we recorded a debt discount of approximately \$1.1 million for the difference between the stated interest rate and the effective borrowing rate. The debt discount is being amortized over the five year term of the note, resulting in additional interest expense of approximately \$224,000 and \$10,000 during fiscal year 2007 and fiscal year 2006, respectively.

Our long-term debt consisted of the following:

	<u>December 30, 2007</u>	<u>December 31, 2006</u>
GE Capital loan, with monthly payments of approximately \$109 through December 2011, fixed annual interest rate of 10.8%, collateralized by all existing and future acquired assets, excluding intellectual property	7,571	8,000
GE Capital loan, with monthly payments of approximately \$65 through January 2010, fixed annual interest rate of 10.84%, collateralized by all existing and future acquired assets, excluding intellectual property	1,456	2,000
Convertible note to LFB, fixed annual interest of 2%, net of debt discount	<u>1,667</u>	<u>1,443</u>
	10,694	11,443
Less current portion.....	<u>1,177</u>	<u>973</u>
	<u>\$ 9,517</u>	<u>\$ 10,470</u>
Maturities of long-term debt are as follows:		
2008	\$ 1,177	
2009	1,311	
2010	708	
2011 ⁽¹⁾	3,275	
2012 and thereafter	<u>5,113</u>	
	<u>\$ 11,584</u>	

⁽¹⁾ Based on our effective borrowing rate of 10.8%, we recorded a debt discount of approximately \$1.1 million for the difference between the stated interest rate and the effective borrowing rate. The debt discount is being amortized over the five-year term of the note.

Based on the borrowing rates currently available to us for loans with similar terms and average maturities, the value of the notes payable approximates fair value.

NOTE 8. STOCKHOLDERS' EQUITY

Authorized Shares

Our authorized capital stock consists of 200,000,000 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 75,000 shares are designated as Series C Junior Participating Convertible Preferred Stock (the Series C Preferred Stock) and 15,000 shares are designated as Series D Preferred Stock, par value \$0.01 per share. In March 2001, our Board of Directors restored all unissued or reacquired shares of our 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

On May 31, 2001, our Board of Directors adopted a Shareholder Rights Plan (the "Plan") as set forth in the Shareholder Rights Agreement, dated May 31, 2001, between GTC and American Stock Transfer and Trust Company, as Rights Agent (the "Rights Agreement"). A series of our preferred stock, designated as Series C Preferred Stock, par value \$0.01 per share, was 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 GTC without offering a fair and adequate price and terms to all of our 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 GTC is made in the future. Pursuant to the Rights Agreement, the Board of Directors declared a dividend distribution of one preferred stock purchase right for each outstanding share of our Common Stock to shareholders of record as of June 1, 2001. The preferred stock purchase rights are attached to, and will trade with, our Common Stock. The purchase rights are currently exercisable upon the occurrence of certain triggering events described in the Rights Agreement.

Common Stock Placements

In January 2005, we sold 7,740,739 shares of our Common Stock at \$1.35 per share in a registered direct offering to institutional investors. We received proceeds from this sale, net of approximately \$700,000 in offering costs and fees, of approximately \$9.7 million.

In August 2005, we sold 4,571,429 shares of our Common Stock at \$1.75 per share and 5-year warrants to purchase an aggregate of 1,828,573 shares of our Common Stock at an exercise price of \$2.68 per share in a private placement to institutional investors, which are exercisable on or after February 10, 2006. We received proceeds from this sale, net approximately \$600,000 in offering costs and fees, of approximately \$7.4 million. Pursuant to the registration rights agreement entered into with the investors in connection with the sale, we filed a registration statement in September 2005 registering the resale of the shares of Common Stock initially sold and the shares issuable upon exercise of the warrants. The exercise price of these warrants is subject to anti-dilution adjustments upon the occurrence of certain subsequent equity offerings. Giving effect to the most recent adjustment that resulted from our registered direct offering in February 2008, the current exercise price of these warrants is \$2.05 per share.

In December 2005, we sold 9,101,912 share of our Common Stock at \$1.83 per share and 5 year warrants to purchase an aggregate of 3,640,762 share of our Common Stock at an exercise price of \$2.05 per share in a registered direct offering to institutional investors. We received proceeds from this sale, net of approximately \$1.2 million in offering costs and fees, of approximately \$15.5 million.

In July 2006, we sold 12 million shares of our Common Stock to institutional investors in a registered direct offering at \$1.38 per share and 10-year warrants to purchase an aggregate of 7.8 million shares of our Common Stock at an exercise price of \$1.4145 per share. The shares and warrants (including the shares issuable upon exercise of the warrants) were issued under a shelf registration statement. We received approximately \$16.2 million in proceeds from this sale, net of approximately \$1.3 million in offering costs and fees.

In August 2006, our Board of Directors, through the Compensation Committee, approved the issuance of 1,000 shares of common stock to every employee of GTC employed as of June 2, 2006, the date we received the positive opinion from EMEA. As a result, we issued a total of 120,028 shares and recorded compensation expense of approximately \$147,000 in the third quarter of 2006.

In January 2007, we sold 3.6 million shares of our Common Stock at a purchase price of \$1.23 to LFB in connection with the third tranche under our securities purchase agreement with LFB. We received approximately \$4.5 million in proceeds from the sale. In addition, we issued to LFB a \$2.6 million, five-year convertible note which is convertible into common stock on terms described in Note 3.

In February 2008, we received approximately \$5.5 million in proceeds from a registered direct offering, net of approximately \$500,000 in offering costs and fees. In the offering, we sold 6.9 million shares of our common stock at \$0.87 per share (rounded price on the date of closing) and 7-year warrants to purchase an aggregate of 6.9 million shares of our common stock at an exercise price of \$0.87 per share.

Preferred Stock Placements

In October 2006, we sold 5,000 shares of our newly designated Series D preferred stock, representing 5 million common share equivalents, to LFB for aggregate proceeds of \$6.1 million in connection with the first tranche under the purchase agreement with LFB.

In December 2006, we sold 9,615 shares of Series D preferred stock at a purchase price of \$1.23, representing 9.6 million common share equivalents, to LFB for aggregate proceeds of \$11.8 million in connection with the second tranche under the purchase agreement with LFB.

Offering costs and fees in conjunction with the two Series D preferred stock placements to LFB were approximately \$270,000.

Warrants

A summary of our outstanding warrants for the purchase of common stock as of December 30, 2007, of which 14,603,668 are currently exercisable, is as follows:

<u>Common Shares Issuable for</u>	<u>Exercise Price Per Share</u>	<u>Warrant Expiration Date</u>
288,000	\$ 4.88	December 28, 2008
55,833	\$ 6.30	November 12, 2009
29,491	\$ 6.30	November 22, 2009
961,009	\$ 3.30	August 1, 2008
1,828,573	\$ 2.05 ⁽¹⁾	February 10, 2011
3,640,762	\$ 2.05	December 13, 2010
7,800,000	\$ 1.4145	July 18, 2016
14,603,668		

⁽¹⁾ The exercise price of these warrants, which was originally \$2.52 per share, is subject to anti-dilution adjustments upon the occurrence of certain subsequent equity issuances. Giving effect to the most recent adjustment that occurred as a result of our registered direct offering in February 2008, the current exercise price of these warrants is \$2.05 per share.

As of December 30, 2007, we have reserved 22,277,285 shares of Common Stock, subject to adjustment, for future issuance under the various classes of warrants, the Equity Plans and Employee Stock Purchase Plans.

NOTE 9. EMPLOYEE BENEFIT PLANS

Equity Plan and Stock Purchase Plan

In May 1993, the Board of Directors adopted and the shareholders approved the 1993 Equity Incentive Plan and the 1993 Director Stock Option Plan (collectively, our "Prior Equity Plan"). In May 2002, our shareholders approved the 2002 Equity Incentive Plan (the "Equity Incentive Plan"), authorizing a total of 2,500,000 shares for issuance to our employees, consultants and directors and to our affiliates. In 2004 and 2007, our shareholders approved increases of 2,000,000 shares, or 4,000,000 in total, in the number of shares authorized for future issuance under the Equity Incentive Plan. In May 2007, our shareholders also approved an automatic annual increase in the number of shares of our common stock available for issuance under the Equity Incentive Plan, which annual increase will be added on December 31 of each year beginning in 2008, and will be equal to 1,500,000 shares, or such lesser amount as may be determined by our Board; provided that any increase will not cause the maximum number of shares that may be issued under the Equity Incentive Plan to exceed the lesser of 10% of the shares of common stock outstanding as of the date of issuance (including, on an as-converted basis, all outstanding Series D preferred stock convertible into common stock); and 15,000,000 shares (subject to adjustment in the event of stock splits and other similar events). In addition, 4,340,000 shares subject to options previously granted under our Prior Equity Plans were transferred to our Equity Incentive Plan. A total

of 7,642,146 shares are subject to outstanding options or reserved for issuance under our Equity Incentive Plan, including 5,910,153 options issued under our equity plans outstanding at December 30, 2007. Shares that became available upon termination of forfeited or expired options under our Prior Equity Plans will be added to reserve under our Equity Incentive Plan.

Under our Equity Incentive Plan, shares of Common Stock are reserved for issuance pursuant to incentive stock options, non-statutory stock options, restricted stock awards, stock appreciation rights, restricted stock units or stock units in accordance with specific provisions to be established by a committee of the Board of Directors at the time of grant. The Equity Incentive Plan also permits us to assume outstanding options in an acquisition without using shares reserved under the Plan. Annual grants to any individual participant are limited to 400,000 shares for any current participant and 600,000 shares for any new hire, in each case subject to adjustment for changes in our capitalization. No options will have a term that can exceed ten years and awards will be subject to a minimum three-year vesting schedule with exceptions in the discretion of the Compensation Committee for retirement, death, disability, termination by GTC, change in control, grants to consultants, directors or new hires, awards in lieu of cash compensation and performance vesting.

Under both our Equity Incentive Plan and our Prior Equity Plans, 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.

At December 30, 2007, a total of 1,731,993 shares were available for grant under our Equity Incentive Plan.

A summary of the status of our stock option plans as of December 30, 2007 and changes during the year then ended is presented below:

	Shares	Weighted Average Exercise Price	Weighted Average Contractual Term
Outstanding at December 31, 2006	4,993,001	\$ 4.23	
Granted at Fair Value	1,183,425	\$ 1.09	
Exercised.....	(5,480)	\$ 0.83	
Cancelled	<u>(260,793)</u>	\$ 5.20	
Outstanding at December 30, 2007.....	5,910,153	\$ 3.56	5.89
Options exercisable at December 30, 2007	4,407,943	\$ 4.36	4.97
Options vested and those expected to vest at			
December 30, 2007	5,725,405	\$ 3.63	5.81

The aggregate intrinsic value related to the options outstanding, exercisable, exercised and vested is immaterial for 2007, 2006 and 2005.

As a result of adopting SFAS 123(R) on January 2, 2006, the net loss for the fiscal year ended December 30, 2007 and December 31, 2006 was approximately \$847,000 and \$566,000 higher, respectively. Of the total, \$359,000 and \$312,000 was recorded to research and development in 2007 and 2006, respectively, and \$488,000 and \$254,000 was recorded to selling, general and administrative, respectively, than if we had continued to account for share-based compensation under APB Opinion 25 for which no expense would be recorded in the financial statements. The impact of SFAS 123(R) on the net loss per share was \$.01 for each of the fiscal year ended December 30, 2007 and December 31, 2006.

The following table illustrates the effect on net loss and net loss per share, for which there is no tax benefit, had we accounted for share-based compensation in accordance with SFAS 123(R) for the fiscal year ended January 1, 2006:

	January 1, 2006	
	Net Loss	Net Loss Per Common Share (basic and diluted)
Net loss reported.....	\$ (30,112)	\$ (0.62)
Add: *.....	—	—
Deduct: **.....	(1,826)	(0.04)
Pro Forma net loss.....	\$ (31,938)	\$ (0.66)

* Total stock-based employee compensation recorded in net loss, as reported

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

We use the Black-Scholes option-pricing model to estimate fair value of share-based awards with the following weighted average assumptions:

	Fiscal year ended		
	December 30, 2007	December 31, 2006	January 1, 2006
<i>Stock Options and Awards:</i>			
Expected life.....	6 years	6 years	6 years
Expected volatility.....	89.03%	90%	90%
Dividend yield.....	0%	0%	0%
Risk-free interest rate.....	3.80%	4.63%	2.47%

In fiscal year ended December 31, 2006, we calculated expected life for stock options and other equity awards using the Staff Accounting Bulletin No. 107, or SAB 107, simplified method. In fiscal year ended December 30, 2007, we calculated expected life for stock options and other equity awards based on the observed and expected time to post-vesting forfeiture and exercise.

We calculate expected volatility for stock options and other equity awards using historical volatility with a look back period over the expected life.

The weighted average estimated fair value at the date of grant for options granted during 2007, 2006 and 2005 was \$1.09, \$1.04 and \$1.67, respectively.

As of December 30, 2007, there was \$927,000 of total unrecognized compensation costs related to unvested stock options. This cost is expected to be recognized over a weighted average period of 2.39 years.

Shares issued from the 2002 Equity Incentive Plan, whether for the exercise of stock options or other equity issuances, will be new shares of common stock as authorized under the plan. We reserve the right to purchase and reissue shares from treasury stock under certain circumstances.

In May 2003, our board of directors adopted and our shareholders approved our 2003 Employee Stock Purchase Plan (the "2003 Purchase Plan"). Under the 2003 Purchase Plan, 750,000 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. Under the 2003 Purchase Plan, the Compensation Committee has established separate three-month offerings every three months.

We record the FAS 123R compensation expense related to the Employee Stock Purchase Plan, however, the amounts are immaterial for the fiscal years ended December 30, 2007 and December 31, 2006. Therefore, we do not disclose the weighted average assumptions related to the Employee Stock Purchase Plan.

On December 22, 2005, in anticipation of the effective date of Statement of Financial Accounting Standards No. 123(R) (Share-Based Payment), the Compensation Committee approved the acceleration of vesting of certain unvested "out-of-the-money" stock options held by current employees as of December 22, 2005, including executive officers. For this purpose, a stock option was considered "out-of-the-money" if the option exercise price was greater than \$3.75 per share. The closing price of our Common Stock on December 22, 2005, the date the Compensation Committee approved the acceleration of vesting of "out-of-the-money" options, was \$1.63. All other terms and conditions of these "out-of-the-money" options remain unchanged. These actions were taken in accordance with the applicable provisions of our 1993 and 2002 Equity Incentive Plans. No stock options held by non-employee directors were accelerated in this action.

As a result of the acceleration of vesting, options to purchase approximately 372,000 shares of our Common Stock (which represents approximately 8.4% of our then currently outstanding stock options) became exercisable immediately. The accelerated options have exercise prices ranging from \$3.80 to \$5.90 per share. The weighted average exercise price of the accelerated options is \$3.92 per share.

Executive officers hold options for 173,000 of the accelerated option shares. As a condition to the acceleration of options held by an executive officer, the executive officer was required to deliver a lock-up agreement. Under the lock up agreement, the executive officer agreed not to sell the underlying shares until the earlier of i) the original vesting date, ii) the last day of employment, or iii) the date of a change in control that includes an option acceleration.

401(k) Plan

All of our employees, subject to certain eligibility requirements, can participate in our defined contribution plan. Currently, we may match up to 50% of each participating employee's contributions to the plan to a maximum of 3% of salary. We 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 \$389,000, \$249,000 and \$191,000 for the fiscal years ended December 30, 2007, December 31, 2006 and January 1, 2006, respectively.

NOTE 10. INCOME TAXES

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

	Fiscal Years Ended		
	December 30, 2007	December 31, 2006	January 1, 2006
Federal tax—expense (benefit)	(34.0)%	(34.0)%	(34.0)%
State taxes—net	(5.9)	(5.2)	(3.9)
Research and development tax credits	(1.0)	(3.7)	(2.6)
Other	3.9	1.0	2.4
Change in valuation allowance	37.0	41.9	38.1
Effective tax rate	<u>0%</u>	<u>0%</u>	<u>0%</u>

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 components of the deferred tax assets and liabilities at December 30, 2007 and December 31, 2006, respectively, are as follows (dollars in thousands):

	<u>December 30, 2007</u>	<u>December 31, 2006</u>
Deferred tax assets/(liabilities):		
Net operating loss carryforwards	\$ 85,076	\$ 77,823
Capitalized research and development expenses	21,967	20,894
Tax credits.....	8,689	9,153
Advance payments.....	3,020	3,726
Inventory.....	1,810	—
Accrued compensation	301	277
Other accruals.....	191	265
Other	187	60
Depreciation.....	(868)	(832)
Total gross deferred tax asset	<u>120,373</u>	<u>111,366</u>
Valuation allowance.....	<u>(120,373)</u>	<u>(111,366)</u>
Net deferred tax asset.....	<u>\$ —</u>	<u>\$ —</u>

As of December 30, 2007, we had a federal and state net operating losses (“NOLs”) of \$230 million and \$103 million, respectively, and federal and state research and experimentation credit carryforwards of approximately \$6.6 million and \$3.1 million, respectively, which will expire at various dates starting in 2008 through 2027. We had approximately \$8.2 million of federal net operating losses generated in 1992 and approximately \$18.6 million of Massachusetts net operating losses generated in 2002 that expired in 2007. We anticipate that approximately \$52 million of federal net operating losses generated between 1993 and 1997 and all of the Massachusetts net operating losses will expire during the next five years. As required by SFAS No. 109, we have evaluated the positive and negative evidence bearing upon the realizability of our deferred tax assets, and we have determined that it is more likely than not that we will not recognize the benefits of the deferred tax assets. Accordingly, a valuation allowance of approximately \$120 million has been established at December 30, 2007.

Utilization of the NOL and R&D credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. We have not currently completed a study to assess whether an ownership change has occurred, or whether there have been multiple ownership changes since our formation, due to the significant complexity and related costs associated with such study. There also could be additional ownership changes in the future which may result in additional limitations in the utilization of the carryforward NOL’s and credits.

We have recorded a deferred tax asset of approximately \$4.9 million reflecting the benefit of deductions from the exercise of stock options which has been fully reserved until it is more likely than not that the benefit will be realized. The benefit from this \$4.9 million deferred tax asset will be recorded as a credit to additional paid-in capital if and when realized through a reduction of cash taxes.

In June 2006, the FASB issued Interpretation No. 48, “Accounting for Uncertainty in Income Taxes, an interpretation of FAS 109” (“FIN 48”). This statement clarifies the criteria that an individual tax position must satisfy for some or all of the benefits of that position to be recognized in a company’s financial statements. We adopted FIN No. 48 on January 1, 2007. The implementation of FIN No. 48 did not have a material impact on our consolidated financial statements, results of operation or cash flows. At the adoption date of January 1, 2007, and also at December 30, 2007, we had no unrecognized tax benefits. We have not, as yet, conducted a study of our research and development credit carryforwards. This study may result in an adjustment to our research and development credit carryforwards, however, until such a study is completed and any adjustment is known, no amounts are being presented as uncertain tax positions under FIN No. 48. A full valuation allowance has

been provided against our research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the consolidated balance sheet or statement of operations if an adjustment were required.

The tax years 1993 through 2006 remain open to examination by major taxing jurisdictions to which we are subject, which are primarily in the United States, as carryforward attributes generated in years past may still be adjusted upon examination by the Internal Revenue Services or state tax authorities if they have or will be used in a future period. We are currently not under examination by the Internal Revenue Service or any other jurisdiction for any tax years. We would recognize both accrued interest and penalties related to unrecognized benefits in income tax expense. We have not recorded any interest or penalties on any unrecognized tax benefits since inception.

NOTE 11. ARRANGEMENTS WITH RELATED PARTIES

LFB Biotechnologies ("LFB")

In September 2006, we entered into a collaboration agreement with LFB to develop selected recombinant plasma proteins and MAb's using our transgenic production platform (see Note 3).

Genzyme Corporation

From our inception, certain facilities and support services, including both research and administrative support, have been provided by Genzyme. For these services, we were charged \$660,445, \$874,735 and \$1,423,457 for the fiscal years ended December 30, 2007, December 31, 2006 and January 1, 2006, respectively. These charges, which are set by Genzyme, represent an allocation of our proportionate share of Genzyme's overhead costs using formulae which our management believes are reasonable based upon our 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 us and have been paid by Genzyme and charged to us.

In December 2005, when Genzyme's stock ownership fell below 10% we ceased to consider Genzyme a related party for financial reporting purposes.

First Negotiation Right for Commercializing ATryn®

If we choose to commercialize ATryn® with a marketing partner outside of Asia, Genzyme has a first right of negotiation for exclusive commercialization rights. This right is triggered on product-by-product and market-by-market basis at such time as we make a submission to a regulatory authority for marketing approval in a given market. This right does not apply if we have already entered into a collaboration or other agreement with a prospective research, development and marketing partner prior to such regulatory submission. It also no longer applies to the LEO territories.

ATHI LLC Re-Acquisition

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

NOTE 12. GEOGRAPHICAL INFORMATION

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

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

	<u>United States</u>	<u>Europe</u>	<u>Israel</u>	<u>Total</u>
2007	\$ 9,485	\$ 4,406	\$ 5	\$ 13,896
2006	4,156	1,969	3	6,128
2005	4,049	100	3	4,152

Of our long-lived assets, \$5.7 million of intangible assets (net) are located in the Cayman Islands.

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

	<u>United States</u>	<u>United Kingdom</u>	<u>New Zealand</u>	<u>Total</u>
2007	\$ 11,000	\$ 5,495	\$ 88	\$ 16,583
2006	12,146	5,068	264	17,478

NOTE 13. UNAUDITED RESULTS OF QUARTERLY OPERATIONS

	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
2007				
Revenue.....	\$ 5,429 ⁽¹⁾	\$ 2,838	\$ 2,576	\$ 3,052
Operating loss.....	(7,758)	(10,677) ⁽²⁾	(8,280)	(9,709) ⁽³⁾
Net loss.....	(7,509)	(10,592)	(8,388)	(9,832)
Net loss per share—basic and diluted	(0.10)	(0.14)	(0.11)	(0.13)
	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
2006				
Revenue.....	\$ 2,201 ⁽⁴⁾	\$ 416	\$ 690	\$ 2,821 ⁽⁵⁾
Operating loss.....	(8,537)	(9,077)	(10,435)	(7,598)
Net loss.....	(8,503)	(9,097)	(10,317) ⁽⁶⁾	(7,428)
Net loss per share—basic and diluted	(0.14)	(0.15)	(0.14)	(0.10)

⁽¹⁾ In the first quarter of 2007, we recognized \$3.3 million of revenue for product shipments to LEO.

⁽²⁾ In the second quarter of 2007, we wrote off \$2.9 million related to in-process inventory which was rendered unusable as a result of the fill/finish process at the facility of our U.S. based third party fill/finish contractor.

⁽³⁾ In the fourth quarter of 2007, we began processing additional material for LEO.

⁽⁴⁾ In the first quarter of 2006, we completed processing of some material for Merrimack and as result were able to recognize the associated revenue.

⁽⁵⁾ In the fourth quarter of 2006, we began shipping ATryn® to LEO and, as a result, were able to recognize the revenue on the product shipments as well as a portion of the revenue on milestone payments previously received.

⁽⁶⁾ In the third quarter of 2006, our expense on the ATryn® program increased as a result of manufacturing of material under our collaboration agreement with LEO.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in Framingham, Massachusetts on the 6th day of March 2008.

GTC BIOTHERAPEUTICS, INC.

By: /s/ Geoffrey F. Cox

Geoffrey F. Cox

*Chairman of the Board, President and
Chief Executive Officer*

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Geoffrey F. Cox</u> Geoffrey F. Cox	Chairman of the Board, President and Chief Executive Officer (Principal Executive Officer)	March 6, 2008
<u>/s/ John B. Green</u> John B. Green	Chief Financial and Accounting Officer (Principal Financial and Accounting Officer)	March 6, 2008
<u>/s/ Robert W. Baldrige</u> Robert W. Baldrige	Director	March 6, 2008
<u>/s/ Kenneth A. Bauer</u> Kenneth A. Bauer	Director	March 6, 2008
<u>/s/ Christian Béchon</u> Christian Béchon	Director	March 6, 2008
<u>/s/ Francis J. Bullock</u> Francis J. Bullock	Director	March 6, 2008
<u>/s/ James A. Geraghty</u> James A. Geraghty	Director	March 6, 2008
<u>/s/ Mary Ann Gray</u> Mary Ann Gray	Director	March 6, 2008
<u>/s/ Michael J. Landine</u> Michael J. Landine	Director	March 6, 2008
<u>/s/ Pamela W. McNamara</u> Pamela W. McNamara	Director	March 6, 2008
<u>/s/ Marvin L. Miller</u> Marvin L. Miller	Director	March 6, 2008
<u>/s/ Alan W. Tuck</u> Alan W. Tuck	Director	March 6, 2008

EXHIBIT INDEX
to Form 10-K for the Year Ended December 30, 2007

<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 GTC's Annual Report on Form 10-K for the year ended December 31, 1993 (File No. 0-21794) and incorporated by reference herein.
3.1.2	Articles of Amendment to the Restated Articles of Organization of GTC 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) filed on March 27, 1998 and incorporated by reference herein.
3.1.3	Articles of Amendment to the Restated Articles of Organization of GTC filed with the Secretary of the 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) filed on August 13, 1997 and incorporated by reference herein.
3.1.4	Articles of Amendment to the Restated Articles of Organization of GTC filed with the Secretary of the Commonwealth of Massachusetts on June 1, 2000. Filed as Exhibit 4.1.5 to GTC's Registration Statement on Form S-8 (File No. 333-38490) filed on June 2, 2000 and incorporated by reference herein.
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 (File No. 0-21794) filed on June 1, 2001 and incorporated by reference herein.
3.1.6	Articles of Amendment to the Restated Articles of Organization of GTC filed with the Secretary of the Commonwealth of Massachusetts on May 31, 2002. Filed as Exhibit 3.1 to GTC's Current Report on Form 8-K (File No. 0-21794) filed on June 3, 2002 and incorporated by reference herein.
3.1.7	Articles of Amendment to the Restated Articles of Organization of GTC filed with the Secretary of the Commonwealth of Massachusetts on October 2, 2006. Filed as Exhibit 3.1 to GTC's Current Report on Form 8-K (File No. 0-21794) filed on October 5, 2006 and incorporated by reference herein.
3.1.8	Articles of Amendment to the Restated Articles of Organization of GTC filed with Secretary of the Commonwealth of Massachusetts on December 11, 2006. Filed as Exhibit 3.8 to GTC's Annual Report on Form 10-K for the year ended December 31, 2006 (File No. 0-21794) filed on March 2, 2007 and incorporated by reference herein.
3.2	By-Laws of GTC, as amended. Filed as Exhibit 3.1 to GTC's Quarterly Report on Form 10-Q for the quarter ended July 4, 1999 (File No. 0-21794) filed on August 18, 1999 and incorporated by reference herein.
4.1	Specimen Common Stock Certificate. Filed as Exhibit 4.1 to GTC's Registration Statement on Form S-1 (File No. 33-62782) and incorporated by reference herein.
4.2	Shareholder Rights Agreement, dated as of May 31, 2001, by and between GTC and American Stock Transfer and Trust Company, as Rights Agent. Filed as Exhibit 4.1 to GTC's Current Report on Form 8-K (File No. 0-21794) filed on June 1, 2001 and incorporated by reference herein.
4.2.1	First Amendment to Shareholder Rights Agreement, dated as of December 14, 2006, by and between GTC and American Stock Transfer and Trust Company. Filed as Exhibit 4.1 to GTC's Current Report on Form 8-K (File No. 0-21794) filed on December 20, 2006 and incorporated by reference herein.

- 4.3 Warrant to Purchase Common Stock, dated as of December 28, 1998, issued to Genzyme Corporation. Filed as Exhibit 4.11 to GTC's Annual Report on Form 10-K for the year ended January 3, 1999 (File No. 0-21794) filed on April 5, 1999 and incorporated by reference herein.
- 4.4 Warrant to Purchase Common Stock, dated November 12, 1999, issued to Genzyme Corporation. Filed as Exhibit 8 to Amendment No. 6 to Schedule 13D of Genzyme Corporation (File No. 005-46637) filed on November 24, 1999 and incorporated by reference herein.
- 4.5 Warrant to Purchase Common Stock, dated November 12, 1999, issued to Genzyme Corporation. Filed as Exhibit 9 to Amendment No. 6 to Schedule 13D of Genzyme Corporation (File No. 005-46637) filed on November 24, 1999 and incorporated by reference herein.
- 4.6 Form of Common Stock Purchase Warrant. Filed as Exhibit 10.2 to GTC's Current Report on Form 8-K (File No. 0-21794) filed on August 4, 2003 and incorporated by reference herein.
- 4.7 Registration Rights Agreement between GTC and certain Stockholders named therein dated March 20, 1998. Filed as Exhibit 10.53 to GTC's Annual Report on Form 10-K for the year ended December 28, 1997 (File No. 0-21794) filed on March 27, 1998 and incorporated by reference herein.
- 4.8 Series A Convertible Preferred Stock Purchase Agreement by and between GTC and Genzyme Corporation, dated May 1, 1993. Filed as Exhibit 4.9 to GTC's Amendment No. 1 to Annual Report on Form 10-K/A for the year ended January 1, 2006 (File No. 0-21794) filed on October 5, 2006 and incorporated by reference herein.
- 4.9 Form of Common Stock Purchase Warrant. Filed as Exhibit 10.3 to GTC's Current Report on Form 8-K (File No. 0-21794) filed on August 8, 2005 and incorporated by reference herein.
- 4.10 Form of Registration Rights Agreement. Filed as Exhibit 10.2 to GTC's Current Report on Form 8-K (File No. 0-21794) filed on August 8, 2005 and incorporated by reference herein.
- 4.11 Form of Common Stock Purchase Warrant. Filed as Exhibit 4.1 to GTC's Current Report on Form 8-K (File No. 0-21794) filed on December 12, 2005 and incorporated by reference herein.
- 4.12 Form of Common Stock Purchase Warrant. Filed as Exhibit 4.1 to GTC's Current Report on Form 8-K (File No. 0-21794) filed on July 20, 2006 and incorporated by reference herein.
- 4.13 Form of Subordinated Convertible Note issued to LFB Biotechnologies, S.A.S.U. Included as Exhibit B to the Stock and Note Purchase Agreement by and between GTC and LFB Biotechnologies, S.A.S.U. dated September 29, 2006, filed as Exhibit 10.1 to GTC's Current Report on Form 8-K (File No. 0-21794) filed October 5, 2006 and incorporated by reference herein.
- 10.1* Agreement by and between GTC and Gene Pharming Europe B.V., dated as of September 21, 1994. Filed as Exhibit 10.49 to GTC's Registration Statement on Form S-1 (File No. 33-62782) and incorporated by reference herein.
- 10.2 Sublease Agreement by and between GTC and Genzyme Corporation, dated as of May 1, 1993. Filed as Exhibit 10.3 to GTC's Registration Statement on Form S-1 (File No. 33-62782) and incorporated by reference herein.
- 10.3 License Agreement by and between GTC and Genzyme Corporation, as successor to IG Laboratories, Inc., dated as of May 1, 1993. Filed as Exhibit 10.4 to GTC's Registration Statement on Form S-1 (File No. 33-62782) and incorporated by reference herein.
- 10.4 Lease dated March 26, 1999 by and between GTC and NDNE 9/90 Corporate Center LLC. Filed as Exhibit 10.1 to GTC's Quarterly Report on Form 10-Q for the quarter ended July 4, 1999 (File No. 0-21794) filed on August 18, 1999 and incorporated by reference herein.

- 10.5 Hazardous Materials Indemnity Agreement by and between the GTC and Genzyme Corporation, dated December 28, 1998. Filed as Exhibit 10.28.5 to GTC's Annual Report on Form 10-K for the year ended January 2, 2000 (File No. 0-21794) filed on April 3, 2000 and incorporated by reference herein.
- 10.6* License Agreement by and among GTC, Pharming Group N.V. and Pharming Intellectual Property B.V., dated June 21, 2002. Filed as Exhibit 10.3.1 to GTC's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002 (File No. 0-21794) filed on August 2, 2002 and incorporated by reference herein.
- 10.7* Amended and Restated License Agreement by and among Pharming Group, N.V. and Pharming Intellectual Property B.V. and GTC dated June 21, 2002. Filed as Exhibit 10.3.2 to GTC's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002 (File No. 0-21794) filed on August 2, 2002 and incorporated by reference herein.
- 10.8* Purchase Agreement by and between GTC and Genzyme Corporation, dated as of July 31, 2001. Filed as Exhibit 10.2 to GTC's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001 (File No. 0-21794) filed on November 13, 2001 and incorporated by reference herein.
- 10.9* Sublease Agreement by and between GTC and Antigenics, Inc., dated July 16, 2002. Filed as Exhibit 10.4 to GTC's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002 (File No. 0-21794) filed on August 2, 2002 and incorporated by reference herein.
- 10.10 Amended and Restated Master Security Agreement by and between GTC and General Electric Capital Corporation, dated as of December 29, 2006. Filed as Exhibit 10.3 to GTC's Current Report on Form 8-K (File No. 0-21794) filed on January 4, 2007 and incorporated by reference herein.
- 10.11 Promissory Note in the amount of \$8 million by and between GTC and General Electric Capital Corporation, dated as of December 29, 2006. Filed as Exhibit 10.1 to GTC's Current Report on Form 8-K (File No. 0-21794) filed on January 4, 2007 and incorporated by reference herein.
- 10.12 Promissory Note in the amount of \$2 million by and between GTC and General Electric Capital Corporation, dated as of December 29, 2006. Filed as Exhibit 10.2 to GTC's Current Report on Form 8-K (File No. 0-21794) filed on January 4, 2007 and incorporated by reference herein.
- 10.13* Licensing and Supply Agreement by and between GTC and LEO Pharma A/S, dated as of October 31, 2005. Filed as Exhibit 10.1 to GTC's Current Report on Form 8-K/A (File No. 0-21794) filed on November 28, 2005 and incorporated by reference herein.
- 10.14** GTC Amended and Restated 1993 Equity Incentive Plan. Filed as Exhibit 10.7 to GTC's Annual Report on Form 10-K for the year ended December 30, 2001 (File No. 0-21794) filed on March 22, 2002 and incorporated by reference herein.
- 10.15** GTC Amended and Restated 2002 Equity Incentive Plan. Filed as Exhibit 10.1 to GTC's Report on Form 8-K (File No. 0-21794) filed on May 30, 2007 and incorporated by reference herein.
- 10.16** GTC 2002 Employee Stock Purchase Plan. Filed as Exhibit 10.7 to GTC's Quarterly Report on Form 10-Q for the quarter ended March 31, 2002 (File No. 0-21794) filed on May 1, 2002 and incorporated by reference herein.
- 10.17 GTC Form of Confidential and Proprietary Information Agreement signed by GTC employees. Filed as Exhibit 10.9 to GTC's Registration Statement on Form S-1 (File No. 33-62782) and incorporated by reference herein.
- 10.18 GTC Form of Agreement Not to Compete. Filed as Exhibit 10.10 to GTC's Registration Statement on Form S-1 (File No. 33-62782) and incorporated by reference herein.

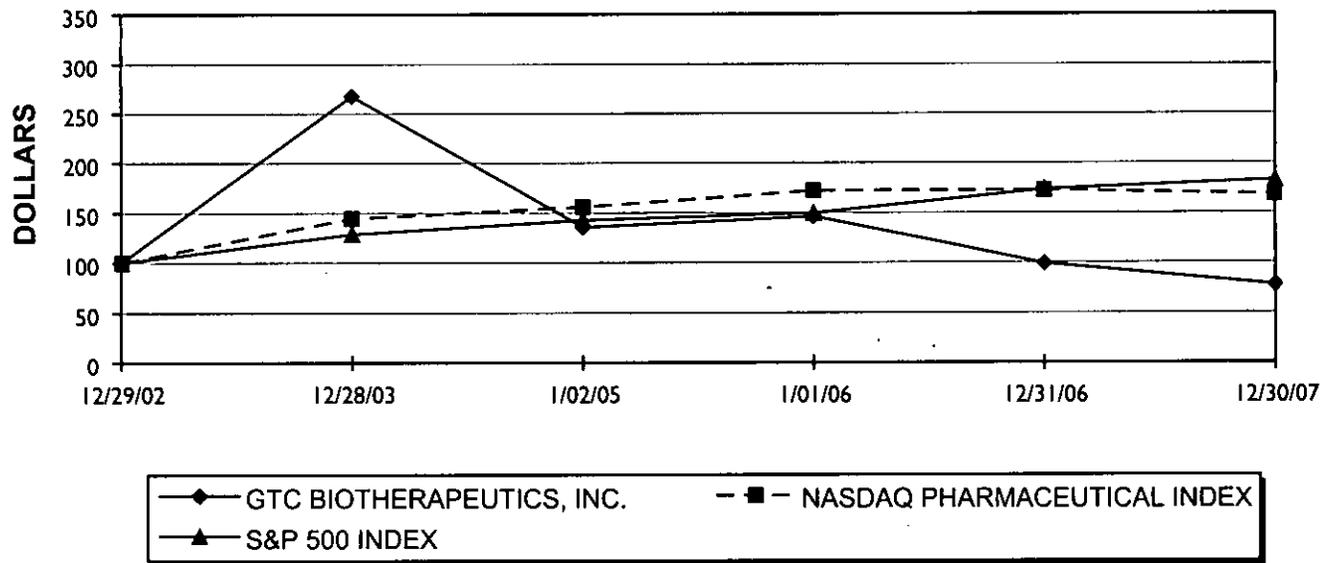
- 10.19 Form of Indemnification Agreement between GTC and its directors. Filed as Exhibit 10.12 to GTC's Annual Report on Form 10-K for the year ended December 31, 1994 (File No. 0-21794) and incorporated by reference herein. Such agreements are materially different only as to the signing directors and the dates of execution.
- 10.20** Employment Agreement, dated as of March 27, 1996, by and between GTC and Harry Meade. Filed as Exhibit 10.44 to GTC's Quarterly Report on Form 10-Q for the quarter ended March 31, 1996 (File No. 0-21794) and incorporated by reference herein.
- 10.21.1** Amended and Restated Employment Agreement, dated as of August 28, 1997, by and between GTC and John B. Green. Filed as Exhibit 10.2 to GTC's Quarterly Report on Form 10-Q for the quarter ended September 28, 1997 (File No. 0-21794) filed on November 5, 1997 and incorporated by reference herein.
- 10.21.2** Amendment No. 1 to Employment Agreement by and between GTC and John B. Green, dated September 21, 1998. Filed as Exhibit 10.3 to GTC's Quarterly Report on Form 10-Q for the quarter ended September 27, 1998 (File No. 0-21794) filed on November 12, 1998 and incorporated by reference herein.
- 10.22** Executive Employment Agreement, dated as of July 18, 2001, by and between GTC and Geoffrey F. Cox. 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) filed on November 13, 2001 and incorporated by reference herein.
- 10.23** Management Agreement by and between GTC and Daniel Woloshen dated as of May 27, 1999. Filed as Exhibit 10.1 to GTC's Quarterly Report on Form 10-Q for the quarter ended March 30, 2003 (File No. 0-21794) filed on May 6, 2003 and incorporated by reference herein.
- 10.24** Management Agreement by and between GTC and Gregory Liposky dated as of June 14, 2000. Filed as Exhibit 10.2 to GTC's Quarterly Report on Form 10-Q for the quarter ended March 30, 2003 (File No. 0-21794) filed on May 6, 2003 and incorporated by reference herein.
- 10.25** Form of Management Agreement. Filed as Exhibit 10.1 to GTC's Current Report on Form 8-K (File No. 0-21794) filed on August 3, 2006 and incorporated by reference herein.
- 10.26** Form of Executive Change in Control Agreement. Filed as Exhibit 10.2 to GTC's Current Report on Form 8-K (File No. 0-21794) filed on August 3, 2006 and incorporated by reference herein.
- 10.27* Joint Development and Commercialization Agreement dated September 29, 2006 by and between GTC and LFB Biotechnologies S.A.S.U. Filed as Exhibit 10.3 to GTC's Quarterly Report on Form 10-Q for the quarter ended October 1, 2006 (File No. 0-21794) filed on November 3, 2006 and incorporated by reference herein.
- 10.28 Stock and Note Purchase Agreement dated September 29, 2006, by and between GTC and LFB Biotechnologies S.A.S.U., including the form of convertible note attached as Exhibit B thereto. Filed as Exhibit 10.1 to GTC's Current Report on Form 8-K (File No. 0-21794) filed on October 5, 2006 and incorporated by reference herein.
- 10.29 Keepwell Agreement dated September 29, 2006, by and between GTC and Laboratoires Francais du Fractionnement et des Biotechnologies S.A. Filed as Exhibit 10.2 to GTC's Current Report on Form 8-K (File No. 0-21794) filed on October 5, 2006 and incorporated by reference herein.
- 21 List of Subsidiaries. Filed herewith.
- 23 Consent of PricewaterhouseCoopers LLP. Filed herewith.

- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith.
- 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith.
- 32 Certifications pursuant to 18 U.S.C. Section 1350. Filed herewith.

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

** Indicates a management contract or compensatory plan.

**Compare 5-Year Cumulative Total Return
Among GTC Biotherapeutics, Inc.,
S&P 500 Index and NASDAQ Pharmaceutical Index**



Assumes \$100 invested on Dec. 30, 2002

Assumes dividend reinvested

Fiscal year ending Dec. 31, 2007

Corporate Information

BOARD OF DIRECTORS

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

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

Kenneth A. Bauer, M.D.
Professor of Medicine
Harvard Medical School
Director Thrombosis Clinical Research
Beth Israel Deaconess Medical Center

Christian Béchon
Chairman and Chief Executive Officer
LFB Group

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

James A. Geraghty
Senior Vice President
Genzyme Corporation

Mary Ann Gray, Ph.D.
President
Gray Strategic Advisors, LLC

Michael J. Landine
Senior Vice President
Corporate Development
Alkermes, Inc.

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

Marvin L. Miller
Former President and CEO of Nextran,
an affiliate of Baxter Healthcare
Corporation and former Vice President
International of Johnson & Johnson

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

EXECUTIVE OFFICERS

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

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

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

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

Richard A. Scotland
Senior Vice President Regulatory Affairs
GTC Biotherapeutics, Inc.

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

CORPORATE OFFICES

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

INDEPENDENT ACCOUNTANTS

PricewaterhouseCoopers LLP
Boston, MA

EXTERNAL LEGAL COUNSEL

Edwards Angell Palmer & Dodge LLP
Boston, MA

TRANSFER AGENT

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

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

MARKET FOR COMMON STOCK

Nasdaq Global Market System
Trading Symbol: GTCB

REPORT ON FORM 10-K

GTC's Annual Report on Form 10-K
for the year ended December 30, 2007 is
included herein. The report on Form
10-K and its accompanying exhibits
are filed with the U.S. Securities and
Exchange Commission and can be
accessed in the SEC's EDGAR
database (at www.sec.gov). Copies are
available without charge upon written
request to the Company at
175 Crossing Boulevard,
Framingham, MA 01702,
Attention: Tom Newberry
or by calling Tom Newberry at
(508) 620-9700 x5374

ANNUAL MEETING

The Annual Meeting of Shareholders
is scheduled to be held on
Tuesday, June 24, 2008
at 10:00 a.m. at the Forefront Center
for Meetings and Conferences
404 Wyman Street, Waltham, MA 02451

END