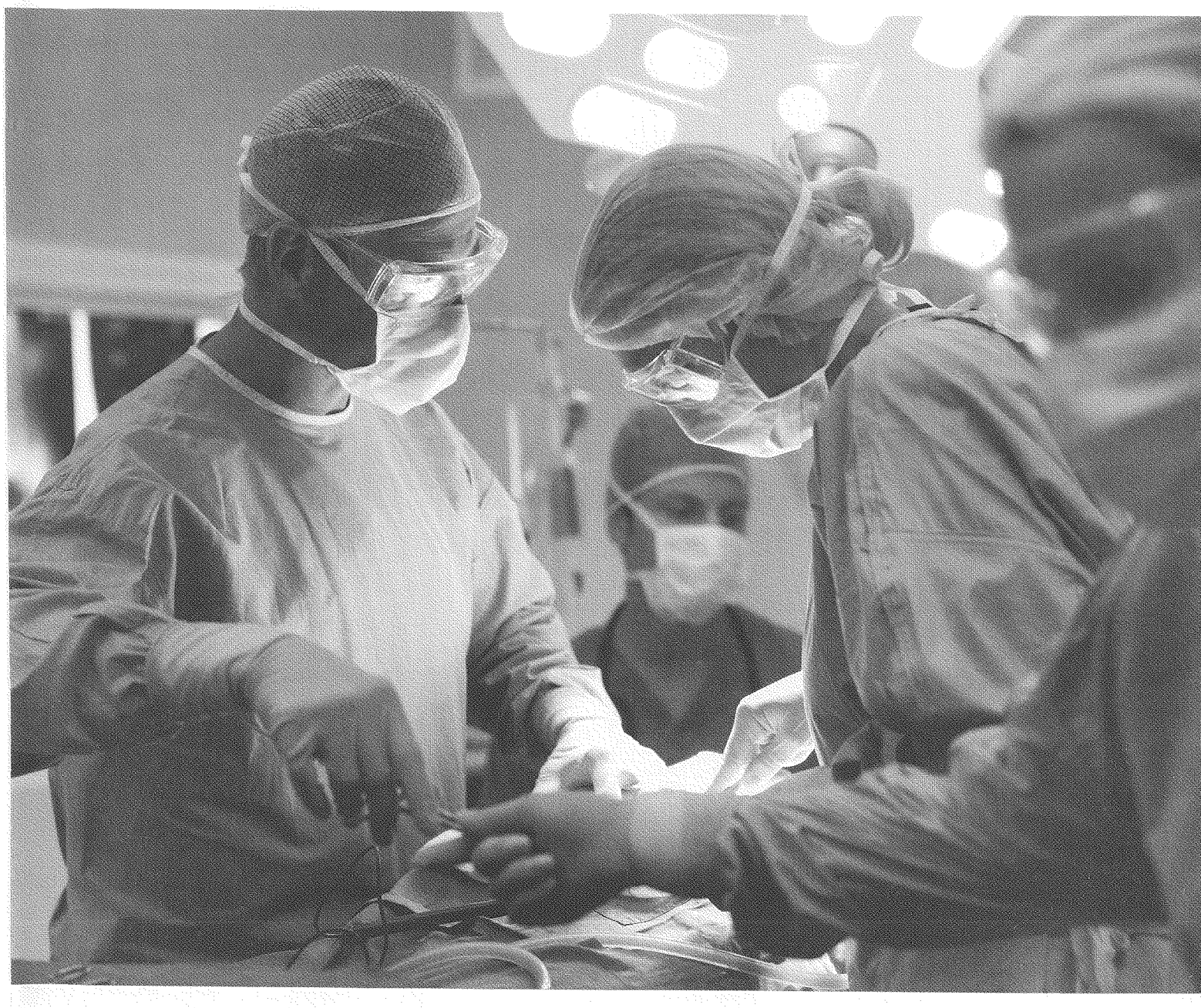
GTC Biotherapeutics, Inc



2009 Annual Report and Form 10-K

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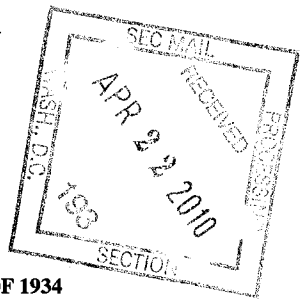
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549



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 January 3, 2010

OR

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

For the transition period from _____ to _____

Commission File No. 0-21794

GTC BIOTHERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

MASSACHUSETTS	**04-3186494**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
175 CROSSING BOULEVARD FRAMINGHAM, MASSACHUSETTS	**01702**
(Address of Principal Executive Offices)	*(Zip Code)*

(508) 620-9700

(Registrant's telephone number, including area code)

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

Title of each class	*Name of each exchange on which registered*
Common Stock, par value $0.01 per share	**Nasdaq Capital Market**
Rights to Purchase Series C Junior Participating Cumulative Preferred Stock	

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 whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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.
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 and non-voting common stock held by non-affiliates of the Registrant as of June 26, 2009, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $22,258,870, based on the closing sale price of the registrant's Common Stock as reported on the Nasdaq Capital Market.
Number of shares of the registrant's Common Stock outstanding as of March 1, 2010: 30,420,517

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the Annual Meeting of Stockholders scheduled to be held May 26, 2010 are incorporated by reference into Part III of this Form 10-K.

GTC Biotherapeutics, Inc.
Form 10-K
For the Fiscal Year Ended January 3, 2010
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PART I

In this Annual Report on Form 10-K, or Annual Report, 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 2009, 2008 and 2007 refer to our fiscal years ended January 3, 2010, December 28, 2008 and December 30, 2007, respectively.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report 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.

NOTE REGARDING REVERSE STOCK SPLIT

On May 26, 2009 we effected a reverse stock split of our outstanding common stock. In order to provide accurate comparisons of our financial position as of the end of the fiscal year ended January 3, 2010 to prior periods, we have adjusted all stock amounts and conversion and exercise prices for transactions reported in prior periods to accurately reflect the impact of the reverse stock split on our currently outstanding common stock.

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 specific human protein in their milk. Using the unique characteristics of this production technology, we are developing two portfolios of therapeutic proteins:

- **Recombinant plasma proteins.** Our portfolio of recombinant plasma proteins is being developed to treat a range of genetic and acquired blood deficiencies, including hemophilia and other blood coagulation disorders. Historically these blood proteins, also known as plasma proteins, have only been available by extraction from human blood. Recombinant versions of plasma proteins are difficult to produce in an economically viable manner using other manufacturing systems.
- **Monoclonal antibodies as follow-on biologics.** Our portfolio of monoclonal antibodies, or MAbs, is being developed for use as potential follow-on biologics targeted at several large markets in oncology and autoimmune diseases.

We also continue to provide production services for external partners, which provides us a continuing source of cash and revenue.

Our production technology has been validated by the regulatory approval of our first product ATryn®, which is a recombinant form of the human plasma protein antithrombin, by the European Medicines Agency, or EMA, in 2006 and by the United States Food and Drug Administration, or FDA, in February 2009. ATryn® remains the only transgenically produced therapeutic protein to be approved anywhere in the world. In connection with the approval of ATryn®, the FDA's Center for Veterinary Medicine also approved our New Animal Drug Application, the first of its kind to regulate genetically engineered animals. We believe that these regulatory approvals of our transgenic technology are important benchmarks for obtaining future approvals for our portfolio of products in development.

The key characteristics of our transgenic production technology include:

- the manufacture of proteins that are difficult to express in other manufacturing systems;
- the production of proteins in large quantities;
- the production of proteins with significantly lower capital cost and lower cost of goods;
- predictable and flexible scale-up;
- naturally enhanced efficacy for oncology MAbs (increased Antibody Dependent Cell-mediated Cytotoxicity, or ADCC);
- strong intellectual property position and freedom to operate; and
- an established commercial scale infrastructure capable of supporting the production of our recombinant plasma protein and MAb products.

We plan to develop our portfolio of recombinant protein products through strategic collaborations:

- In September 2006, we entered into a collaboration agreement with LFB Biotechnologies, S.A.S, or LFB, to develop selected recombinant plasma proteins and MAbs. 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. This collaboration is established in a separate joint venture entity, and we have added other programs to this joint venture, including a recombinant form of human blood coagulation factor IX, which we in-licensed from ProGenetics, LLC, and a recombinant human alpha-1 antitrypsin, as well as an antibody to the CD20 immune system receptor, the same target as for the MAb marketed as Rituxan® or MabThera®.
- In June 2008, we entered into a collaboration agreement with Lundbeck Inc. (formerly OVATION Pharmaceuticals, Inc.), to develop and market ATryn® in the United States. The collaboration agreement includes the commercialization of ATryn® in the HD indication and the further development of ATryn® in acquired antithrombin deficiency indications, or AD. In the second quarter of 2009, Lundbeck commercially launched and reported the first sales of ATryn® in the U.S.
- We are also seeking collaborations for the further development and commercialization of all of our proteins in development including those in the portfolio with LFB, as well as recombinant alpha-fetoprotein, or AFP, for the treatment of multiple sclerosis and myasthenia gravis, and our portfolio of MAbs. We acquired exclusive worldwide rights to AFP in 2009.

The following summarizes our portfolio of proprietary products in development:

Recombinant Plasma Protein Products

We believe that our transgenic technology offers well-characterized supplies of recombinant forms of therapeutic human plasma proteins with lower development risk than other biotherapeutics. The reason for lower risk is that our recombinant plasma protein products do not require development of novel pathways or novel mechanisms of action. These products are recombinant versions of well established and well characterized plasma proteins.

Importantly, our technology provides the capability to create markets significantly in excess of those which exist today for plasma derived products due to its ability to provide virtually unlimited supply at costs that are significantly lower than for competitor products.

Therapeutic human plasma proteins have traditionally been derived from the plasma portion of human blood but in some cases have also been produced using recombinant DNA techniques. The availability of plasma-derived proteins is limited by the capabilities of the blood collection system. Many plasma proteins are difficult to express in economically viable quantities in traditional recombinant production technologies such as mammalian cell culture or bacterial fermentation . We believe that our transgenic recombinant production technology offers a strategic advantage for the development of recombinant plasma protein products due to:

- a validated production platform as a result of the approval of ATryn® by the EMA and the FDA;
- 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;
- the ability to establish new markets based on the development of new indications and a greater supply of these therapeutic proteins; and
- the ability to develop transgenic animals and maintain appropriate production facilities with substantially lower capital investment than building a cell culture bioreactor production facility.

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 in 2008 generated $5 billion of annual sales worldwide, compared to the $1.1 billion of annual sales worldwide for coagulation factor products that are produced by extraction from human plasma. The availability of plasma-derived proteins is limited by the capabilities of the blood collection system. The recombinant products that have been developed and approved to date for multiple indications have expanded the products' markets. We believe we can produce our recombinant versions of these products at much lower costs and, therefore, further expand these markets where the efficiency of recombinant products has already been established.

- **ATryn®:** Our first product, ATryn®, is approved in the U.S. for the treatment of HD patients undergoing surgery or childbirth. The FDA has designated ATryn® an Orphan Drug, providing seven years of market exclusivity in this indication. Lundbeck, our partner for ATryn® in the U.S., initiated the commercial launch of ATryn® in the second quarter of 2009. While the initial HD indication is expected to be a modest market, our collaboration with Lundbeck provides for the further clinical development of ATryn® for larger AD indications in the U.S. The first of these indications is expected to be heparin resistance, or HR, in cardiopulmonary bypass surgery, where we believe our existing clinical data in this indication will allow us to proceed to a Phase III study. We estimate the market opportunity for the HR indication in the U.S. to be approximately $100 million to $150 million. We estimate that the existing worldwide annual sales for plasma-sourced antithrombin to be approximately $250 million, split principally between Japan and Europe, with $20 million being sold in the U.S. as Thrombate III® by Talecris. Historically there has been limited availability of plasma-derived antithrombin in the U.S., and this product has not been developed in the broader AD indications. Antithrombin products from European-sourced plasma are not approved for sale in the U.S.
- **rhFVIIa:** Our lead product in development is a recombinant human coagulation factor VIIa, or rhFVIIa, a plasma protein for the treatment of patients with hemophilia with inhibitors to coagulation factors VIII or IX. This is the first program in our joint venture with LFB. We have completed the development of a production system for rhFVIIa in transgenic rabbits. Following discussions with the FDA, we anticipate filing an Investigational New Drug Application, or IND, and initiating a Phase I clinical study in the second quarter of 2010. This clinical study will be

performed in normal healthy volunteers to assess product safety and to compare pharmacokinetic and pharmacodynamic properties of our product, rhFVIIa, against NovoSeven®, an existing rhFVIIa product marketed by Novo Nordisk. Following the successful completion of this clinical trial, we and LFB intend to pursue development of rhFVIIa in the target patient population of hemophilia A and hemophilia B patients that have developed inhibitors. NovoSeven® is commercially available at a selling price in excess of $1,000/mg. The patents for NovoSeven® expire in 2011. The estimated 2009 annual sales of NovoSeven® were in excess of approximately $1.3 billion, an 11% increase over 2008. 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. Any resulting increase in demand for product could provide significant upside to the value of the existing market.

- **rhFIX:** In late 2007, we obtained a license from ProGenetics, LLC granting us exclusive rights in North America, Europe and Japan to commercially develop recombinant human factor IX, or rhFIX, a plasma coagulation factor for the treatment of type B hemophilia. An existing rhFIX product marketed as BeneFIX® by Pfizer (formerly Wyeth) is commercially available with estimated 2008 annual sales of $587 million, which is demonstrating continuing growth. In 2008 this program was brought into our joint venture with LFB. ProGenetics is responsible for the production of rhFIX in the milk of transgenic pigs. We are responsible for developing the downstream processing, conducting clinical programs and managing regulatory requirements. Our objective is to develop an extended half life version of rhFIX while taking advantage of our transgenic production technology to lower the cost of treatment. We anticipate initiating clinical studies for rhFIX in 2011.
- **rhAFP:** In 2009, we obtained exclusive worldwide rights from Merrimack Pharmaceuticals for the development and commercialization of recombinant human alpha-fetoprotein, or rhAFP, including the recombinant, non-glycosylated version of rhAFP for the treatment of autoimmune diseases. We have established a production herd of transgenic goats for this product. We believe that rhAFP has the potential for the treatment of multiple sclerosis, or MS, and myasthenia gravis, or MG. We anticipate initiating Phase II clinical studies for rhAFP in 2010 in MG, provided that we can secure a development and commercialization partner that will provide funding for the program.
- **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, including chronic obstructive pulmonary disease. Patients with hereditary deficiency of alpha-1 antitrypsin are likely to experience declining lung function throughout their lives. The genetic defect leading to HD 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. In 2008, this program was also brought into our joint venture with LFB. Currently the U.S. market for plasma-derived alpha-1 antitrypsin is approximately $400 million and is dominated by Prolastin® produced by Talecris. We are seeking a partner to support the further clinical development and commercialization of this product.

Follow-on Biologics (FOBs)

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 MAbs, which in total had worldwide sales of more than $18 billion in 2009. The patents for the first generation of these therapeutic MAbs begin to expire in 2013, creating a significant opportunity for companies that are capable of producing follow-on biologics, or FOBs, which are also known as biosimilars. We believe that we also have the opportunity, using enhanced ADCC which is a key feature of our technology, to produce improved versions of innovator MAbs or,

biobetters, which have the potential to demonstrate improved clinical efficacy in oncology indications. We believe our transgenic technology platform enables the commercialization of follow-on biologic MAbs independent of key mammalian cell culture patents. This would enable these products to be marketed earlier than competitive MAbs derived from cell culture. In addition, the decreased royalty burden on our transgenic versions of MAbs will provide an additional cost of goods advantage. This market opportunity combines relatively low risk with potentially 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 four MAbs targeted at CD20; human epidermal growth factor receptor 2, or HER2; tumor necrosis factor, or TNF; and epidermal growth factor receptor, or EGFR as potential biosimilars or biobetters. The currently marketed products have patents expiring from 2014 onwards. We are co-developing the TG20 MAb with LFB, which is our transgenically produced antibody targeted to CD20. We own worldwide rights for the other three antibody FOBs in our portfolio. Currently marketed products for these four targets include Rituxan®, Herceptin®, Humira® and Erbitux® , respectively. Our transgenic platform technology enables the production of biobetter MAbs with naturally enhanced ADCC, which may provide antibodies, such as CD20, HER2 and EGFR, with superior efficacy for oncology indications. We have initiated the development of the production systems for all of these programs. We are seeking partnerships to support the development and commercialization of our portfolio of follow-on biologic MAbs. We also have a development agreement in place with AgResearch in New Zealand for the co-funding of further development of selected FOB MAbs.

- **CD20 MAb:** Under our joint venture with LFB, we are developing TG20, a MAb that targets the CD20 receptor of the immune system, which has target specificity similar to the rituximab MAb (Rituxan®, MabThera®). This antibody has demonstrated a significantly higher ADCC than rituximab. ADCC is one of the mechanisms that the immune system uses to kill cells targeted by a specific antibody. Therapeutic MAbs with increased ADCC are believed to offer more potent treatments for oncology indications. Rituximab is used as a single-agent treatment for relapsed or refractory indolent Non-Hodgkin's Lymphoma, or NHL, and also in combination with chemotherapy for the treatment of aggressive NHL. Rituximab has received marketing approval in both the EU and the U.S. for rheumatoid arthritis. Sales of rituximab were approximately $5.6 billion in 2009.

  We have developed transgenic goats that produce TG20 at high levels.

- **HER2 MAb:** We are developing an anti-human epidermal growth factor receptor 2, or anti-HER2, MAb that is expected to have similar characteristics to the trastuzumab MAb (Herceptin®). Trastuzumab, as a single agent, is approved for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease and, in combination with paclitaxel, it is also approved for the first-line treatment of HER2 overexpressing metastatic breast cancer. Worldwide sales of trastuzumab in 2009 were approximately $4.8 billion.

  We have generated transgenic goats that express an anti-HER2 MAb and, after characterizing the product, we plan to select appropriate founder animals for production.

- **TNF MAb:** We are developing an anti-tumor necrosis factor, or anti-TNF, MAb that is expected to have similar characteristics to the adalimumab MAb (Humira®). Adalimumab has been approved for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease and plaque psoriasis. Worldwide sales of adalimumab were $5.5 billion in 2009.

  We have initiated the generation of transgenic goats that are expected to produce an anti-TNF MAb. We expect the first animals to be born during 2010.

- **EGFR MAb:** We are developing an anti-epidermal growth factor receptor, or anti-EGFR, MAb that is expected to have similar characteristics to the cetuximab MAb (Erbitux®). Cetuximab is a chimeric MAb that has been approved for the treatment of metastatic colorectal cancer and head and neck cancer. Worldwide sales of cetuximab were approximately $2.7 billion in 2009.

Working with our collaboration partner, AgResearch, in New Zealand we have initiated the generation of transgenic animals that are expected to produce an anti-EGFR MAb. We anticipate that the first transgenic animals will be born in 2010. New Zealand provides advantages with respect to earlier patent expiries in ex-U.S. territories that will allow earlier marketing of certain products, such as an anti-EGFR MAb, than would be possible if the product was produced in the U.S. A significant portion of the funding for this program is provided by the New Zealand government as part of our research collaboration with AgResearch.

External Programs

In addition to our proprietary programs, we have programs in which our collaboration partner for the program owns the underlying product rights while we are contracted to produce or purify the product through our transgenic technology. We refer to these as our "external" programs.

- **JCOM:** In February 2009, we entered into a licenses and development agreement with JCOM Co. Ltd., an affiliate of Dong-A Pharmaceuticals (a leading pharmaceutical company in South Korea), whereby we granted to JCOM an option for an exclusive license for Asia and a separate option for a co-exclusive license for the rest of the world, under our patent and know-how rights to make, use, sell, offer for sale and import recombinant human insulin products in these territories. We are developing cell lines to demonstrate production of recombinant human insulin for JCOM. The agreement contemplates the subsequent establishment of a transgenic production system in South Korea.
- **PharmAthene, Inc.:** We have provided PharmAthene, Inc. a license to our broad patent for the production of Protexia® in their transgenic goats. Protexia® is a recombinant form of butyrylcholinesterase that is being developed by PharmAthene as a pre- and post-exposure therapy for casualties on the battlefield or civilian victims of chemical nerve agent attacks. We have manufactured product for preclinical and clinical studies for PharmAthene and we continue to provide development support for this program. PharmAthene's development of Protexia® as a biodefense product is funded by the United States Department of Defense, or DOD.
- **LFB:** In July 2009, we entered into a services agreement with LFB under which we provide research, process and product development and regulatory services for LFB's benefit in North America and for which we receive compensation at commercial rates.

Partnering Strategy

Until our 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. Our strategy is to expand our partnering arrangements across the range of our portfolio of products to support the further clinical development and commercialization of these products.

Proprietary Product Programs

The progress and timing of development of our proprietary products will be dependent upon our financial resources and our partnering arrangements. Our proprietary product programs are listed below in order of their priority.

ATryn® (Recombinant Human Antithrombin)

We have developed a transgenically produced recombinant form of antithrombin, known as ATryn®. In February 2009 ATryn® was approved by the FDA in the U.S. for patients undergoing surgery or childbirth and ATryn® was approved in 2006 by the EMA in the EU for patients undergoing surgical procedures. Our intention is to file for label expansion in the EU for patients undergoing childbirth. As part of the FDA approval we are required to conduct a post-marketing surveillance study to continue gathering data on this rare patient population.

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 2,000 to 5,000 people have HD, which suggests that approximately 60,000 to 150,000 people in the U.S. have HD.

Patients with HD have low levels of antithrombin in their blood stream and are prone to spontaneously develop thromboses 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®. When these HD patients are undergoing high-risk procedures, such as surgery or childbirth, the preferred course of treatment is to take them off their blood thinners and give them antithrombin to bring their antithrombin to normal levels in order to prevent the occurrence of thromboembolisms during the course of such procedures. The use of antithrombin in this indication, therefore, is an acute treatment for a chronic disorder.

Our strategy is to leverage the availability of ATryn® with readily scalable production capacity to support the development of additional clinical indications and the creation of markets significantly larger than those supported by today's plasma-sourced products. We also plan to seek approval for AD indications in the U.S. and Europe, which are significantly larger market opportunities than the HD indication, and to develop ATryn® in Japan and the rest of the world through further partnering arrangements.

We estimate that the existing worldwide annual sales for plasma-sourced antithrombin are approximately $250 million, split principally between Japan and Europe, with $20 million being sold in the U.S. as Thrombate III® by Talecris. Historically there has been periodic limited availability of plasma-derived antithrombin in the U.S., and this product has not been developed in the broader AD indications. Antithrombin products from European-sourced plasma are not approved for sale in the U.S.

We have a collaboration agreement with Lundbeck to develop and market ATryn® in the United States. The collaboration agreement includes the commercialization of ATryn® in the HD indication and the potential for further development of ATryn® in AD indications. The milestone payments to us under this agreement include a total of $9 million paid through approval of ATryn® for HD in the U.S. The collaboration anticipates further development of ATryn® in larger market acquired deficiencies such as the treatment of HR in patients undergoing coronary artery bypass graft (CABG) surgery and the treatment of DIC associated with severe sepsis, or DIC. 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 indications may lead to subsequent complications that increase patient risk for morbidity and mortality. Other examples of AD conditions include severe burns and bone marrow transplant procedures.

Under our agreement with Lundbeck, we anticipate continuing the development of ATryn® for the treatment of HR in patients undergoing CABG surgery that requires the use of a cardio pulmonary bypass (CPB) machine. Patients undergoing this surgery require anticoagulation with heparin to prevent clotting, which can occur when blood comes into contact with the tubing of the CPB machine performing the heart's function during surgery. Patients with HR do not respond adequately to the dose of heparin normally required to achieve sufficient anticoagulation for them to go on to the CPB machine. The overall incidence of HR has been reported to range from 10% to over 22% of CABG patients. Treatment of heparin resistant patients with fresh frozen plasma, which contains low concentrations of antithrombin, is one option to restore heparin sensitivity and achieve adequate anticoagulation to permit initiation of CPB. We previously completed two studies in the HR indication, and we are planning to conduct an additional Phase III study to determine the safety and efficacy of ATryn® in restoring heparin sensitivity in heparin resistant CABG patients as a basis for marketing approval in this indication.

Under our Lundbeck collaboration, we are responsible for production of ATryn® and receive a transfer price for commercial product, a royalty on net sales, $257 million in potential clinical, regulatory and sales milestone payments, including those already received, and payment for product used in clinical trials. Our agreement provides for Lundbeck to fund the further development of ATryn® in larger market acquired deficiencies indications. Lundbeck is responsible for sales and marketing and all associated commercialization costs of ATryn® in the U.S. ATryn® was launched by Lundbeck in the U.S. during the second quarter of 2009.

We also had a collaboration agreement with LEO Pharma A/S, or LEO, for the commercialization and further development of ATryn® in Europe, Canada, and the Middle East. In March 2009, we terminated the collaboration agreement with LEO and we entered into arbitration proceedings with the International Chamber of Commerce as described in more detail under Item 3 of this Annual Report. We are planning to establish alternative commercialization partners for ATryn® in these territories in 2010.

Recombinant Factor VIIa (rhFVIIa)

The research program for a transgenic version of FVIIa was initiated by LFB and became the first program in our LFB collaboration in 2006. We have now established transgenic production of rhFVIIa in rabbits. Following discussions with the FDA regarding our proposed clinical development plans for rhFVIIa, we plan to proceed with the filing of an IND for a Phase I study in normal healthy volunteers and to initiate this study in the second quarter of 2010. We expect to have results from this clinical study by the end of 2010. Following successful completion of this trial we will continue clinical development of rhFVIIa in the target hemophilia population in 2011.

Factor VIIa is used in treating Type A and Type B hemophilia patients who 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 ability to produce blood clots. A deficiency in either factor can prevent normal blood coagulation, resulting in abnormal and spontaneous bleeding. Hemophilia with inhibitors is a condition in which hemophilia A or B patients develop antibodies when their immune system incorrectly recognizes supplemental factors VIII or IX as foreign and impedes their function. This is the initial indication that we and LFB are developing. Providing supplemental factor VIIa enables the formation of blood clots even with existing factor VIII or IX deficiency. There are also potential further indications such as excessive bleeding in non-hemophilia patients 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 in excess of approximately $1.3 billion for 2009 from about 1kg of material, or in excess of $1,000/mg. Our transgenic production technology can produce essentially unlimited quantities of rhFVIIa at a lower cost, which will support the competitive pricing of our rhFVIIa product and is expected to enable its utilization in a broader range of indications and geographical territories.

Recombinant Alpha-Fetoprotein (rhAFP)

We acquired the exclusive worldwide commercial rights to develop recombinant human alpha-fetoprotein, or rhAFP, for the treatment of autoimmune diseases, from Merrimack Pharmaceuticals in July 2009. Based on epidemiological data, input from key opinion leaders and data from disease animal models, we are targeting rhAFP as a treatment for multiple sclerosis, or MS, and myasthenia gravis, or MG. Alpha-fetoprotein, or AFP is produced at high levels during pregnancy by the fetus and appears at peak levels in the maternal serum during the third trimester. It has been well documented that pregnant women who suffer from MS and MG often experience remission of their disease during pregnancy and, in the case of MS, it reaches its lowest incidence by the third trimester. Post-partum the disease rebounds quickly to the pre-pregnancy rate. This pattern is mirrored by the maternal serum levels of AFP which following their peak in the third trimester, rapidly plummet following the birth of the child. Well-characterized, robust animal models exist for MS. AFP derived from human cord blood as well as rhAFP have been shown to be effective in these models.

Merrimack conducted several clinical trials of our rhAFP in a number of indications that have provided a human safety database containing clinical data from more than 250 patients that were treated with multiple subcutaneous injections of rhAFP over periods of up to 39 weeks. The data suggests that rhAFP is well tolerated and has a benign side-effect profile. The safety data and the preclinical data package that is available to us on rhAFP should facilitate human clinical trials for MS and MG indications to be initiated as Phase II studies. We plan to initiate Phase II studies in MG after a source of development and commercialization funding is secured. Our current business development activities are directed at identifying and securing such funding.

The potential annual market for MS is currently greater than $8 billion, and the potential annual market for MG is estimated at approximately $200 million. Although the potential annual market for MS is significantly greater than that for MG we believe that MG offers a faster path as a first indication for approval.

Recombinant Factor IX (rhFIX)

In 2007, we obtained a license from ProGenetics, LLC, granting us exclusive rights in North America, Europe and Japan for commercial development of 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 its existing herd of transgenic pigs. We are responsible for developing the downstream processing, conducting clinical programs and managing regulatory requirements. This program is also being developed as part of our joint venture with LFB. Our objective is to develop an extended half-life version of rhFIX to provide an improved treatment option for hemophilia B patients while taking advantage of the transgenic production technology to lower the cost of treatment. We anticipate initiating clinical studies for rhFIX in the hemophilia B target patients in 2011.

Other Recombinant Plasma Proteins

Alpha-1 Antitrypsin (rhAAT). Alpha-1 antitrypsin, AAT, is a plasma protein that is known to be an inhibitor of elastase. Scientists believe that uninhibited elastase activity in the lungs may lead to the progressive development of emphysema and several other respiratory disorders, including chronic obstructive pulmonary disease, severe asthma and cystic fibrosis. Patients diagnosed with AAT deficiency can be treated weekly with injections of AAT to mitigate the onset of these debilitating conditions. Like antithrombin, AAT is a product that is currently sourced from fractionated human plasma and has proven difficult to express in traditional recombinant production systems in economically viable quantities.

We have developed goats that produce a recombinant form of AAT, or rhAAT in significant quantities, which we believe can provide a highly pure and unconstrained supply of rhAAT to the market. In 2008, this program was brought into our joint venture with LFB. Our objective is to establish partnership arrangements to support the further development and commercialization of rhAAT.

We estimate that plasma-sourced AAT products currently generate worldwide annual sales of between $300 million to $400 million, principally in the U.S. The largest supplier of plasma-derived AAT in the U.S. is Talecris. Talecris has disclosed that sales of its Prolastin® product were $316.5 million in 2008. Similar to our other recombinant plasma protein programs, we believe the market for our rhAAT product may be expanded significantly beyond the market for the current plasma-derived products as a result of our unconstrained production capacity. This is a hereditary condition, which is significantly under-diagnosed and under-treated. We believe there are also further opportunities for multiple indications, which will require the development of pulmonary delivery systems for this product.

Other Proteins. We obtained exclusive rights from ProGenetics to 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. We are not yet developing this recombinant human factor VIII. We have subsequently sub-licensed the exclusive license to the transgenic production of fibrinogen to Pharming N.V.

Follow-on Biologics (FOBs)

We believe that the cost, large scale supply and patent advantages of our transgenic production technology are ideally suited to developing cost-effective FOBs, particularly MAbs, once the innovator products no longer have patent protection. MAbs are proteins that bind to a specific target and can be used in a variety of treatments including infectious diseases, auto-immune disease and cancers. MAbs typically express at reasonable levels in traditional recombinant production systems, but are often required in large quantities (>500kg) for their use in chronic disease indications. The patents for the first generation of therapeutic MAbs and other antibody-like proteins begin to expire in 2013, creating a significant opportunity for companies that are capable of producing

FOBS. The regulatory path for FOBs products following patent expiration has been defined in Europe, and the U.S. Congress is considering similar legislation. We anticipate that each FOB product will generally require some level of clinical study, although not necessarily as extensive as that performed for the innovator antibody. We also have a development agreement in place with AgResearch in New Zealand for co-funding further development of selected FOB MAbs. New Zealand provides advantages with respect to earlier patent expiries in ex-U.S. territories that will allow earlier marketing of certain products, such as an anti-EGFR MAb, than would be possible if the product was produced in the U.S.

We have demonstrated transgenic production of a number of MAbs in both our proprietary and contract research and development programs. We have 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 which, through license fees, significantly increase the cost of goods for products produced using these manufacturing systems.

The process and timing of development of FOB MAbs will be dependent upon our financial resources and our partnering arrangements, as well as the regulatory pathway for the approval of these products. Legislation to enable the approval of FOBs by the FDA is currently under consideration by Congress. We have initiated the development of transgenic founder lines for the production of MAbs to CD20, HER2, TNF and EGFR.

CD20 Monoclonal Antibody (MAb)

Under our joint venture with LFB, we are developing TG20, a MAb to the CD20 immune system receptor, which has target specificity similar to Rituximab® (Rituxan®, MabThera®). This antibody has demonstrated significantly higher ADCC than Rituximab®. ADCC is one of the mechanisms that the immune system uses to kill cells targeted by a specific antibody. Therapeutic MAbs that elicit increased ADCC are likely to offer more potent treatments for oncology indications. Rituximab® is used as a single-agent treatment for relapsed or refractory indolent Non-Hodgkin's 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 rheumatoid arthritis. Sales of Rituximab® were approximately $5.6 billion in 2009. We have developed transgenic goats that produce TG20 at high levels.

HER2 MAb

We are developing an anti-human epidermal growth factor receptor 2, or anti-HER2, MAb that is expected to have similar characteristics to trastuzumab (Herceptin®). Trastuzumab, as a single agent, is approved for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease and, in combination with paclitaxel, is approved for the first-line treatment of HER2-overexpressing metastatic breast cancer. Worldwide sales of trastuzumab in 2009 were approximately $4.8 billion.

We have generated transgenic goats that express an anti-HER2 MAb, and we plan to characterize the product and from these animals select appropriate founders.

TNF MAb

We are developing an anti-tumor necrosis factor, or anti-TNF, MAb that is expected to have similar characteristics to adalimumab (Humira®). Adalimumab is a human MAb that has been approved for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease and plaque psoriasis. Worldwide sales of adalimumab were $5.5 billion in 2009.

We have initiated the generation of transgenic goats that are expected to produce an anti-TNF MAb. We expect the first animals to be born during 2010.

EGFR MAb

We are developing an anti-epidermal growth factor receptor, or anti-EGFR, MAb that is expected to have similar characteristics to cetuximab (Erbitux®). Cetuximab is a chimeric MAb that has been approved for the treatment of metastatic colorectal cancer and head and neck cancer. Worldwide sales of cetuximab were approximately $2.7 billion in 2009.

Working with our collaboration partner in New Zealand, AgResearch, we have initiated the generation of transgenic animals that are expected to produce an anti-EGFR MAb. We anticipate the first transgenic animals will be born in 2010. New Zealand provides advantages with respect to earlier patent expiries in ex-U.S. territories that will allow earlier marketing of certain products, such as an anti-EGFR MAb, than would be possible if the product was produced in the US. A significant portion of the funding for this program is provided by the New Zealand government as part of our research collaboration with AgResearch.

Other Programs

CD137 Antibody

We have developed animals that produce an antibody to CD137, a protein 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 production capacity necessary to meet the anticipated demand for a CD137 antibody can be achieved more economically using our transgenic production technology rather than traditional cell culture and bacterial fermentation methods.

We have obtained key 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.

External Programs

Our external programs are ones in which our 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 had a number of external programs where we have successfully developed a transgenically produced version of the partner's protein on a service contract basis.

We currently have the following external programs:

JCOM Co. Ltd.

In February 2009, we entered into a licenses and development agreement with JCOM Co. Ltd., an affiliate of Dong-A Pharmaceuticals (a leading pharmaceutical company in South Korea), whereby we granted to JCOM an option for an exclusive license for Asia and, a separate option for a co-exclusive license for the rest of the world, under our patent and know-how rights to make, use, sell, offer for sale and import recombinant human insulin products in these territories. We are developing cell lines to demonstrate production of recombinant human insulin for JCOM. The agreement contemplates the subsequent establishment of a transgenic production system in South Korea.

PharmAthene, Inc.

We have provided PharmAthene, Inc. a license to our broad patent for the production of Protexia® in their transgenic goats. Protexia® is a recombinant form of butyrylcholinesterase that is being developed by PharmAthene as a pre- and post-exposure therapy for casualties on the battlefield or civilian victims of chemical

nerve agent attacks. We have manufactured product for preclinical and clinical studies for PharmAthene, and we continue to provide development support for this program. PharmAthene's development of Protexia® as a biodefense product is funded by the DOD.

LFB:

In July 2009, we entered into a services agreement with LFB under which we provide research, process and product development and regulatory services for LFB's benefit in North America and for which we receive compensation at commercial rates.

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. We also believe that we have the freedom to operate outside of the principle patents covering mammalian cell culture derived products.

Our transgenic production technology capabilities include the molecular biology expertise and intellectual property to generate transgenic animals that express a specific recombinant protein in their milk and to collect and purify the proteins once produced. We primarily utilize goats for production of proteins, but where advantageous, we also utilize rabbits, pigs, and cattle. We have also demonstrated 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 and product consistency in expanding production capacity and lower unit production costs. Of particular importance is the ability to be able to expand capacity by breeding a herd of animals. Since each animal duplicates each others' production characteristics, this duplication prevents the variation in protein characteristics frequently encountered during the scale-up of mammalian cell and bacterial culture systems. The absence of variation eliminates the need for the significant time and expense associated with re-validation of the scaled-up system and the early large investment in commercial scale production prior to Phase III trials. 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 1,450 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. We specifically do not permit the utilization of any of our transgenic or non-transgenic animals in the food chain, including their milk products.

While we have both the technical capability and the patent protection to work with a wide range of mammals, we typically utilize goats. However we also use rabbits, pigs or cattle in our development programs and 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 or nuclear transfer technology to develop our transgenic animals. Microinjection involves introducing the desired DNA into a fertilized single cell embryo. 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 into 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 can offer more rapid development of large-scale production capacity by producing a larger number of transgenic animals in one generation than through microinjection.

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 economically attractive expression rates with complex molecules, such as recombinant plasma proteins and MAbs.
- *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. In addition, since the herd can be expanded following product approval, our technology avoids the need for large high risk capital investment at an early stage of product development which can significantly increase return on investment.
- *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. In addition, our intellectual property position enables development and commercial production of MAbs without relying on patents normally associated with cell culture and bacterial production technologies which, through license fees, significantly increase the cost of goods for products produced using these manufacturing systems.
- *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. At the very least the scale-up of such cell culture systems requires a revalidation of the new system that is expensive and time-consuming. Sometimes products are sufficiently different that they require additional clinical trials to demonstrate bioequivalence. The scale-up of transgenic systems is achieved by increasing the number of animals by natural breeding. Since each animal duplicates each others' production characteristics this prevents the variation in protein structure.
- *Glycosylation and ADCC Benefits.* Glycosylation refers to the natural process or result of adding sugars, or carbohydrates, to the amino acid structure of a protein during its production. Glycosylation of MAbs produced in the mammary gland may have beneficial characteristics such as enhanced ADCC compared to those expressed in traditional cell culture and bacteria based technologies because of

naturally low fucose levels. ADCC is one of the mechanisms that the immune system uses to kill cells targeted by a specific antibody. Therapeutic MAbs that elicit increased ADCC are likely to offer more potent treatments for oncology indications where targeted cell death is a desired outcome.

Collaborations

Lundbeck Inc. (formerly OVATION Pharmaceuticals, Inc.)

In June 2008, we entered into a collaboration agreement with Lundbeck to develop and market ATryn® in the United States. The collaboration agreement includes the commercialization of ATryn® in the HD indication and the potential further development of ATryn® in AD indications. Under the terms of our agreement, Lundbeck is obligated to make milestone payments to us for a total of $9 million through approval of ATryn® for HD in the U.S., all of which has been received to date. The collaboration anticipates further development of ATryn® in larger market acquired deficiencies of antithrombin, such as the treatment of HR in patients undergoing CABG surgery that requires the use of a CPB machine and the treatment of DIC associated with severe sepsis.

We are responsible for production of ATryn® and receive a transfer price for commercial product, a royalty on net sales, $257 million in potential clinical, regulatory and sales milestone payments, including those already received, and payment for product used in clinical trials. Our agreement provides for Lundbeck to fund the further development of ATryn® in larger market AD indications. Lundbeck is responsible for sales and marketing and all associated commercialization costs of ATryn® in the U.S. ATryn® was launched in the U.S. during the second quarter of 2009.

LFB Biotechnologies

In September 2006, we entered into a collaboration agreement with LFB to develop selected recombinant plasma proteins and MAbs using our transgenic production platform. LFB is a subsidiary of LFB S.A., a vertically integrated plasma fractionation company based in Les Ulis near 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 our collaboration with LFB is for the development of rhFVIIa. We have added to the LFB collaboration programs to develop a recombinant form of human factor IX, TG20 an antibody to the CD20 immune system receptor, and recombinant human alpha-1 antitrypsin.

Our agreement with LFB provides that we are to share equally with LFB in the cost of the development and commercialization of each product and that we 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. Through 2009, LFB has contributed 76% of the costs of the joint venture and owns that same percentage of future profits, subject to our right, not our obligation, to reestablish our 50% ownership by repaying LFB our share of the costs plus a specified premium that increases over time as clinical development progresses. Under the agreement, a joint steering committee of each company's representatives determines product development and commercialization plans. We are responsible for development of the production system for the products and retain exclusive commercial rights to the products in North America. LFB is responsible for clinical development and regulatory review of the programs in this collaboration, and has exclusive commercial rights in Europe. We hold co-exclusive rights with LFB in the rest of the world to all 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. We have amended our agreement with LFB to establish LFB/GTC LLC as a separate legal entity for the joint venture. This amendment added LFB/GTC LLC as a party to the agreement and provided that rights to the intellectual property of the new joint venture will flow through this entity. All other terms and conditions remain the same.

In September 2006, LFB purchased $25 million of our securities (see Note 3 to the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report).

In December 2008, we completed a $15 million convertible debt financing with LFB (see Note 3 to the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report).

In June 2009, we entered into agreements with LFB as part of a convertible preferred stock financing. Under these agreements, LFB purchased shares of our newly-designated Series E preferred stock in July 2009 and exercised an option to purchase additional shares of Series E preferred stock, which we issued to LFB in November 2009. The two issuances of Series E preferred stock provided us a total of $12.3 million of cash proceeds (see Note 8 to the Notes to Consolidated Financial Statements including in Item 8 of this Annual Report).

In connection with the preferred stock financing described above, in June 2009 we also entered into agreements to refinance our senior debt, which was effected by repaying our outstanding obligations to GE Capital Corporation in full and issuing to LFB a new $3.5 million promissory note. The terms of this note were subsequently amended, effective January 2010 (see Note 3 to the Notes to Consolidated Financial Statements including in Item 8 of this Annual Report).

In July 2009, we entered into a services agreement with LFB under which we provide research, process and product development and regulatory services for LFB's benefit in North America and for which we receive compensation at commercial rates.

In addition, in November 2009, LFB purchased $3.625 million of our common stock (see Note 3 to the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report).

In February 2010 we issued a secured note payable to LFB in the principal amount of $7,000,000. The secured note is a 4%, 36-month secured note that has a single payment of principal and interest at maturity.

LEO Pharma

We also had a collaboration agreement with LEO Pharma A/S, or LEO, for the commercialization and further development of ATryn® in Europe, Canada, and the Middle East. In March 2009, we terminated the collaboration agreement with LEO and we entered into arbitration proceedings with the International Chamber of Commerce as described in more detail under Item 3 of this Annual Report. We are planning to establish alternative commercialization partners for ATryn® in these territories in 2010.

Patents and Proprietary Rights

We currently hold 24 issued or allowed U.S. patents and 202 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 2010 and 2023. In accordance with ongoing research and development efforts, we have 29 pending U.S. patent applications and 81 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., PharmAthene and JCOM. 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 and the production of recombinant antithrombin in the milk of transgenic goats. Pursuant to our debt financing with LFB, LFB has a first lien on all of our intellectual property, including trademarks, not otherwise assigned to third parties. These liens do not prevent us from licensing technology in the ordinary course of business.

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 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 its 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 us exclusive rights for North America, Europe and Japan to commercially develop recombinant human factor VIII and recombinant human factor IX. LFB subsequently purchased a 50% share of these rights, and these rights have are being assigned to the LFB/GTC joint venture. 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 ATryn® comes from a number of companies regionally 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 is the only company that has commercially available fractionated antithrombin, Thrombate III®, that is approved for sale in the U.S. Talecris' U.S. sales are a small portion of the worldwide antithrombin market. There are several regional providers of plasma-derived antithrombin in Europe, including Octopharma, Grifols, Baxter International, Pfizer, Inc., CSL Behring and LFB. ATryn®, as a result of its EMA approval, is the only antithrombin product with a market authorization for all countries of the EU. A Grifols plasma-derived antithrombin product is in clinical studies in the U.S. to support a planned request for FDA approval. Antithrombin products from European-sourced plasma are not approved for sale in the U.S. As part of the orphan drug designation of ATryn®, we have been granted U.S. market exclusivity for seven years for the treatment of patients in the HD indication.

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 plasma-derived factor VIIa products for the treatment of hemophilia patients. The NovoSeven® patents expire in 2011. A number of companies including Novo Nordisk are developing second generation factor VIIa products that may compete with our product.

An existing rhFIX product marketed as BeneFIX® by Pfizer (formerly Wyeth) is commercially available with estimated 2008 annual sales of $587 million, which is demonstrating continuing growth. A number of companies are developing second generation factor IX products that may compete with our product.

Talecris has disclosed that sales of its Prolastin® product were $316.5 million in 2008. We estimate that plasma-sourced AAT products in total currently generate worldwide annual sales in excess of $400 million.

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 our competitors.

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 EMA in Europe. As of the filing of this report, ATryn® is the only transgenically produced drug approved for marketing in Europe and the U.S.

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 is compiled by the manufacturer into either a New Drug Application, or NDA, for new drugs, or a Biologics License Application, or 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.

For technologies such as ours where animals incorporate additional DNA into their genome, the FDA has established guidance that New Animal Drug Applications shall be submitted to permit review by the Center for

Veterinary Medicine. This NADA review is focused on the control of the transgene, the health of the animals involved, and any environmental impact. The ATryn® program was reviewed under an NADA, and all elements of our care and use of animals program were deemed to meet the standards required for approval when ATryn® was approved in February 2009.

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 product 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 2009, 2008 and 2007, we incurred development expenses of $25.4 million, net of a $1.5 million receivable from LFB, $21 million, net of $5.1 million of funding from LFB, and $28.9 million, net of $1.2 million of funding from LFB, respectively, including preclinical and clinical development expenses related to our proprietary programs. Of the total spent on research and development, $11 million, $15.5 million and $21 million, was for costs spent on the ATryn® development program in fiscal years 2009, 2008 and 2007, 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.

New Zealand Goats

Since 1993 we have maintained a reserve herd of goats in New Zealand as security and as a backup herd for our goats in the U.S. We have resourced our goats from New Zealand because of the exceptional record of low levels of adventitious organisms in New Zealand livestock.

Employees

As of January 3, 2010, we employed 109 people, including 1 part-time employee. Of our total employees, 66 were engaged in farm operations, clarification processes, quality assurance and control, 12 were engaged in research and development and 31 were engaged in administration, business development and marketing. Of our employees, 10 have Ph.D. degrees and 2 have D.V.M. degrees. None of our employees are covered by collective bargaining agreements. We believe our employee relations are satisfactory. During the fourth quarter of 2009, we implemented a restructuring plan, including a headcount reduction of 30% that included 45 full time equivalent employees. This reduction will help enable us to meet the requirements of our key programs and extend the duration of our cash resources. These changes are expected to provide savings of $5 to $6 million on an annualized basis.

Executive Officers

Our executive officers and their respective ages and positions as of March 1, 2010 are as follows:

Name	Age	Position
Geoffrey F. Cox, Ph.D.	66	Chairman of the Board, President and Chief Executive Officer
John B. Green	54	Senior Vice President, Chief Financial Officer and Treasurer
Harry M. Meade, Ph.D.	63	Senior Vice President, Research and Development
Richard A. Scotland.	54	Senior Vice President, Regulatory Affairs
Daniel S. Woloshen	61	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 30 years of financial experience, including 20 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.

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 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 at least the next two years and we may never receive material revenues from product sales or become profitable.

We have had operating losses since our inception, and we may never receive material revenues from product sales or become profitable. From our inception in 1993 to January 3, 2010, we have incurred cumulative losses of approximately $329 million. These losses have resulted principally from the costs of our research and development activities. Our net losses for fiscal years 2009, 2008 and 2007 have been $27.9 million, $22.7 million and $36.3 million, respectively.

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.

As of January 3, 2010, we had $3.8 million in cash and cash equivalents, which were offset by our $23.5 million in current liabilities. We expect our current cash resources including the bridge loan financing from LFB of $7 million received in the first quarter of 2010, as well as potential cash receipts from existing programs, to be sufficient to fund operations to the end of the second quarter of 2010. 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 funding from a combination of these sources, to fund a sufficient number of our clinical development plans through to regulatory approval to allow us to be self-sustaining.

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

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. 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 or scale back our operations.

Our drug development programs and the further development of ATryn® 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 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 Lundbeck to develop and market ATryn® and a collaboration agreement with LFB to develop selected recombinant plasma proteins and MAbs. In March 2009, we terminated the collaboration agreement with LEO and we entered into arbitration proceedings with the International Chamber of Commerce as described in more detail under Item 3 of this Annual Report. We are planning to establish alternative commercialization partners for ATryn® in these territories in 2010. 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 and significant funding.

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 first receive regulatory approvals from federal, state and local governmental authorities, including the FDA and corresponding agencies in other countries, such as the EMA in Europe. We received our only regulatory approvals of any of our transgenically produced products in August 2006 from the EMA for use of ATryn® as a prophylactic treatment of patients with hereditary antithrombin deficiency undergoing surgical procedures and from the FDA in February 2009 for surgical procedures and childbirth. Our Marketing Authorization Application for ATryn® was approved by the EMA 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. 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.

In addition to traditional regulatory review by the FDA, the FDA established guidance for New Animal Drug Applications to be submitted to permit review by the Center for Veterinary Medicine of technologies such as ours where animals have additional DNA incorporated into their genome. This NADA review is focused on control of the transgene, the health of the animals involved, and any environmental impact. Although the ATryn® program was reviewed and approved under an NADA and all elements of our care and use of animals were deemed to meet the standards required for approval, there is no guarantee that we will continue to meet NADA standards in future periods or for future products.

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.

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 Group N.V. is the only other entity to have completed human clinical trials sufficient to support the filing for regulatory approval of a product produced from a transgenic mammal. If we are unable to complete all clinical trials and to satisfy other requirements that may be required by the FDA or the EMA 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 rely on third party contract manufacturers to purify and formulate our transgenically produced products.

Our business requires us to manufacture ourselves, or contract for the supply of, current and future supplies of our transgenically produced products. In order for us to be successful, such supplies must (i) be of the appropriate quantity, quality and cost, (ii) be available on a timely basis, and (iii) be in compliance with all applicable regulatory requirements. 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 fill/finish 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, EMA and other regulations; and
- high production costs.

These contract manufacturers may not be able to manufacture our products at a cost or in sufficient 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.

Additionally, the quantities of products that we contract for our third party contract manufacturers to purify and formulate are based upon our estimates and the estimates of our collaboration partners of the market demand for our products. Market demand for our products is difficult to forecast, and if estimates for our products are greater than actual product demand, then we may be forced to incur additional manufacturing expenses, including production cancellation fees, and not be able to recoup them through sales.

We have contracted with 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 ability to manufacture bulk delivery of ATryn® for timely delivery to our collaborators or to make timely 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
- the relative risk-benefit profile and cost-effectiveness of transgenically produced product designed to replace or supplement currently marketed non-transgenically produced products.

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 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 and LFB supply the European market with plasma-derived antithrombin products, none of which have 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 2011.

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. 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.

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.

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 24 issued or allowed U.S. patents and 202 corresponding foreign patents. Our patents generally expire between 2013 and 2015, with the exception being a patent in the United States that 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 29 pending U.S. patent applications and 81 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 invalidated in favor of a patent application now licensed to Start Licensing, Inc. In response to the ultimate resolution of that invalidation, we 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.

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 conducted to support the 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 Lundbeck. 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 expected to be delisted from the Nasdaq Capital Market, which may adversely affect the price, liquidity and volatility of our common stock

We do not expect to regain compliance with the minimum $35 million market value of listed securities requirement for continued listing under the NASDAQ Listing Rules and, therefore, we expect that our common stock will cease to be listed on The NASDAQ Capital Market on or after March 18, 2010. We are making plans to have trading in our common stock transferred to the Over-the-Counter Bulletin Board ("OTCBB"), an

electronic quotation service operated by the Financial Industry Regulatory Authority ("FINRA"). While we have been advised by a market maker that it has filed the necessary application to quote our common stock with FINRA, we understand that the market maker will not receive clearance from FINRA to commence trading in our common stock on the OTCBB until our common stock is no longer listed on NASDAQ. Accordingly, we do not yet have confirmation that our shares will trade on the OTCBB.

The OTC Bulletin Board is generally considered to be a less efficient market than the Nasdaq Capital Market. As a result of trading on the OTC Bulletin Board and not on an active exchange, our common stock may experience: lower trading volumes, larger spreads between bid and ask prices, and/or significant price and volume volatility, factors which may adversely impact the market price of our common stock. Additionally, trading on the OTC Bulletin Board through market makers could affect our shareholders' ability to find a liquid market for our shares.

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

As of January 3, 2010, in addition to approximately 24.7 million shares of our common stock outstanding, there were:

(i) warrants outstanding to purchase an aggregate of approximately 4.4 million shares of our common stock at exercise prices ranging from $3.10 to $20.50 per share, which were issued to investors in various prior financings;

(ii) an outstanding convertible note to LFB that is convertible into 4.8 million shares of our common stock;

(iii) outstanding Series E preferred stock that is convertible into 5.3 million shares of our common stock; and

(iv) options to purchase an aggregate of 870,276 shares of common stock at varying exercise prices outstanding, of which total, options to purchase 603,634 shares were immediately exercisable and the underlying shares could be immediately resold into the public market.

The warrants to purchase an aggregate of 182,857 of shares of our common stock, which we issued in our August 2005 private placement, had an initial exercise price of $26.80 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 November 2009, the exercise price of the August 2005 warrants has been reduced to approximately $5.9848 per share.

We have 115 shares of Series D convertible preferred stock outstanding as of January 3, 2010, which are convertible into a total of 115 shares of common stock at the option of the preferred stock holder, LFB, any time.

We had 12,750 shares of Series E convertible preferred stock outstanding as of January 3, 2010, which was converted into a total of 5.3 million shares of common stock on January 8, 2010 at the option of the preferred stockholder, LFB.

We also have a convertible note payable to LFB in the remaining amount of approximately $800,000 as of January 3, 2010, the principal and accrued interest of 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.

In addition, in February 2010 we issued a secured note payable to LFB in the principal amount of $7,000,000, the principal and accrued interest of which may be cancelled at LFB's option and credited to the purchase of shares of our common stock or securities convertible or exchangeable into shares of our common stock in connection with certain future offerings or our securities at the price per share of the respective offering.

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, 2008, the trading price of our stock has fluctuated from a high of $11.90 to a low of $0.61. 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;
- sales of substantial amounts of our common stock in the public market, or the perception that such sales may occur;
- 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 reported average daily trading volume of our common stock for the twelve-month period ending January 3, 2010 was 59,788 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.

LFB, the stockholder with the largest beneficial ownership of our common stock, may seek to influence our business in a manner that is adverse to us or adverse to other stockholders who may be unable to prevent actions by LFB.

As our largest shareholder, LFB has substantial control over the outcome of most actions requiring the approval of our shareholders. As of January 3, 2010, LFB owned approximately 65% of our common stock and also held convertible debt, warrants and convertible preferred stock which they can convert and exercise into 12,468,637 shares of our common stock. If the convertible debt is converted, the warrants exercised and the convertible preferred stock converted, LFB would own 28,469,474 shares, or approximately 76.6%. Additionally, we have granted LFB nomination rights with respect to members of our Board of Directors commensurate with LFB's ownership of us, and in October 2009 LFB nominated, and our Board elected, four new directors in place of four of our independent directors. Now five of our eleven directors have been nominated by LFB, and LFB has the right to nominate up to eight directors if our Board continues to have eleven directors. We cannot assure that LFB will not seek to influence our business in a manner that is contrary to our goals or strategies or the interests of other shareholders. Moreover, persons who are directors of GTC and who are also directors and/or officers of LFB may decline to take action in a manner that might be favorable to us but adverse to LFB.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

All of our facilities are located in Massachusetts. 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 1,450 goats. This facility is subject to a mortgage in favor of LFB. 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 believe that our owned and leased facilities are adequate for significant further development of commercial transgenic products.

ITEM 3. LEGAL PROCEEDINGS

LEO Pharma informed us in September 2008 of its internal reprioritization and desire to transfer the ATryn® program to us or a third party, and LEO attempted to terminate its 2005 collaboration agreement with us for

alleged cause before completion of the Phase II study in DIC. However, LEO made it clear to us that their decision was not based on any safety or efficacy issues. We did not believe that LEO had any basis for such termination, and we further believed that LEO was in breach of the agreement. We initiated International Chamber of Commerce (ICC) arbitration proceedings in the fourth quarter of 2008 and asked the tribunal to determine that LEO is not legally entitled to exercise its contractual remedies on termination for alleged cause and that we are entitled to damages with respect to LEO's actions. In March 2009, we notified LEO that we were terminating the agreement pursuant to the terms of the agreement. LEO has asserted counterclaims for the return of unused ATryn® product under the terms of the agreement and for its costs of maintaining the clinical program on hold during the ICC proceeding, as well as unspecified charges for breach of confidentiality and for interest on any amounts awarded to LEO. A hearing on the dispute was held in the third quarter of 2009 before a tribunal of the ICC and we are awaiting a decision of the tribunal regarding the claims presented. We expect a decision in the first half of 2010, but cannot predict its likely outcome. A ruling by the ICC in favor of LEO would have a material adverse effect on our business.

BioProtein Technologies Company, a French corporation, brought a legal action against LFB and GTC in France on a breach of contract claim regarding a contract between BioProtein and LFB. LFB is the principal defendant, but we were joined in the lawsuit based on the allegations by BioProtein that we tortiously interfered with an existing contract between LFB and BioProtein. The total claim against both parties is for 31 million euros. We have retained counsel in France, and we will vigorously defend ourselves. However, pursuant to our Joint Commercialization and Development Agreement with LFB, LFB has agreed to fully indemnify us with respect to any legal fees and damages arising from this lawsuit.

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

ITEM 4. (REMOVED AND RESERVED)

PART II

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

Our Common Stock was traded on the Nasdaq Global Market under the symbol GTCB until July 2008 when we transferred our listing to the Nasdaq Capital Market under the same symbol. Quarterly high and low sales prices for our Common Stock as reported by the Nasdaq Global Market and the Nasdaq Capital Market for those respective periods are shown below:

2008:		
1st Quarter (ended March 30)	$ 11.19	$ 4.50
2nd Quarter (ended June 29)	7.30	3.60
3rd Quarter (ended September 28)	7.60	2.80
4th Quarter (ended December 28)	4.20	1.10
2009:		
1st Quarter (ended March 29)	$ 9.36	$ 2.70
2nd Quarter (ended June 28)	5.88	2.20
3rd Quarter (ended September 27)	2.68	1.58
4th Quarter (ended January 3)	1.82	0.61

On March 1, 2010, the closing price of our Common Stock was $1.08 per share as reported on the Nasdaq Capital Market.

As of March 1, 2010, we had approximately 212 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 January 3, 2010 and December 28, 2008 and for each of the three fiscal years in the period ended January 3, 2010 are derived from our consolidated financial statements included elsewhere in this Annual 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 December 30, 2007, December 31, 2006 and January 1, 2006 and for the years ended December 30, 2007, December 31, 2006 and January 1, 2006 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 Annual Report and our consolidated financial statements and related notes thereto under Item 8 of this Annual Report.

SELECTED FINANCIAL DATA

(Dollars in thousands except per share data)

	January 3, 2010	December 28, 2008	December 30, 2007	December 31, 2006	January 1, 2006
Statement of Operations Data:					
Revenue	$ 2,826	$ 16,656	$ 13,896	$ 6,128	$ 4,152
Costs of revenue and operating expenses:					
Cost of revenue	2,256	8,624	11,561	6,651	4,344
Research and development	25,417	21,031	28,925	25,401	21,145
Selling, general and administrative	11,407	10,208	9,834	9,723	8,428
	39,080	39,863	50,320	41,775	33,917
Operating loss from continuing operations	(36,254)	(23,207)	(36,424)	(35,647)	(29,765)
Other income and (expenses):					
Interest income	21	184	1,443	1,237	547
Interest expense	(3,443)	(1,183)	(1,329)	(1,001)	(1,140)
Other income (expense)	12,723	1,541	(11)	66	246
Net loss	$ (26,953)	$ (22,665)	$ (36,321)	$ (35,345)	$ (30,112)
Dividends/accretion on redeemable convertible preferred stock	(900)	—	—	—	—
Net loss attributable to common shareholders	$ (27,853)	$ (22,665)	$ (36,321)	$ (35,345)	$ (30,112)
Net loss per common share (basic and diluted)	$ (2.18)	$ (2.31)	$ (4.66)	$ (5.29)	$ (6.19)
Weighted average number of shares outstanding (basic and diluted)	12,778,445	9,819,996	7,786,300	6,686,035	4,865,814

	January 3, 2010	December 28, 2008	December 30, 2007	December 31, 2006	January 1, 2006
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 3,816	$ 11,643	$ 15,765	$ 43,385	$ 36,169
Working capital	(16,085)	(2,302)	(1,740)	29,382	18,601
Total assets	26,000	40,403	40,713	73,235	66,719
Long-term liabilities	24,968	28,469	13,970	16,443	9,688
Redeemable convertible preferred stock and Shareholders' equity (deficit)	(22,484)	(4,123)	8,024	37,956	36,709

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 specific human protein in their milk. Using the unique characteristics of this production technology, we are developing two portfolios of therapeutic proteins:

- **Recombinant plasma proteins.** Our portfolio of recombinant plasma proteins is being developed to treat a range of genetic and acquired blood deficiencies, including hemophilia and other blood coagulation disorders. Historically these blood proteins, also known as plasma

proteins, have only been available by extraction from human blood. Recombinant versions of plasma proteins are difficult to produce in an economically viable manner using other manufacturing systems.

- **Monoclonal antibodies as follow-on biologics**. Our portfolio of monoclonal antibodies, or MAbs, is being developed for use as potential follow-on biologics targeted at several large markets in oncology and autoimmune diseases.

We also continue to provide production services for external partners, which provides us a continuing source of cash and revenue.

Our production technology has been validated by the regulatory approval of our first product ATryn®, which is a recombinant form of the human plasma protein antithrombin, by the European Medicines Agency, or EMA, in 2006 and by the United States Food and Drug Administration, or FDA, in February 2009. ATryn® remains the only transgenically produced therapeutic protein to be approved anywhere in the world. In connection with the approval of ATryn®, the FDA's Center for Veterinary Medicine also approved our New Animal Drug Application, the first of its kind to regulate genetically engineered animals. We believe that these regulatory approvals of our transgenic technology are important benchmarks for obtaining future approvals for our portfolio of products in development.

The key characteristics of our transgenic production technology include:

- the manufacture of proteins that are difficult to express in other manufacturing systems;
- the production of proteins in large quantities;
- the production of proteins with significantly lower capital cost and lower cost of goods;
- predictable and flexible scale-up;
- naturally enhanced efficacy for oncology MAbs (increased Antibody Dependent Cell-mediated Cytotoxicity, or ADCC);
- strong intellectual property position and freedom to operate; and
- an established commercial scale infrastructure capable of supporting the production of our recombinant plasma protein and MAb products.

We plan to develop our portfolio of recombinant protein products through strategic collaborations:

- In September 2006, we entered into a collaboration agreement with LFB Biotechnologies, S.A.S, or LFB, to develop selected recombinant plasma proteins and MAbs. 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. This collaboration is established in a separate joint venture entity, and we have added other programs to this joint venture, including a recombinant form of human blood coagulation factor IX, which we in-licensed from ProGenetics, LLC, and a recombinant human alpha-1 antitrypsin, as well as an antibody to the CD20 immune system receptor, the same target as for the MAb marketed as Rituxan® or MabThera®.
- In June 2008, we entered into a collaboration agreement with Lundbeck Inc. (formerly OVATION Pharmaceuticals, Inc.), to develop and market ATryn® in the United States. The collaboration agreement includes the commercialization of ATryn® in the HD indication and the further development of ATryn® in acquired antithrombin deficiency indications, or AD. In the second quarter of 2009, Lundbeck commercially launched and reported the first sales of ATryn® in the U.S.

We are also seeking collaborations for the further development and commercialization of all of our proteins in development including those in the portfolio with LFB, as well as recombinant alpha-fetoprotein, or AFP, for the treatment of multiple sclerosis and myasthenia gravis, and our portfolio of MAbs. We acquired exclusive worldwide rights to AFP in 2009.

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 have operated on a service contract basis, generally receiving fees for the development of the production platform and production and purification of the proteins. As of January 3, 2010 we had two active external programs, one with PharmAthene and one with JCOM.

We have operated at a net loss since our inception in 1993, and we used $27.3 million of cash in operating cash flows in 2009. 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 January 3, 2010, including the bridge loan financing from LFB of $7 million received in the first quarter of 2010, as well as potential cash receipts from existing programs, we believe our resources will be sufficient to fund operations to the end of the second quarter of 2010. We expect that future sources of funding may include new or expanded collaboration arrangements and sales of equity or debt securities. If no funds are available, we would have to sell or liquidate the business. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, 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 commercialize independently. Additionally, any future equity funding would dilute ownership of our existing equity investors.

Our key value drivers include the following:

ATryn®

We have a collaboration agreement with Lundbeck to develop and market ATryn® in the United States. The collaboration agreement includes the commercialization of ATryn® in the HD indication and the potential for further development of ATryn® in AD indications. The milestone payments to us under this agreement include a total of $9 million through approval of ATryn® for HD in the U.S., all of which has been received to date. The collaboration anticipates further development of ATryn® in larger market acquired deficiencies such as the treatment of heparin resistance in patients undergoing cardiopulmonary bypass surgery and the treatment of DIC associated with severe sepsis.

Under our agreement with Lundbeck, we are developing ATryn® for the treatment of heparin resistance in patients undergoing coronary artery bypass graft (CABG) surgery that requires the use of a cardio pulmonary bypass (CPB) machine. Patients undergoing this surgery require anticoagulation with heparin to prevent clotting, which can occur when blood comes into contact with the tubing of the CPB machine performing the heart's function during surgery. Patients with heparin resistance generally do not respond adequately to the dose of heparin normally required to achieve sufficient anticoagulation for them to go on to the CPB machine. The overall incidence of heparin resistance has been reported to range from 10% to over 22% of CABG patients. Treatment of heparin resistant patients with fresh frozen plasma, which contains low concentrations of antithrombin, is one option to restore heparin sensitivity and achieve adequate anticoagulation to permit initiation of CPB. We previously completed two Phase III studies in the heparin resistance indication, and we are planning to conduct one additional Phase III study to determine the safety and efficacy of ATryn® in restoring heparin sensitivity in heparin resistant CABG patients as a basis for marketing approval in this indication.

We also had a collaboration agreement with LEO Pharma A/S, or LEO, for the commercialization and further development of ATryn® in Europe, Canada, and the Middle East. In March 2009, we terminated the collaboration agreement with LEO and we entered into arbitration proceedings with the International Chamber of Commerce as described in more detail under Item 3 of this Annual Report. We are planning to establish alternative commercialization partners for ATryn® in these territories in 2010.

LFB Collaboration Agreement

Under our collaboration agreement with LFB for the development of selected recombinant plasma proteins, we now have four ongoing programs. In 2008, we amended our agreement with LFB to establish LFB/GTC LLC, a separate legal entity for the joint venture. This amendment added LFB/GTC LLC as a party to the agreement and provided that rights to the intellectual property of the new joint venture will flow through this entity. This amendment also reflected LFB's agreement to provide up to $6 million in funding for our 2008 development costs related to the programs under the LFB collaboration. All other terms and conditions remain the same.

Under this joint venture, we are to share equally with LFB in the cost of the development and commercialization of each product and we are entitled to 50% of any profits derived from products developed through the joint venture, provided we each contribute equally to the costs of their development. In the event that contributions to the development are not equal, the profit allocation will be adjusted based on development costs incurred. Through 2009, LFB has contributed 76% of the costs of the joint venture and owns the same percentage of future profits, subject to our right, not our obligation, to reestablish our 50% ownership by repaying LFB our share of costs plus a specified premium that increases over time as clinical development progresses. Under the agreement, a joint steering committee of each company's representatives determines product development and commercialization plans. Our activities under the collaboration in 2009 were primarily focused on rhFVIIa, including the development of the production and purification system, definition of clinical and regulatory strategy and partnering and business development activities. We anticipate that the rhFVIIa product will enter clinical studies in 2010 initially in normal healthy volunteers and subsequently to evaluate its use in treating hemophiliacs that have developed inhibitors to coagulation factors VIII or IX. At January 3, 2010, we had a $1.5 million receivable from LFB related to a portion of our costs incurred in these programs during 2009, which was recorded against the program costs in research and development and subsequently received in January 2010. During 2008, we received approximately $5.6 million in funding from LFB, of which $5.1 million was recorded against the program costs in research and development for our actual costs incurred during 2008, the remaining $500,000 was recorded as a payable to the joint venture. During 2007, we received approximately $1.2 million in funding from LFB as reimbursement for an agreed upon portion of our costs incurred in these programs which was recorded against the program costs in research and development.

For a detailed discussion of the programs that are included in the joint venture, see Item 1 of this Annual Report.

In July 2009, we entered into a services agreement with LFB under which we provide research, process and product development and regulatory services for LFB's benefit in North America and for which we receive compensation at commercial rates.

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 and product consistency 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.

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 Annual 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, transfer price payments for manufactured material, payments based upon the achievement of certain milestones and royalties on future product sales, if any.

We recognize revenue in accordance with the accounting standards for revenue recognition and revenue agreements with multiple deliverables.

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 a model that uses 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.

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

	2009	2008	2007
Merrimack	0%	23%	29%
Lundbeck	64%	0%	0%
LEO	0%	27%	32%
PharmAthene	17%	39%	28%
Other	19%	11%	11%
	100%	100%	100%

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 January 3, 2010 and December 28, 2008 related to ATryn®. Currently, because we have only two customers, we only capitalize inventory if orders have been received. Any inventory that we may capitalize in the future will be based on our expectation that it will be sold for clinical trials and commercial sale. If at any time we believe that the sale of inventory 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 based on orders received. 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. We anticipate our cost of production will be substantially reduced as we move to larger production volumes to support clinical and commercial requirements.

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 the accounting standard for share based payments, which requires companies to measure and recognize compensation expense for all share-based payments at fair value.

Under the modified prospective approach, this accounting standard applies to new awards and to awards that were outstanding on January 2, 2006. Under the modified prospective approach 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 the accounting standards for share based payments.

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, which includes both options and restricted stock units:

	(dollars in thousands)		
	January 3, 2010	December 28, 2008	December 30, 2007
Research and development expense	$ 312	$ 293	$ 359
Selling, general and administrative expense	394	367	488
Total share-based compensation	$ 706	$ 660	$ 847

Results of Operations

The key components to our losses are revenue, cost of revenue, research and development expenses, and selling, general and administrative expenses. During the fourth quarter of 2009, we implemented a restructuring plan, which included a headcount reduction of 30%, or 45 full time equivalent employees. This restructuring included employees from most departments located at both our Framingham and central Massachusetts locations. We recorded severance expense in the amount of $460,000 for the year ended January 3, 2010 of which approximately $374,000 and $86,000 was recorded to research and development expense and selling, general and administrative expense, respectively. During the year ended January 3, 2010, approximately $301,000 had been paid out of the severance reserve. At January 3, 2010, $159,000 remained in accrued liabilities in relation to unpaid severance costs, which will be paid out through the second quarter of 2010. This reduction will help enable us to meet the requirements of our key programs and maximize the impact of our cash resources. These changes are expected to provide savings of $5 to $6 million on an annualized basis.

2009 as Compared to 2008

	($ in thousands)			
	2009	2008	$ Change	% Change
Revenue	$ 2,826	$ 16,656	$(13,830)	(83%)
Cost of revenue	$ 2,256	$ 8,624	$ (6,368)	(74%)
Research and development	$ 25,417	$ 21,031	$ 4,386	21%
Selling, general and administrative	$ 11,407	$ 10,208	$ 1,199	12%
Other income	$ 9,301	$ 542	$ 8,759	1,616%

Revenue. Our revenue for 2009 was primarily derived from Lundbeck, of which approximately $1.4 million related to the sale of ATryn® product and approximately $359,000 related to the amortization of milestone payments previously received. We also derived approximately $467,000 of revenue from our external development program with PharmAthene during 2009. During 2008, we derived approximately $11.6 million of revenue from our external development programs, of which $6.6 million related to our work with PharmAthene, $3.8 million to the Merrimack program and $626,000 to the CD137 program and $4.2 million represented sales of ATryn® to LEO. Our work on the Merrimack program was completed in the third quarter of 2008, and our work on the PharmAthene agreement was substantially completed during the fourth quarter of 2008, although a scope of work extension on the existing program was awarded to us from PharmAthene during the third quarter of 2009, which extends into 2010. We expect revenue from external programs to continue to vary from quarter to quarter due to the nature, timing and specific requirements for these development activities. In subsequent quarters we expect shipments of ATryn® product to continue to generate revenue, though the amounts will vary from quarter to quarter.

Cost of revenue. The decrease in cost of revenue in 2009 from 2008 was primarily the result of a decrease of approximately $3 million on the ATryn® program related to termination of clinical development by LEO in 2008, as well as a decrease of approximately $2.6 million on the PharmAthene program related to development activities. 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.

Expenses. Our 2009 expenses include a $460,000 charge associated with the corporate restructuring that was implemented in the fourth quarter of 2009, of which approximately $86,000 and $374,000 are included in selling, general and administrative expense and research and development expense, respectively. Also, an additional week of operating expense is included in 2009 due to the fact that the fourth quarter was a fourteen week fiscal quarter. The impact of the additional week of operating expense in 2009 was approximately $300,000 as compared with 2008.

The increase in research and development expense in 2009 from 2008 was primarily due to our bearing a majority of our $7.3 million share of the expense of the LFB collaboration programs in 2009 compared to our $5.1 million share that was assumed by LFB when it fully funded the joint collaboration programs in 2008. There was also $2 million of additional expense in 2009 (primarily internal resources) on our follow-on biologics programs. In addition, in July 2009, we obtained from Merrimack Pharmaceuticals exclusive worldwide rights to the development and commercialization of recombinant human alpha-fetoprotein, or rhAFP, including the recombinant, non-glycosylated version of rhAFP for the treatment of autoimmune diseases. We incurred $1.7 million of expenses related to the Merrimack program in 2009. These increases were partially offset by a decrease of ATryn® related expenses of approximately $4.55 million. In consideration for the rights granted to us from Merrimack we transferred back to Merrimack our holding of Merrimack preferred stock, which was issued to us in December 2003 and recorded on our balance sheet at a value of $1.2 million, in the third quarter of 2009. The cost of the Merrimack preferred stock which was recorded at the time of issuance to us at $1.2 million, was recorded as a non-cash charge to in-process research and development expense at the time of our July 2009 purchase of the rights to rhAFP.

The research and development expense for 2009 included $11 million related to the ATryn® program as compared to $15.5 million in 2008. Details of ATryn® related expenses for the respective years are as follows:

	($ in thousands)	
	2009	2008
ATryn® manufacturing expenses	$ 7,210	$ 9,232
EMA regulatory process expenses	1,065	1,040
U.S. clinical trial and regulatory expenses	2,731	5,247
Total	$ 11,006	$ 15,519

Manufacturing costs included costs of producing clinical material in excess of the maximum transfer price to Lunbeck, 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 2009 we incurred approximately $7.3 million of expense for our joint collaboration programs with LFB (FVIIa, FIX, CD20 and AAT). On January 3, 2010, we recorded a $1.5 million receivable from LFB related to an agreed upon portion of our costs incurred in these programs during 2009 which was recorded against the program costs in research and development and was subsequently received in January 2010. During 2008, we incurred approximately $5.1 million of expense in support of the programs in our LFB collaboration (FVIIa, FIX, CD20 and AAT). During 2008 we were reimbursed approximately $5.6 million in funding from LFB, of which approximately $500,000 was recorded as a payable to the joint venture at the end of 2008.

We also incurred approximately $3.1 million of expense on other research and development programs during 2009 as compared to $4.2 million in 2008.

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.

The increase in SG&A expenses was primarily a result of increased costs related to the LEO arbitration of approximately $1.9 million as well as an increase of approximately $850,000 in consulting costs related to our financing and partnering efforts. These increases were partially offset by a decrease in other legal and patent costs of approximately $1.3 million as well as a decrease of approximately $200,000 related to the elimination of a senior management position.

Other Income. The increase in other income was primarily a result of $12.5 million in non-cash other income as a result of the change in the fair value of the derivative and warrants associated with the redeemable convertible preferred stock (see Note 8) partially offset by an increase in interest expense of $2.3 million related to the convertible debt issued to LFB in December 2008 as well as $1.5 million received and recorded in 2008 from the settlement of arbitration related to the write-off of ATryn® inventory that was rendered unusable as a result of the fill/finish process conducted at a U.S. based third party fill/finish contractor during 2007.

2008 as Compared to 2007

	($ in thousands)			
	2008	2007	$ Change	% Change
Revenue	$ 16,656	$ 13,896	$ 2,760	20%
Cost of revenue	$ 8,624	$ 11,561	$ (2,937)	(25%)
Research and development	$ 21,031	$ 28,925	$ (7,894)	(27%)
Selling, general and administrative	$ 10,208	$ 9,834	$ 374	4%
Other income	$ 542	$ 103	$ 439	426%

Revenue. During 2008, we derived approximately $11.6 million of revenue from our external development programs, of which $6.6 million related to our work with PharmAthene, $3.8 million related to the Merrimack program, which was completed in the third quarter of 2008, $4.2 million from sales to LEO as well as $626,000 from the CD137 program. 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 $4.2 million from sales to LEO. We expect revenue from external programs and product shipments relating to ATryn® to continue to vary due to the nature, timing and specific requirements for these development activities.

Cost of revenue. The decrease in cost of revenue was primarily the result of write-offs that resulted in higher costs in 2007, including a $2.9 million write-off of ATryn® inventory which was rendered unusable 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 during 2007 of in-process inventory which was determined not to meet specifications during release testing for commercial use. In 2008, we received $1.5 million from the contractor for settlement of this loss which was recorded to other income. These decreases were partially offset by a net increase 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 2008 research and development expense included $15.5 million related to the ATryn® program, a decrease of $5.5 million over the $21 million in 2007. Details of expenses for the ATryn® program for the respective years are as follows:

	($ in thousands)	
	2008	2007
ATryn® manufacturing expenses	$ 9,232	$ 13,178
EMA regulatory process expenses	1,040	2,708
U.S. clinical trial expenses	5,247	5,091
Total	$ 15,519	$ 20,977

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 2008 we incurred approximately $5.1 million of expense related to the programs under the LFB joint venture (rhFVIIa - $2.2M; CD20 - $1.3M; rhFIX - $851,000; rhAAT - $795,000) and we received approximately $5.6 million of funding from LFB, of which approximately $500,000 was recorded as a payable to the joint venture at the end of 2008. During 2007 we incurred approximately $3.9 million related to the programs under the LFB collaboration (FVIIa - $3.3 million; FIX - $600,000; CD20 - $70,000), and we received approximately $1.2 million in funding from LFB in 2007 as reimbursement for an agreed upon portion of our costs incurred in these programs.

Selling, General and Administrative Expense. The increase in SG&A expenses was primarily a result increased legal costs related to patents and partnering and financing transactions.

Other Income. The increase in other income was primarily a result of $1.5 million received and recorded in 2008 from the settlement of arbitration related to the write-off of ATryn® inventory that was rendered unusable as a result of the fill/finish process conducted at a U.S. based third party fill/finish contractor during 2007, partially offset by lower interest income based on our cash balance and interest expense.

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 we have sufficient product sales and royalties to achieve positive cash flow from operations. We expect that our ability to raise future funds will be affected by our ability to enter into some combination of new or expanded partnering arrangements with contracts for external programs, the terms of such arrangements and contracts, the success of ATryn® sales in the U.S. for HD, the progress of initial clinical trials of ATryn® for AD indications, 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 2009 we had a net decrease in cash and marketable securities of $7.8 million, which reflects $27.3 million used in operations and $1.4 million used to pay down debt, net of $21.3 million of LFB funding and $387,000 used for capital expenditures. We are currently engaged in discussions for potential new partnering arrangements and plan to bring in further financial resources through some combination of partnering transactions, including milestones, and other debt or equity financings. 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.

On January 3, 2010, we had cash, cash equivalents and marketable securities of $3.8 million compared to $11.6 million on December 28, 2008, and we had negative working capital of $16.1 million on January 3, 2010, compared to negative working capital of $2.3 million on December 28, 2008.

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 2009 and since inception, and we have an accumulated deficit of approximately $329 million at January 3, 2010. The primary sources of additional capital raised in 2009, 2008 and 2007 have been equity financings and debt financings. Based on our cash balance as of January 3, 2010, including the bridge loan financing from LFB of $7 million

received in the first quarter of 2010, as well as potential cash receipts from existing programs, we believe our resources will be sufficient to fund operations including debt service requirements to the end of the second quarter of 2010. We expect that future sources of funding may include new or expanded collaboration arrangements and sales of equity or debt securities. If no funds are available, we would have to sell or liquidate the business. 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 commercialize independently. Additionally, any future equity funding would dilute the ownership percentage of our existing equity investors. On November 5, 2009, we implemented a restructuring plan to enable us to meet the requirements of key programs and to maximize the impact of our cash resources. The restructuring plan, which is expected to provide savings of $5 to $6 million on an annualized basis, included a reduction in our workforce from 154 to 109 employees.

Cash Flows used in Operating Activities

Cash used in operating activities increased by approximately $9.3 million from $18 million in 2008 to $27.3 million in 2009. The increase is primarily a result of an increase in our net loss of $4.3 million which included non-cash other income of approximately $12.5 million related to a change in the fair value of the derivative and warrants resulting from the redeemable convertible preferred stock financing, partially offset by milestone payments of $4 million received from Lundbeck and $750,000 received from JCOM in 2009 as well as an increase of approximately $1.5 million in accounts receivable from LFB.

Cash Flows from Investing Activities

There were no significant cash flows provided by or used in investing activities during 2009 as compared to $5.9 million provided by investing activities in 2008. The decrease is a result of the redemption of all of our short term investments during 2008 in order to finance our operations.

Cash Flows from Financing Activities

Equity Financing Activities

In February 2008, we received approximately $5.4 million in proceeds from a registered direct offering, net of approximately $600,000 in offering costs and fees. In the offering, we sold approximately 690,000 shares of our common stock at $8.70 per share (pos-split equivalent of the market price on the date of the agreement) and 7-year warrants to purchase an aggregate of approximately 690,000 shares of our common stock at an exercise price of $8.70 per share.

In November 2009, we sold approximately 3.4 million shares of our common stock to LFB at $1.07 per share (market price on the date of the agreement). We received approximately $3.5 million in proceeds from the sale.

Debt Financing Activities

In June 2009, we entered into agreements with LFB that provided a total of $12.3 million of cash proceeds in exchange for the issuance of shares of convertible preferred stock and an option for LFB to purchase additional convertible preferred stock. Shareholder approval for these transactions was granted at a special shareholder meeting held on July 30, 2009. LFB purchased a total of $25.5 million of convertible preferred stock of which $12.75 million was subject to an escrow arrangement to secure the future dividends payable on this convertible preferred stock, which accrue at a rate of 10% over five years. On October 30, 2009 LFB converted the redeemable convertible preferred stock into a total of approximately 10.6 million shares of our common stock, terminating LFB's obligation to fund the escrow for the redeemable convertible preferred stock purchased in July 2009. LFB had the option for six months to purchase $12.8 million of additional shares of convertible preferred stock with the same conversion prices allocated in the same proportions as in the original investment. On October 30, 2009 LFB notified us that it was exercising the option in full, and on November 3, 2009 we issued an

additional $12.75 million of Series E Preferred Stock. We received an additional $6.375 million of cash funding to us on the same terms as the initial investment, with the balance of the purchase price subject to the same escrow arrangement between us and LFB. In January 2010, LFB converted this remaining convertible preferred stock into a total of approximately 5.3 million shares of our common stock, terminating LFB's obligation to fund the escrow for this investment.

As part of these agreements, LFB also paid off the remaining net principal amount of our term loan with GE Capital for $3.5 million, in June 2009. Under the terms of these agreements, this $3.5 million of new debt to LFB will be repaid on a 10-year amortization schedule at a 10.8% interest rate with a balloon payment on January 1, 2012. LFB holds a first lien on all of our assets, including intellectual property, to secure this debt and its existing debt from us. The payoff of the GE Capital term loan was considered an extinguishment of debt and, therefore, we wrote off approximately $211,000 of deferred financing costs associated with the GE Capital term loan to interest expense during the second quarter of 2009. We were also charged an early termination fee of approximately $133,000 in accordance with the GE Capital term loan, which was also recorded to income expense during the second quarter of 2009. In December 2009, we amended the promissory note to reduce the interest rate to 4% effective January 1, 2010.

At the close of the LFB financing on July 31, 2009, LFB received an additional $25.5 million of preferred stock, including the conversion of the $4.5 million convertible note into preferred stock, which when converted in full into common stock in November 2009 increased LFB's holdings to approximately 70.1% of our common stock.

In addition, in February 2010 we issued a secured note payable to LFB in the principal amount of $7,000,000, the principal and accrued interest of which may be cancelled at LFB's option and credited to the purchase of shares of our common stock or securities convertible or exchangeable into shares of our common stock in connection with certain future offerings or our securities at the price per share of the respective offering.

In December 2008, we issued a $15 million convertible note and a warrant to LFB. The convertible note will mature on June 20, 2012 and bears interest at an annual rate of 8%. The debt may be converted into our common stock at a conversion price of $3.10 per share at LFB's discretion. The warrant we issued to LFB is a 5-year warrant to purchase 2,319,354 shares of our common stock at an exercise price of $3.10 per share. If we pay the note in full upon maturity, LFB has the right to require us to redeem the warrant for $1.5 million, which we have the option to pay in shares of our common stock. The proceeds of $15 million were allocated to the convertible note and the warrant based on their relative fair values. Based on that allocation, we recorded approximately $2.3 million to additional paid in capital and a debt discount which is being amortized over the term of the note, resulting in additional interest expense of $697,000 and $19,000 during the fiscal years 2009 and 2008, respectively. In connection with the agreement, we also recorded a debt discount of approximately $500,000 for costs incurred by us on LFB's behalf for completing the transaction, which is being amortized over the term of the note, resulting in additional interest expense of approximately $142,000 and $4,000 during fiscal years 2009 and 2008, respectively. In December 2009, we entered into an amended and restated secured convertible note which reduced the interest rate to 4% effective January 1, 2010.

In December 2006, we entered into a term loan with GE Capital in the amount of $10 million, of which $7.1 million was used to pay off a previous loan from GE Capital. As a result of the June 2009 financing with LFB (discussed above) the term loan with GE Capital was repaid in full on June 18, 2009.

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 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 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 $74,000, $92,000 and $225,000 during fiscal years 2009, 2008 and 2007, respectively.

Contractual Obligations

The following summarizes our contractual obligations at January 3, 2010, and the effect such obligations are expected to have on our liquidity and cash flow in future periods.

	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	Total
Contractual Obligations:					
Long-term debt obligations, principal and interest, including current portion[1]	$ 492	$ 19,189	$ 15	$ —	$ 19,696
Operating lease obligations	1,469	395	2	—	1,866
Minimum royalty obligation	250	500	500	354	1,604
Third party contractual obligations	1,701	1,458	243	—	3,402
Service and sublease agreement with Genzyme	480	—	—	—	480
Total contractual cash obligations	$ 4,392	$ 21,542	$ 760	$ 354	$ 27,048

(1) Our $17.1 million of outstanding long-term debt (principal) at January 3, 2010 includes approximately $12.9 million owed to LFB (net of unamortized discount of approximately $354,000) on the convertible note that we issued to LFB in December 2008, approximately $697,000 owed to LFB (net of an unamortized discount of approximately $144,000) on the convertible note that we issued to LFB in December 2006, and approximately $3.4 million owed to LFB on the term debt promissory note that we issued in June 2009. Of the $17.1 million, approximately $351,000 was classified as current, which reflects the amount due through September 2010 on the term debt promissory note with LFB that we issued in June 2009.

We are party to license agreements for certain technologies (see Note 7 to the Notes to Consolidated Financial Statements included in Item 8 of this Annual 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 June 2008, the FASB ratified the consensus reached on the clarification whether an instrument (or an embedded feature) is indexed to an entity's own stock, which would qualify as a scope exception under a previous rule. We adopted this change as of January 1, 2009. In August 2005, we sold 457,143 shares of our Common Stock at $17.50 per share and 5- year warrants to purchase an aggregate of 182,857 shares of our Common Stock at an exercise price of $26.80 per share in a private placement to institutional investors. These warrants were reassessed under the new rules and due to a price adjustment clause included in these warrants, they are no longer deemed to be indexed to our stock and therefore, no longer meets the scope exception of the previous rules. Therefore, these warrants were determined to be derivatives and were reclassified to a liability and will be adjusted to fair value at each reporting period with changes in fair value recorded in other income (expense). As a result, we recorded a cumulative adjustment of approximately $2.3 million to additional paid in capital and approximately $97,000 to other liabilities.

In June 2009, the FASB issued an amendment to the accounting and disclosure requirements for the consolidation of variable interest entities (VIEs). The elimination of the concept of a qualified special purpose entity removes the exception in this amendment for applying the consolidation guidance. This amendment requires an enterprise to perform a qualitative analysis when determining whether or not it must consolidate a VIE. The amendment also requires an enterprise to continuously reassess whether it must consolidate a VIE. Additionally, the amendment requires enhanced disclosures about an enterprise's involvement with VIEs and any significant change in risk exposure due to that involvement, as well as how its involvement with VIEs impacts the enterprise's financial statements. Finally, an enterprise will be required to disclose significant judgments and assumptions used to determine whether or not to consolidate a VIE. This amendment is effective for financial statements issued for fiscal years beginning after November 15, 2009. We do not expect the adoption of this Standard to have an impact on our financial position or results of operations.

In October 2009, the FASB issued an update to existing guidance on revenue recognition for arrangements with multiple deliverables. This update will require companies to allocate consideration received for qualified separate deliverables using estimated selling price for both delivered and undelivered items when vendor-specific objective evidence or third-party evidence is unavailable. Additional disclosures discussing the nature of multiple element arrangements, the types of deliverables under the arrangements, the general timing of their delivery, and significant factors and estimates used to determine estimated selling prices are required. This amendment is effective for financial statements issued for fiscal years beginning on or after June 15, 2010. Companies may elect to early adopt in any interim or annual financial statements that have not previously been issued. We have not yet determined when we will adopt this update or what the impact will be on our condensed consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We had certain fixed rate financial instruments at January 3, 2010, including three convertible promissory notes payable and three stand-by letters of credit, all of which are not sensitive to changes in interest rates. Two of our stand-by letters of credit totaling $449,360 are required under a facility lease and one letter of credit of $150,000 is in connection with the LEO collaboration. The total of our stand-by letters of credit is recorded as restricted cash. At January 3, 2010, nothing had been drawn down on the stand-by letters of credit. Our convertible note issued to LFB in 2008 had a principal balance of approximately $15 million at January 3, 2010. The proceeds were allocated to the convertible note and a warrant based on their relative fair values, resulting in $2.4 million allocated to the warrant and recorded to additional paid in capital. Our five-year convertible note payable to LFB had a principal balance of approximately $800,000 at January 3, 2010 and our three year promissory note to LFB had a principal balance of approximately $3.4 million at January 3, 2010. These instruments are not leveraged and are held for purposes other than trading.

For the remaining LFB convertible promissory notes outstanding, the table below presents the principal cash payments that exist by maturity date as of January 3, 2010.

	($ in 000's)						
	2010	2011	2012	2013	2014	Thereafter	Total
LFB Convertible Note Payable[1]	$ —	$ 843	$ —	$ —	$ —	$ —	$ 843
LFB Convertible Note Payable[2]	—	—	13,261	—	—	—	13,261
LFB Promissory Note Payable	300	—	3,099	—	—	—	3,399
Total	$ 300	$ 843	$ 16,360	$ —	$ —	$ —	$ 17,503

The interest rate on the LFB convertible notes payable were 2%, 8% and 10.8%, respectively, at January 3, 2010.[3]

(1) Based on our effective borrowing rate of 10.8%, we recorded a debt discount 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. The debt discount balance as of January 3, 2010 was approximately $145,000.

(2) We recorded a debt discount of approximately $500,000 for the expenses incurred by us on LFB's behalf. The debt discount is being amortized over the term of the note. The debt discount balance as of January 3, 2010 was approximately $354,000.

(3) In December 2009, we entered into an amended and restated secured convertible note and an amended and restated promissory note which reduced the interest rate to 4% from 8% and 10.8%, respectively, effective January 1, 2010.

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. Historically our primary market risk was interest rate risk on our investment portfolio however we did not have any investments as of January 3, 2010.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Financial Statements

Response to this item is submitted as a separate section of this Annual 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 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 January 3, 2010. The effectiveness of our internal control over financial reporting as of January 3, 2010, has been audited by PricewaterhouseCoopers LLP, an independent accounting firm, as stated in their report which is included in the index to this Annual Report under Item 15(a)(1).

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 Annual Report, 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, which is scheduled to be held on May 26, 2010 (the "2010 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 2010 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 2010 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 2010 Proxy Statement and is incorporated herein by reference. See also Note 11 to the Consolidated Financial Statements included in Item 8 of this Annual Report.

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 2010 Proxy Statement and is incorporated herein by reference.

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PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

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

(1) Financial Statements

(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 Annual Report.

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 January 3, 2010 and December 28, 2008, and the results of their operations and their cash flows for each of the three years in the period ended January 3, 2010 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 January 3, 2010, 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.

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 limited available funds as of January 3, 2010, which raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to this matter 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 12, 2010

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

	January 3, 2010	December 28, 2008
Current assets:		
Cash and cash equivalents	$ 3,816	$ 11,643
Accounts receivable and unbilled contract revenue	243	287
Related party receivable	1,500	—
Inventory	56	863
Restricted cash	599	—
Other current assets	1,217	962
Total current assets	7,431	13,755
Property, plant and equipment, net	12,456	13,396
Intangible assets, net	5,348	6,249
Other assets	765	2,404
Restricted cash	—	4,599
Total assets	$ 26,000	$ 40,403
Current liabilities:		
Accounts payable	$ 6,945	$ 8,024
Accrued liabilities	6,685	5,962
Short-term deferred contract revenue	6,875	688
Derivative liability	2,660	—
Current portion of long-term debt	51	1,383
Current portion promissory note to related party, net of debt discount	300	—
Total current liabilities	23,516	16,057
Long-term deferred contract revenue	8,173	9,180
Long-term debt, net of current portion	54	6,577
Long-term promissory note to related party	3,100	—
Long-term convertible note to related party, net of debt discount	13,604	12,692
Other long-term liabilities	37	20
Total liabilities	48,484	44,526
Commitments and contingencies (see Notes 6 and 8)		
Redeemable convertible preferred stock:		
Series E-1 Redeemable Convertible Preferred stock, net of offering costs; redemption amount of issued shares $6,000,000; $.01 par value; 18,000 shares authorized 6,000 shares and 0 shares were issued and outstanding at January 3, 2010 and December 28, 2008, respectively	4,223	—
Series E-2 Redeemable Convertible Preferred stock, net of offering costs; redemption amount of issued shares $6,750,000; $.01 par value; 20,250 shares authorized 6,750 shares and 0 shares were issued and outstanding at January 3, 2010 and December 28, 2008, respectively	4,370	—
Related party subscription receivable	(6,375)	—
Total redeemable convertible preferred stock	2,218	—
Shareholders' equity (deficit):		
Preferred stock, $.01 par value; 5,000,000 shares authorized: 15,000 shares designated as Series D convertible preferred stock, $.01 par value; 115 shares were issued and outstanding at January 3, 2010 and December 28, 2008	—	—
Common stock, $.01 par value; 210,000,000 shares authorized; 24,727,010 shares and 10,296,477 shares issued and outstanding at January 3, 2010 and December 28, 2008, respectively	247	91
Additional paid-in capital	303,869	299,901
Accumulated deficit	(328,818)	(304,115)
Total shareholders' equity (deficit)	(24,702)	(4,123)
Total liabilities, redeemable convertible preferred stock and shareholders' equity (deficit)	$ 26,000	$ 40,403

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		
	January 3, 2010	December 28, 2008	December 30, 2007
Revenues:			
Service revenue	$ 954	$ 12,185	$ 9,490
Product revenue	1,872	4,471	4,406
Total revenue	2,826	16,656	13,896
Costs of revenue and operating expenses:			
Cost of service revenue	1,081	4,453	7,163
Cost of product revenue	1,175	4,171	4,398
Research and development, net of related party reimbursements	25,417	21,031	28,925
Selling, general and administrative	11,407	10,208	9,834
Total cost of revenue and operating expenses	39,080	39,863	50,320
Operating loss	(36,254)	(23,207)	(36,424)
Other income (expense):			
Interest income	21	184	1,443
Interest expense	(3,443)	(1,183)	(1,329)
Other income (expense)	12,723	1,541	(11)
Net loss	$ (26,953)	$ (22,665)	$ (36,321)
Dividends/accretion on redeemable convertible preferred stock	(900)	—	—
Net loss attributable to common shareholders	$ (27,853)	$ (22,665)	$ (36,321)
Net loss per common share (basic and diluted)	$ (2.18)	$ (2.31)	$ (4.66)
Weighted average number of common shares outstanding (basic and diluted)	12,778,445	9,819,996	7,786,300

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 Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Amount			
Balance, December 31, 2006	15	$—	7,362	$(202)	$283,281	$(245,129)	$ 6	$ 37,956
Net loss						(36,321)		(36,321)
Common stock sold under Employee Stock Purchase Plan			18	2	166			168
Common stock issuance to the GTC Savings and Retirement Plan			28	4	307			311
Common stock issued under GTC Director Compensation Plan			5		55			55
Proceeds from the exercise of stock options			1		4			4
Proceeds from the issuance of common stock			363	36	4,446			4,482
Stock based compensation					847			847
Unrealized (loss) on investment							(3)	(3)
Common stock issued for Technology License			27	3	297			300
Common stock issued for legal settlement			22	2	223			225
Balance, December 30, 2007	15	$—	7,826	$(155)	$289,626	$(281,450)	$ 3	$ 8,024
Net loss						(22,665)		(22,665)
Common stock sold under Employee Stock Purchase Plan			9	2	39			41
Common stock issuance to the GTC Savings and Retirement Plan			42	4	206			210
Common stock issued under GTC Director Compensation Plan			14		52			52
Common stock issued under GTC Bonus Plan			63	6	392			398
Proceeds from the issuance of common stock			690	69	5,376			5,445
Stock based compensation					660			660
Unrealized (loss) on investment							(3)	(3)
Warrants issued for services					91			91
Conversion of LFB debt	(14)		1,652	165	3,459			3,624
Balance, December 28, 2008	1	$—	10,296	$ 91	$299,901	$(304,115)	$—	$ (4,123)
Net loss						(26,954)		(26,954)
Reclassification of warrant under current accounting standards					(2,347)	2,251		(96)
Common stock sold under Employee Stock Purchase Plan			13	1	27			28
Common stock issuance to the GTC Savings and Retirement Plan			118	12	781			793
Common stock issued under GTC Director Compensation Plan			27		46			46
Common stock issued under GTC Bonus Plan			227	2	272			274
Common stock issued under GTC Retention Plan			45					—
Proceeds from the issuance of common stock			3,388	34	3,498			3,532
Conversion of Series E preferred stock			10,598	106	1,356			1,462
Stock based compensation					711			711
Warrants issued for services			15	1	99			100
Dividends on redeemable convertible preferred stock					(212)			(212)
Accretion to redemption value of redeemable convertible preferred stock					(263)			(263)
Balance, January 3, 2010	1	$—	24,727	$ 247	$303,869	$(328,818)	$—	$(24,702)

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

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

	For the Fiscal Years Ended		
	January 3, 2010	December 28, 2008	December 30, 2007
Cash flows for operating activities:			
Net loss from operations	$ (26,953)	$ (22,665)	$ (36,321)
Adjustments to reconcile net loss from operations to net cash used in operating activities:			
Depreciation and amortization	2,187	2,650	3,320
Non-cash other income	(12,544)	—	—
Purchase of in-process research and development	1,250	—	—
Stock based compensation	757	712	902
Amortization of premium on marketable securities	—	90	57
Common stock issuance to GTC savings and retirement plan	793	210	311
Inventory write off	—	—	3,412
Non-cash interest expense	1,028	115	225
Changes in assets and liabilities:			
Accounts receivable and unbilled contract revenue	(1,456)	(47)	45
Inventory	807	(863)	(320)
Other assets and liabilities	527	(520)	62
Accounts payable	79	(1,880)	537
Accrued liabilities	997	1,820	(399)
Deferred contract revenue	5,180	2,368	(1,754)
Net cash used in operating activities	(27,348)	(18,010)	(29,923)
Cash flows from investing activities:			
Purchase of property, plant and equipment	(387)	(550)	(1,567)
Purchase of intangible asset	—	—	(200)
Restricted cash	—	(150)	—
Purchase of marketable securities	—	—	(16,987)
Redemption of marketable securities	—	6,600	28,716
Net cash (used in) provided by investing activities	(387)	5,900	9,962
Cash flows from financing activities:			
Proceeds from the LFB convertible debt financing, net of offering costs	3,923	—	—
Proceeds from the LFB convertible preferred stock financing, net of offering costs	13,849	—	—
Proceeds from the issuance of common stock, net of offering costs	3,532	5,445	4,482
Net proceeds from employee stock purchase plan	28	41	168
Net proceeds from the exercise of stock options	—	—	4
Proceeds from long-term debt, net of financing costs	—	10,403	—
Repayment of long-term debt, convertible note to LFB and capital leases	(1,424)	(1,211)	(974)
Net cash provided by financing activities	19,908	14,678	3,680
Net (decrease) increase in cash and cash equivalents	(7,827)	2,568	(16,281)
Cash and cash equivalents at beginning of the period	11,643	9,075	25,356
Cash and cash equivalents at end of the period	$ 3,816	$ 11,643	$ 9,075
Supplemental disclosure of cash flow information:			
Cash paid during the period for interest	$ 1,157	$ 930	$ 961
Conversion of LFB debt, net of debt discount	4,512	1,135	—
Restricted cash	4,000	(4,000)	—
Settlement of GE capital debt by LFB	3,500	—	—
Assets purchased under capital lease	(181)	(144)	—
Settlement of liability due to LFB conversion to convertible note	513	—	—
Settlement of liability due to vendor converted to promissory note	644	—	—
Reclassification of warrants to liability	96	—	—
Merrimack preferred stock in consideration for AFP license	1,250	—	—
Warrants issued to LFB	—	2,455	—
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 January 3, 2010, December 28, 2008 and December 30, 2007 (all tabular $ in thousands, except per share data). All historical and per share amounts have been adjusted to reflect the reverse stock split of our common stock effected in May 2009.

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 specific human protein in their milk. Using the unique characteristics of this production technology, we are developing two portfolios of therapeutic proteins:

- **Recombinant plasma proteins.** Our portfolio of recombinant plasma proteins is being developed to treat a range of genetic and acquired blood deficiencies, including hemophilia and other blood coagulation disorders. Historically these blood proteins, also known as plasma proteins, have only been available by extraction from human blood. Recombinant versions of plasma proteins are difficult to produce in an economically viable manner using other manufacturing systems.
- **Monoclonal antibodies as follow-on biologics.** Our portfolio of monoclonal antibodies, or MAbs, is being developed for use as potential follow-on biologics targeted at several large markets in oncology and autoimmune diseases.

We also continue to provide production services for external partners, which provides us a continuing source of cash and revenue.

Our production technology has been validated by the regulatory approval of our first product ATryn®, which is a recombinant form of the human plasma protein antithrombin, by the European Medicines Agency, or EMA, in 2006 and by the United States Food and Drug Administration, or FDA, in February 2009. ATryn® remains the only transgenically produced therapeutic protein to be approved anywhere in the world. In connection with the approval of ATryn®, the FDA's Center for Veterinary Medicine also approved our New Animal Drug Application, the first of its kind to regulate genetically engineered animals. We believe that these regulatory approvals of our transgenic technology are important benchmarks for obtaining future approvals for our portfolio of products in development.

The key characteristics of our transgenic production technology include:

- the manufacture of proteins that are difficult to express in other manufacturing systems;
- the production of proteins in large quantities;
- the production of proteins with significantly lower capital cost and lower cost of goods;
- predictable and flexible scale-up;
- naturally enhanced efficacy for oncology MAbs (increased Antibody Dependent Cell-mediated Cytotoxicity, or ADCC);
- strong intellectual property position and freedom to operate; and
- an established commercial scale infrastructure capable of supporting the production of our recombinant plasma protein and MAb products.

We plan to develop our portfolio of recombinant protein products through strategic collaborations:

- In September 2006, we entered into a collaboration agreement with LFB Biotechnologies, S.A.S, or LFB, to develop selected recombinant plasma proteins and MAbs. 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. This collaboration is established in a separate joint venture entity, and we have added other programs to this joint venture, including a recombinant form of human blood coagulation, which we in-licensed from ProGenetics LLC, and a recombinant human alpha-1 antitrypsin, as well as an antibody to the CD20 immune system receptor, the same target as for the MAb marketed as Rituxan® or MabThera®.

- In June 2008, we entered into a collaboration agreement with Lundbeck Inc. (formerly OVATION Pharmaceuticals, Inc.), to develop and market ATryn® in the United States. The collaboration agreement includes the commercialization of ATryn® in the HD indication and the further development of ATryn® in acquired antithrombin deficiency indications, or AD. In the second quarter of 2009, Lundbeck commercially launched and reported the first sales of ATryn® in the U.S.

We are also seeking collaborations for the further development and commercialization of all of our proteins in development including those in the portfolio with LFB, as well as recombinant alpha-fetoprotein, or AFP, for the treatment of multiple sclerosis and myasthenia gravis and our portfolio of MAbs. We acquired exclusive worldwide rights to AFP in 2009.

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 risks of development of new biological products, the need for additional capital and collaboration partners, 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 of fiscal years 2009, 2008 and 2007 and have an accumulated deficit of approximately $329 million at January 3, 2010. We also have negative working capital of $16.1 million as of January 3, 2010. Based on our cash balance as of January 3, 2010, including the bridge loan financing from LFB of $7 million received in the first quarter of 2010, as well as potential cash receipts from existing programs, we believe our capital resources will be sufficient to fund operations to the end of the second quarter of 2010. Our recurring losses from operations and our limited available funds raise substantial doubt about our ability to continue as a going concern. Our plans with regard to this matter include seeking additional financing arrangements and seeking collaboration arrangements. If no funds are available, we would have to sell or liquidate the business. 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 2009, 2008 and 2007 were equity financings and debt financings including approximately $21.3 million and $15 million from LFB in 2009 and 2008, respectively. Management expects that future sources of funding may include new or expanded partnering arrangements and additional 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, 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 commercialize independently. Additionally, any future equity funding would dilute ownership of our existing 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. All significant inter-company transactions have been eliminated, and we operate in one business segment.

In June 2008, we amended our Joint Development and Commercialization Agreement with LFB to establish LFB/GTC LLC as a separate legal entity for the joint venture. Our investment in this joint venture is being accounted for at cost and is not being consolidated in accordance with the accounting standards for variable interest entities as we are not the primary beneficiary of the joint venture.

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, derivative liability, 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 consist principally of money market funds and municipal notes purchased with initial maturities of three months or less.

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 January 3, 2010 and December 28, 2008, 100% of cash and cash equivalents were held by one United States financial institution and exceeded 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 2009, 2008 or 2007, nor were there any write-offs for fiscal 2009, 2008 or 2007.

At January 3, 2010 and December 28, 2008, three customers 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:

	2009	2008	2007
Merrimack	0%	23%	29%
Lundbeck	64%	0%	0%
LEO	0%	27%	32%
PharmAthene	17%	39%	28%
Other	19%	11%	11%
	100%	100%	100%

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. Costs for repairs and maintenance are expensed as incurred. 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.

The following is the summary of property, plant and equipment and related accumulated amortization and depreciation as of January 3, 2010 and December 28, 2008.

	Years of Life	January 3, 2010	December 28, 2008
Land	—	$ 909	$ 909
Buildings	20-30	14,135	14,135
Livestock (NZ)	3-5	2,842	2,842
Leasehold improvements	lease life	2,362	2,359
Laboratory, manufacturing and office equipment	3-10	14,152	14,092
Laboratory, manufacturing and office equipment—capital leases	3-10	1,468	1,287
		35,868	35,624
Less accumulated amortization and depreciation		(23,412)	(22,228)
Net property, plant and equipment		$ 12,456	$ 13,396

Depreciation and amortization expense was $1,286,000, $1,744,000 and $2,432,000, for the fiscal years ended January 3, 2010, December 28, 2008 and December 30, 2007, respectively. Accumulated amortization for equipment under capital lease was $1,307,000, $1,173,000 and $1,127,000 at January 3, 2010, December 28, 2008 and December 30, 2007, respectively.

During 2009 and 2008, we purchased $181,000 and $144,000 of fixed assets and financed these additions with capital lease obligations, respectively.

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 cumulative discounted cash flows. Any write-downs are treated as permanent reductions in the carrying amount of the assets.

Share-Based Compensation

We measure and recognize compensation expense for all share-based payments at fair value over the employees' service periods or the derived service period for awards with market conditions. Compensation expense is measured at fair value of the award at the grant date, including estimated forfeitures, and is adjusted to reflect actual forfeitures and the outcome of certain conditions.

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 for manufacture of drug product, payments based upon the achievement of certain milestones and royalties on future product sales, if any.

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 or 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 under an accounting model whereby 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

At January 3, 2010 and December 28, 2008, all of our inventory consisted of finished goods.

We carry inventory at the lower of cost or market using the first-in, first-out method. We expect that all inventory which we capitalize will be sold for clinical trials and commercial use. Currently, because we have only two customers, we only capitalize inventory if orders have been received. If at any time we believe that the sale of inventory 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. Inventories on hand at January 3, 2010 and December 28, 2008 were related to ATryn®, which we capitalized after completion of the clinical trials in anticipation of marketing approval for commercial sale in the U.S. Once our cost of production falls below the agreed upon maximum price, we will capitalize all those costs.

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 $2.9 million to cost of sales in connection with the write-off. None of this material had been released for clinical or commercial use. In 2008, we received $1.5 million from the contractor for settlement of this loss, which was recorded to other income in 2008. In addition, in 2007, 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. 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

Per share information is based upon the weighted average number of shares of common stock outstanding during the period. Potential common shares consist of warrants (see Note 10), stock options (see Note 11) and stock to be issued under our defined contribution retirement plan (see Note 11). We recorded a net loss from operations in 2009, 2008 and 2007, and, therefore, 10.7 million, 5.2 million, 3.5 million of potential common shares, respectively, were not used to compute diluted loss per share, as the effect was antidilutive. We also have two convertible notes payable to LFB. The first convertible note has a current principal balance of $698,000, net of unamortized debt discount of $145,000, 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. The second convertible note has a current principal balance of $12.9 million, net of unamortized debt discount of $354,000, which may be converted into our common stock at $3.10 per share at LFB's discretion.

Reverse Stock Split

On May 26, 2009, we implemented a reverse split of our common stock in the ratio of one-for-ten. The reverse stock split was effective at 11:59 p.m. on May 26, 2009. All fractional shares created by the reverse stock split were cashed out. All historical share and per share amounts have been adjusted to reflect the reverse stock split.

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 June 2008, the FASB ratified the consensus reached on the clarification whether an instrument (or an embedded feature) is indexed to an entity's own stock, which would qualify as a scope exception under a previous rule. We adopted this change as of January 1, 2009. In August 2005, we sold 457,143 shares of our Common Stock at $17.50 per share and 5- year warrants to purchase an aggregate of 182,857 shares of our Common Stock at an exercise price of $26.80 per share in a private placement to institutional investors. These warrants were reassessed under the new rules and due to a price adjustment clause included in these warrants, they are no longer deemed to be indexed to our stock and therefore, no longer meets the scope exception of the previous rules. Therefore, these warrants were determined to be derivatives and were reclassified to a liability and will be adjusted to fair value at each reporting period with changes in fair value recorded in other income (expense). As a result, we recorded a cumulative adjustment of approximately $2.3 million to additional paid in capital and approximately $97,000 to other liabilities.

In June 2009, the FASB issued an amendment to the accounting and disclosure requirements for the consolidation of variable interest entities (VIEs). The elimination of the concept of a qualified special purpose entity removes the exception in this amendment for applying the consolidation guidance. This amendment requires an enterprise to perform a qualitative analysis when determining whether or not it must consolidate a VIE. The amendment also requires an enterprise to continuously reassess whether it must consolidate a VIE. Additionally, the amendment requires enhanced disclosures about an enterprise's involvement with VIEs and any significant change in risk exposure due to that involvement, as well as how its involvement with VIEs impacts the enterprise's financial statements. Finally, an enterprise will be required to disclose significant judgments and assumptions used to determine whether or not to consolidate a VIE. This amendment is effective for financial statements issued for fiscal years beginning after November 15, 2009. We do not expect the adoption of this Standard to have an impact on our financial position or results of operations.

In October 2009, the FASB issued an update to existing guidance on revenue recognition for arrangements with multiple deliverables. This update will require companies to allocate consideration received for qualified separate deliverables using estimated selling price for both delivered and undelivered items when vendor-specific objective evidence or third-party evidence is unavailable. Additional disclosures discussing the nature of multiple element arrangements, the types of deliverables under the arrangements, the general timing of their delivery, and significant factors and estimates used to determine estimated selling prices are required. This amendment is effective for financial statements issued for fiscal years beginning on or after June 15, 2010. Companies may elect to early adopt in any interim or annual financial statements that have not previously been issued. We have not yet determined when we will adopt this update or what the impact will be on our condensed consolidated financial statements.

NOTE 3. SIGNIFICANT AGREEMENTS

Lundbeck, Inc. ("Lundbeck") (formerly OVATION Pharmaceuticals, Inc.)

In June 2008, we entered into a collaboration agreement with Lundbeck Inc., to develop and market ATryn® in the United States. The collaboration agreement includes the commercialization of ATryn® in the HD indication and provides for the further development of ATryn® in AD. Under the terms of our agreement, Lundbeck was obligated to make milestone payments to us for a total of $9 million through approval of ATryn® for HD in the U.S., all of which has been received to date. These milestone revenues will be recognized over the life of the agreement on a straight-line basis beginning with the first delivery of ATryn® to Lundbeck, which began in the first quarter of 2009. Since there is a right of return on our first shipment of product to Lundbeck, we are deferring the recognition of this product revenue until this product has been sold to end users. At January 3, 2010, we have approximately $652,000 in deferred revenue related to Lundbeck's right to return product. The collaboration anticipates further development of ATryn® in larger market AD indications, such as the treatment of heparin resistance in patients undergoing surgery requiring cardiopulmonary bypass and the treatment of disseminated intravascular coagulation, or DIC, associated with severe sepsis.

We are responsible for production of ATryn® and receive a transfer price for commercial product, a royalty on net sales, $257 million in potential clinical, regulatory and sales based milestone payments, including $9 million already received, and payment for product used in clinical trials. Our agreement provides for Lundbeck to further develop ATryn® in AD and to fund our anticipated costs of clinical development. Lundbeck will be responsible for sales and marketing of ATryn® in the U.S., including all launch activities, which began in the second quarter of 2009.

LFB Biotechnologies

Collaboration Agreement

In September 2006, we entered into a collaboration agreement with LFB, a related party, to develop selected recombinant plasma proteins and MAbs using our transgenic production platform. LFB is a subsidiary of LFB S.A., a vertically integrated plasma fractionation company based in 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 programs to develop a recombinant form of human factor IX, an antibody to the CD20 immune system receptor, and recombinant human alpha-1 antitrypsin.

We have amended our agreement with LFB to establish LFB/GTC LLC, as a separate legal entity for the joint venture. This amendment added LFB/GTC LLC as a party to the agreement and provided that rights to the intellectual property of the new joint venture will flow through this entity. All other terms and conditions remain the same. Both parties are performing work under the joint venture and are cross charging their respective expenses incurred to the joint venture. Our investment in the joint venture is being accounted for at cost based and is not being consolidated in accordance with the accounting standards for variable interest entities, as we are not the primary beneficiary of the joint venture. As of December 28, 2008, we had a $500,000 payable to the joint venture which was settled in 2009 as part of our June 2009 financing from LFB.

Under this collaboration, we share equally with LFB in the cost of the development and commercialization of each product and we are entitled to 50% of any profits derived from products developed through the joint venture, 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. Through 2009, LFB had contributed 76% of the costs of the joint venture and owned that same percentage of future profits, subject to our right, not our obligation, to reestablish our 50% ownership by repaying LFB our share of the costs plus a specified premium that increases over time as clinical development progresses. At January 3, 2010, we had a $1.5 million receivable from LFB related to a portion of our costs incurred in these programs during 2009 which was recorded against the program costs in research and development which was subsequently received in January 2010. During 2008 and 2007, we received approximately $5.6 million and $1.2 million, respectively, in funding from LFB for an agreed upon portion of our costs incurred in the programs in the joint venture, which was recorded against research and development expenses. Under the agreement, a joint steering committee of each company's representatives determines product development and commercialization plans. We are responsible for development of the production system for the products and retain exclusive commercial rights to the products in North America. LFB is responsible for clinical development and regulatory review of the programs in the joint venture, and has exclusive commercial rights in Europe. We hold co-exclusive rights with LFB in the rest of the world to any products developed through the joint venture. 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.

2006 Equity and Debt Financing

In connection with the collaboration agreement, we entered into a purchase agreement with LFB in which LFB committed to purchase up to an aggregate of $25 million shares of convertible preferred stock, shares of common stock and a subordinated convertible note. Each share of preferred stock is convertible into 100 shares of common stock at the option of LFB any time. The purchase price of the shares of preferred stock was $12.30 per common share equivalent, which was the post-split market value of our common stock on the date of the agreement. These shares 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 500,000 common share equivalents at an aggregate purchase price of $6.2 million. In the second tranche, LFB purchased an additional 9,615 shares of Series D preferred stock and a subordinated convertible note in the principal amount of approximately $2.6 million, for an aggregate purchase price of approximately $14.4 million.

The convertible note has a term of five years, 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. Based on our effective borrowing rate of 10.8%, upon issuance of the note, we recorded a debt discount of approximately $1.1 million for the difference between the stated interest rate and our effective borrowing rate. The discount is being amortized over the five year term of the note, resulting in additional interest expense of approximately $74,000, $92,000 and $225,000 during fiscal years 2009, 2008 and 2007, respectively. Upon the February 2008 partial conversion of the note, approximately $600,000 of unamortized debt discount was reclassified to additional paid in capital. 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 363,000 shares of common stock at a price of $12.30 per share, for an aggregate purchase price of approximately $4.5 million. In connection with the closing of our February 2008 registered direct offering, $1.7 million of the principal amount of the convertible note and approximately $40,000 of accrued interest were converted into 201,840 shares of our common stock at a rate of $8.70 per share, representing the fair value of our common stock on the date of conversion.

2008 Convertible Note Financing

In December 2008, we issued a $15 million convertible note and a warrant to LFB. Under this agreement, the convertible note will mature on June 20, 2012 and bears interest at an annual rate of 8%. This debt may be converted at LFB's discretion into our common stock at a conversion price of $3.10 per share. The proceeds of $15 million were allocated to the convertible note and the warrant based on their relative fair values. Based on that allocation, we recorded approximately $2.5 million to additional paid in capital and a debt discount which is being amortized over the term of the note, resulting in additional interest expense of $697,000 and $19,000 during the fiscal years 2009 and 2008, respectively. In connection with the agreement, we also recorded a debt discount of approximately $500,000 for costs incurred by us on LFB's behalf for completing the transaction, which is being amortized over the term of the note, resulting in additional interest expense of approximately $142,000 and $4,000 during fiscal years 2009 and 2008, respectively. In December 2009, we amended the convertible note to reduce the interest rate to 4%, effective January 1, 2010.

Under this agreement we also granted LFB certain nomination rights with respect to our Board of Directors upon LFB's conversion of the note in full or in part. These nomination rights remain in effect and are substantially similar to the nomination rights that we granted to LFB in the 2009 preferred stock financing with LFB, which are described in detail below. We also issued to LFB a 5-year warrant to purchase approximately 2,319,354 shares of our common stock at an exercise price of $3.10 per share. If we pay the note in full upon maturity, LFB has the right to require us to redeem the warrant for $1.5 million, which we have the option to pay in shares of our common stock. Under this agreement, LFB has the right to participate in all of our future offerings of common stock or securities exercisable or convertible into common stock to purchase a number of shares in proportion to its then *pro rata* ownership of our common stock, on an as converted basis. LFB's participation will be on the terms agreed upon by us and other investors in the future offerings, including price and closing date; provided that LFB will have 10 calendar days upon notice of any offering to choose to participate.

LFB also has a right of first refusal and right of first negotiation with respect to any proposed sale by us of common stock or securities exercisable or convertible into common stock. Pursuant to this right, if we intend to undertake an offering, we must notify LFB of the proposed terms of such offering, and LFB has the right to refuse to purchase the securities on the proposed terms and the right to negotiate with us alternative terms to purchase all of the securities to be sold in the proposed offering.

2009 Equity Financing

In June 2009, we entered into agreements with LFB that provided a total of $12.3 million of cash proceeds to us. This financing was completed in two steps. In the first step we issued to LFB a $4.5 million secured convertible note resulting in $4 million of cash proceeds to us and relieving a payable amount of approximately $500,000 owed to LFB for their excess funding of costs in our joint venture. The convertible note automatically converted into $9 million of a new series of redeemable convertible preferred stock upon shareholder approval, which occurred on July 30, 2009. In the second step LFB purchased $16.6 million of redeemable convertible preferred

stock through payment to us of $8.3 million. Under the terms of the agreement, $12.8 million of the purchase price was subject to an escrow arrangement to secure the future dividends payable on this convertible preferred stock, which was to accrue at a rate of 10% over five years.

In November 2009, LFB converted the redeemable convertible preferred stock into approximately 10.6 million shares of our common stock, terminating LFB's obligation to fund the escrow.

Under the June 2009 financing, LFB also had the option for six months to purchase $12.8 million of additional shares of redeemable convertible preferred stock with the same conversion prices allocated in the same proportions as in the original investment. In October 2009 LFB notified us that it was exercising the option in full, and on November 3, 2009 we issued an additional $12.8 million of Series E redeemable convertible stock. We received an additional $6.4 million of cash on the same terms as the initial investment, with the balance of the purchase price subject to an escrow arrangement between us and LFB. In January 2010, LFB converted these shares of redeemable convertible preferred stock into a total of approximately 5.3 million shares of our common stock, terminating LFB's obligation to fund the escrow for this redeemable convertible preferred stock.

As part of these agreements, LFB also paid off the remaining net principal amount of our term loan with GE Capital for $3.5 million. We entered into a promissory note with LFB for $3.5 million which will be repaid on a 10-year amortization schedule at a 10.8% interest rate with a balloon payment on January 1, 2012. LFB holds a first lien on all of our assets, including intellectual property, to secure this debt and its existing debt from us. The payoff of the GE Capital term loan was considered an extinguishment of debt and, therefore, we wrote off approximately $211,000 of deferred financing costs associated with the GE Capital term loan to interest expense during the second quarter of 2009. We were also charged an early termination fee of approximately $133,000 in accordance with the GE Capital term loan, which was also recorded to income expense during the second quarter of 2009. In December 2009, we amended the promissory note to reduce the interest rate to 4% effective January 1, 2010.

As of January 3, 2010, LFB owned shares of common stock constituting approximately 65% of our common stock outstanding and held convertible debt, warrants and convertible preferred stock which it can convert and exercise into 12,468,637 shares of our common stock. On January 8, 2010, LFB converted all of its remaining Series E Convertible Preferred Stock into 5,299,073 shares of our common stock, resulting in LFB holding 71% of our common stock. If the convertible debt is converted, the warrants exercised and the Series D convertible preferred stock converted, LFB would own 28,469,474 shares, or approximately 76.6% of our common stock.

Under this agreement we also granted to LFB the right to designate one or more directors to our Board of Directors, in addition to its current board representative, and in proportion to its equity ownership, on a fully diluted basis, provided that in any case, LFB has the right to appoint the maximum number of directors permissible under Nasdaq requirements. As required by Nasdaq, the number of board representatives would decrease ratably, to the extent that LFB's ownership decreases, such that LFB's board representation would not be disproportional to its equity ownership. The LFB designated directors will be appointed across our three classes of directors in as equal proportions as possible. As long as LFB owns at least 21% of our outstanding common stock on an as-converted basis, LFB's board representatives will be nominated for election at our annual meeting of stockholders. In October 2009 LFB nominated, and our Board elected, four new directors in place of four of our independent directors. Now five of our eleven directors have been nominated by LFB.

Services Agreement

In July 2009, we entered into a services agreement with LFB under which we provide research, process and product development and regulatory services for LFB's benefit in North America and for which we receive compensation at commercial rates.

LEO Pharma A/S ("LEO")

We also had a collaboration agreement with LEO Pharma A/S, or LEO, for the commercialization and further development of ATryn® in Europe, Canada, and the Middle East. In March 2009, we terminated the collaboration agreement with LEO and we entered into arbitration proceedings with the International Chamber of Commerce as described in more detail under Item 3 of this Annual Report. We are planning to establish alternative commercialization partners for ATryn® in these territories in 2010.

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. FAIR VALUE

The accounting standards define fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. This accounting standard also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1 - Quoted prices in active markets for identical assets or liabilities.

Level 2 - Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company utilizes the market approach to measure fair value for its financial assets and liabilities. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets or liabilities.

Assets and liabilities measured at fair value on a recurring basis are summarized below:

	Fair Value Measure as of January 3, 2010 (dollars in thousands)			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Money Market Fund	$ 448	$ 448	$ —	$ —
Derivative Liability	2,660	—	—	2,660
Total	$ 3,108	$ 448	$ —	$ 2,660

	Fair Value Measure as of December 28, 2008 (dollars in thousands)			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Money Market Fund	$ 2,947	$ 2,947	$ —	$ —
Total	$ 2,947	$ 2,947	$ —	$ —

The fair value of the derivative was calculated using unobservable inputs that are supported by little or no market activity.

Given the complex structure of the derivative liability, we engaged a third party consulting firm to assist us with our valuation. We used the valuation model from the third party consulting firm to establish the fair value for this instrument. The model utilized assumptions for volatility based on our historical volatility and credit spread based on Standard & Poor's Corporate Ratings criteria (see Note 8). We record all changes in the fair value of the derivative to other income (expense).

The following table provides a reconciliation of fair value for which we used Level 3 or significant unobservable inputs for the years ended January 3, 2010 and December 28, 2008 (in thousands):

	December 28, 2008 Balance[1]	Purchase of Series E Preferred Stock	Fair Value Adjustments	Conversion of Series E Preferred Stock	January 3, 2010 Balance
Derivative Liability	$ —	$ 19,953	$ (9,163)	$ (8,130)	$ 2,660
Warrant Liability	—	7,121	(3,381)	(3,740)	$ —
Total	$ —	$ 27,074	$ (12,544)	$ (11,870)	$ 2,660

(1) There were no Level 3 measurements at any time during the year ended December 28, 2008.

NOTE 5. ACCRUED LIABILITIES

Accrued liabilities included the following:

	At January 3, 2010	At December 28, 2008
Accrued payroll and benefits	$ 1,969	$ 2,456
Accrued bonuses	1,172	1,254
Other	3,544	2,252
Total accrued expenses	$ 6,685	$ 5,962

In November 2009, we announced a restructuring of our organization to meet the requirements of our key programs and extend the duration of our cash resources. Under the restructuring plan, headcount was reduced by approximately 30% from 154 to 109 full time equivalent employees. This restructuring included employees from most departments located at both our Framingham and central Massachusetts locations. We recorded severance expense in the amount of $460,000 for the year ended January 3, 2010 of which approximately $374,000 and $86,000 was recorded to research and development expense and selling, general and administrative expense, respectively. During the year ended January 3, 2010, approximately $301,000 had been paid out of the severance reserve. At January 3, 2010, $159,000 remained in accrued liabilities in relation to unpaid severance costs, which will be paid out through the second quarter of 2010.

NOTE 6. COMMITMENTS AND CONTINGENCIES

We lease equipment and facilities under various operating and capital leases. Rent expense for the fiscal years ended January 3, 2010, December 28, 2008 and December 30, 2007 was approximately $2,596,000, $2,656,000 and $2,540,00, respectively.

At January 3, 2010, our future minimum payments required under these leases were as follows:

	Operating	Capital
2010	$ 1,949	$ 32
2011	336	32
2012	59	21
2013	1	7
2014 and thereafter	1	3
Total	$ 2,346	$ 95
Less amount representing interest		19
Present value of minimum lease payments		$ 76

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 7). 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 future royalty amounts payable under these agreements and any resulting commitments on our behalf are unknown and cannot be reasonably estimated since the level of future sales, if any, is uncertain. We also have a minimum annual royalty commitment under one of these license agreements in the amount of $250,000 through 2016.

We have a contractual agreement with a third party under which we have a minimum annual commitment of $729,000 through 2013.

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 7. 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 and are being amortized over a 15-year period, the remaining life of the underlying patents.

We determined that minimizing further investment in a joint venture between GTC and Fresenius Kabi 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 27,837 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:

	Amortization Life	January 3, 2010	December 28, 2008
Marketing rights	15 years	$ 11,210	$ 11,210
Accumulated amortization—marketing rights		(6,975)	(6,228)
Net		4,235	4,982
Technology licenses	9 years to 15 years	2,017	2,017
Accumulated amortization—technology licenses		(904)	(750)
Net		1,113	1,267
Total intangible assets, net		$ 5,348	$ 6,249

Amortization expense was $902,000, $902,000 and $888,000 in 2009, 2008 and 2007, respectively.

At January 3, 2010, the estimated aggregate amortization expense was as follows:

2010	$ 902
2011	$ 902
2012	$ 902
2013	$ 902
2014	$ 902
2015 and thereafter	$ 840

NOTE 8. REDEEMABLE CONVERTIBLE PREFERRED STOCK

On July 30, 2009, our shareholders approved the issuance of newly-designated Series E-1 and Series E-2 redeemable convertible preferred stock ("Series E Preferred Stock").

The Series E Preferred Stock has a par value of $0.01 and a stated value per share equal to $1,000. Series E Preferred Stock is senior to all other outstanding series of preferred stock and common stock and accrues cumulative dividends as a percentage of the initial stated value at a rate of 10% per year, payable semi-annually on January 1 and July 1, beginning January 1, 2010. Series E Preferred Stock is convertible at any time at the

option of LFB into common stock. The conversion price for the Series E-1 redeemable convertible preferred stock is $2.63 per share and for Series E-2 redeemable convertible preferred stock is $2.2368 per share, based on the volume weighted average market price on July 30, 2009. After five years, the Series E Preferred Stock is redeemable at the option of LFB or GTC for cash equal to the then aggregated stated value and any accrued but unpaid dividends.

LFB had the option for six months from the July 31, 2009 closing date of the initial issuance of Series E Preferred Stock to purchase $12.8 million of additional shares of Series E Preferred Stock with the same terms as described above and in the same proportions of Series E-1 and Series E-2 convertible preferred stock as in the original issuance. In accordance with the accounting and reporting standards on freestanding warrants and other similar instruments on shares that are redeemable, this option to purchase redeemable convertible preferred stock was measured at fair value and reported as a liability on the consolidated balance sheet with changes in fair value recorded as a component of other income (expense) in the consolidated statement of operations. The fair value of the option was determined using an American binomial model which utilized assumptions including 80% volatility resulting in fair value of approximately $7.1 million on the date of issuance. During 2009, we recorded approximately $3.4 million to other income as a result of the change in the fair value of the option. In October 2009, LFB notified us that it was exercising the option in full. As a result, the liability was remeasured and credited against additional paid in capital.

The Series E Preferred Stock has been classified within the mezzanine section of the consolidated balance sheet because of the redemption feature. Because the redemption price and redemption date is fixed, the difference between the carrying value and redemption price is being accreted using the interest method from the issuance date through the earliest redemption date which is July 30, 2014.

We have evaluated the one year conversion feature under the accounting literature and reporting standards for derivatives and have determined that it must be separated and recorded at fair value as a liability on the consolidated balance sheet. Subsequent changes in fair value will be recorded as a component of other income (expense) in the consolidated statement of operations. The fair value of the derivative was determined using a convertible bond model which utilized assumptions including 75% volatility and a 15% credit spread resulting in fair value of approximately $15.9 million on the date of issuance of the Series E Preferred stock purchased in July 2009 and approximately $4.1 million on the date of issuance of the Series E Preferred Stock, purchased in November 2009. On October 30, 2009, LFB converted their outstanding shares of Series E convertible preferred stock, purchased in July 2009, into common stock and as a result, the derivative was remeasured and credited against additional paid in capital. During 2009 we recorded approximately $9.2 million to other income as a result of the change in the fair value of the derivatives.

As of January 3, 2010, on an as converted basis, LFB beneficially owned approximately 76.6% of our common stock through its holdings of common stock, convertible debt, Series D preferred stock and Series E Preferred Stock, exclusive of its warrants.

A summary of activity related to issuance and accretion of the Series E convertible preferred stock is as follows (in thousands):

	Series E-1 and E-2 Redeemable Convertible Preferred Stock
Balance, December 28, 2008	$ —
Issuance of series E units	38,250
Amount allocated to series E derivative	(19,953)
Amount allocated to detachable warrants	(7,120)
Issuance costs	(718)
Net issuance of series E units	10,459
Conversion of series E units	(2,343)
Accrual of dividends	214
Accretion of series E to redemption value	263
Subscription receivable	(6,375)
Balance, January 3, 2010	$ (2,218)

NOTE 9. BORROWINGS

Our long-term debt consisted of the following:

	January 3, 2010	December 28, 2008
GE Capital loan	$ —	$ 7,051
GE Capital loan	—	798
Capital leases, with monthly payments of approximately $3 through May 2014	76	111
Convertible note to LFB, fixed annual interest of 2%, net of debt discount[1]	698	623
Convertible note to LFB, fixed annual interest of 4%[3], net of debt discount[2]	12,907	12,069
Promissory note to LFB, fixed annual interest of 4%[3]	3,400	—
Other debt	28	—
	17,109	20,652
Less current portion	(351)	(1,383)
	$ 16,758	$ 19,269

Maturities of long-term debt are as follows:

2010	$ 351
2011	724
2012	16,025
2013	6
2014 and thereafter	3
	$ 17,109

(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. The debt discount balance as of January 3, 2008 is approximately $145,000.

(2) We recorded a debt discount of approximately $500,000 for the expenses incurred by us on LFB's behalf. The debt discount is being amortized over the term of the note. The debt discount balance as of January 3, 2010 is approximately $354,000.

(3) In December 2009, we amended the convertible note and promissory note reducing the interest rate to 4% from 8% and 10.8%, respectively, effective January 1, 2010.

At January 3, 2010, the fair values of our debt instruments were as follows:

	(dollars in thousands)
Convertible note to LFB, fixed annual interest of 2%	$ 688
Convertible note to LFB, fixed annual interest of 4%	17,022
Promissory note to LFB, fixed annual interest of 4%	2,802

The fair values of our LFB convertible notes and promissory note were calculated using a net present value approach using unobservable inputs that are supported by little or no market activity. We used an effective interest rate of 15% in our fair value calculation.

In December 2006, we entered into a term loan with GE Capital in the amount of $10 million. As a result of the June 2009 debt financing with LFB (see Note 3) the term loan with GE Capital was repaid in full on June 18, 2009.

We have several other financing arrangements with LFB (see Note 3).

NOTE 10. STOCKHOLDERS' EQUITY

Authorized Shares

Our authorized capital stock consists of 210,000,000 shares of Common Stock, $0.01 par value per share, and 5,000,000 shares of preferred stock, $0.01 par value per share, of which 75,000 shares are designated as Series C Junior Participating Convertible Preferred Stock (the Series C Preferred Stock), 15,000 shares are designated as Series D Preferred Stock, $0.01 par value per share, 18,000 shares are designated as Series E-1 10% Convertible Preferred Stock, $0.01 par value per share, and 20,250 shares are designated as Series E-2 10% Convertible Preferred Stock, $0.01 par value per share

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. In connection with our transactions with LFB, our Board of Directors amended the Plan to provide that LFB would be excluded from the forfeiture provisions of the Plan so long as it only purchased our securities directly from us.

Common Stock Placements

In January 2007, we sold 360,000 shares of our Common Stock at a purchase price of $12.30 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, 5-year convertible note which is convertible into common stock on terms described in Note 3.

In February 2008, we received approximately $5.4 million in proceeds from a registered direct offering, net of approximately $500,000 in offering costs and fees. In the offering, we sold 689,655 shares of our common stock at $8.70 per share (rounded price on the date of closing) and 7-year warrants to purchase an aggregate of 689,655 shares of our common stock at an exercise price of $8.70 per share.

In December 2008, we issued to LFB a $15 million, a convertible note which matures on June 30, 2012, which is convertible into common stock on terms described in Note 3 and a 5-year warrant to purchase 2,319,354 shares of our common stock at an exercise price of $3.10 per share.

In October 2009, LFB converted Series E Preferred Stock into a total of 10,598,146 shares of our common stock (see Note 8).

In November 2009, we sold 3,387,850 shares of our common stock to LFB at a purchase price of $1.07 per share. In the offering we received $3.625 million of gross proceeds.

On January 8, 2010, LFB converted Series E Preferred Stock into a total of 5,299,073 shares of our common stock (see Note 8).

Preferred Stock Placements

On July 30, 2009, our shareholders approved of the issuance of newly-designated Series E-1 and Series E-2 redeemable convertible preferred stock to LFB, which was issued in July and November 2009 (see Note 8).

Warrants

A summary of our outstanding warrants for the purchase of common stock as of January 3, 2010, of which 4,356,825 are currently exercisable, is as follows:

Common Shares Issuable for	Exercise Price Per Share	Warrant Expiration Date
182,857	$ 5.9848[1]	February 10, 2011
364,076	$ 20.50	December 13, 2010
780,000	$ 14.145	July 18, 2016
689,655	$ 8.70	February 7, 2015
5,882	$ 7.10	April 16, 2013
15,000	$ 6.10	May 6, 2013
2,319,355	$ 3.10	December 10, 2013
—		
4,356,825		

(1) The exercise price of these warrants, which was originally $25.20 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 financing with LFB in November 2009, the current exercise price of these warrants is $5.9848 per share.

At the time of issuance, the warrants were assessed under the accounting standard for derivative financial instruments, indexed to, and potentially settled in, a company's own stock, and were recorded as a credit to additional paid in capital. In June 2008, the FASB ratified the consensus reached on the clarification whether an instrument (or an embedded feature) is indexed to an entity's own stock, which would qualify as a scope exception under a previous rule. We adopted this change as of January 1, 2009. In August 2005, we sold 457,143 shares of our Common Stock at $17.50 per share and 5 year warrants to purchase an aggregate of 182,857 shares of our Common Stock at an exercise price of $26.80 per share in a private placement to institutional investors, which were exercisable on or after February 10, 2006. This warrant was reassessed under the new rules and due to a price adjustment clause included in this warrant, it is no longer deemed to be indexed to our stock and therefore, no longer meets the scope exception of the previous rules. Therefore, this warrant was determined to be a derivative and was reclassified to a liability and will be adjusted to fair value at each reporting period with

changes in fair value recorded in other income (expense). As a result, we recorded a cumulative catch up adjustment of approximately $2.3 million to additional paid in capital and approximately $97,000 to other liabilities.

As of January 3, 2010, we have reserved 5,528,339 shares of Common Stock, subject to adjustment, for future issuance under the various classes of warrants, the Equity Plan and Employee Stock Purchase Plans.

NOTE 11. 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 (together with the Prior Equity Plan, the "Equity Plan"), authorizing a total of 250,000 shares for issuance to our employees, consultants and directors and to our affiliates. In 2004, 2007, 2008 and 2009 our shareholders approved increases of 200,000 shares, or 800,000 in total, in the number of shares authorized for future issuance under the Equity 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 Plan, which annual increase will be added on December 31st of each year beginning in 2008, and will be equal to 150,000 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 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), or 10% cap; and 1,500,000 shares (subject to adjustment in the event of stock splits and other similar events). In December 2008, our shareholders approved an additional 200,000 share increase in the Equity Plan and an amendment to the automatic adjustment provision so that the 10% cap includes shares issuable upon conversion of any convertible debt, as long as such convertible debt is convertible without payment of additional consideration by the holder. In addition, 434,000 shares subject to options previously granted under our Prior Equity Plans were transferred to our Equity Plan. A total of 1,037,386 shares are subject to outstanding options or reserved for issuance under our Equity Plan, including 870,746 options issued under our equity plans outstanding at January 3, 2010. Shares that became available upon termination of forfeited or expired options under our Prior Equity Plan will be added to reserve under our Equity Plan.

In June 2008, we established a Retention Incentive Plan, or Retention Plan, the purpose of which is to encourage the continued employment of our executive officers and other senior personnel through the grant of equity awards and other payments conditioned on continued employment with the Company. Our Compensation Committee is administering the Retention Plan and has the authority to determine the individual participants and the amount of any awards under the Retention Plan. Eligible participants besides our executive officers include Vice Presidents, Senior Directors, Directors and Associate Directors.

Participants in the Retention Plan are eligible to receive awards of restricted stock units issued pursuant to our Equity Plan. We granted 61,583 restricted stock units during 2008 and 10,260 in January 2009. The restricted stock units awarded under the Retention Plan vested on June 30, 2009, for all participants who remained our employee until that date.

Participant's in the Retention Plan who remain employed by us through March 31, 2010 will also receive a specified retention payment, payable at the discretion of our Compensation Committee either in a lump sum cash payment or in shares of our common stock. If the payment is made in shares of our common stock, the plan provides for specified minimum valuation levels of our common stock, depending on the employee's level of seniority, which will be used in determining the number of shares to be issued in lieu of cash. If we terminate a participant's employment without cause prior to March 31, 2010, the participant will be entitled to receive his or her retention payment within 30 days following the date of termination.

In December 2008, we granted 222,500 stock options to our executive officers and other senior personnel pursuant to a retention plan under our Equity Plan. The options give the right to purchase our common stock for $3.10 share. Fifty percent of the options vested on September 30, 2009 and the remaining options will vest on June 30, 2010.

Under our Equity 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 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 40,000 shares for any current participant and 60,000 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, retention, change in control, grants to consultants, directors or new hires, awards in lieu of cash compensation and performance vesting.

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

At January 3, 2010, a total of 166,640 shares were available for grant under our Equity Plan.

A summary of the status of our stock options as of January 3, 2010 and changes during the year then ended is presented below:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term
Outstanding at December 28, 2008	813,034	$ 22.86	
Granted	101,050	3.55	
Exercised	—	—	
Cancelled	(43,338)	26.63	
Outstanding at January 3, 2010	870,746	$ 20.43	4.85
Options exercisable at January 3, 2010	630,285	$ 26.37	4.23
Options vested and those expected to vest at January 3, 2010	862,491	$ 20.58	4.83

The aggregate intrinsic value related to the options outstanding, exercisable, exercised and vested is immaterial for 2009, 2008 and 2007.

A summary of the status of our restricted stock units as of January 3, 2010 and changes during the year then ended is presented below:

	Shares	Weighted Average Grant Date Fair Value
Outstanding at December 28, 2008	58,895	$ 4.68
Granted	10,385	3.51
Released and issued	(69,280)	2.66
Cancelled	—	—
Outstanding at January 3, 2010	—	$ —
Restricted stock units exercisable at January 3, 2010	—	$ —
Restricted stock units vested and those expected to vest at January 3, 2010	—	$ —

The aggregate intrinsic value related to the restricted stock units outstanding, exercisable, exercised and vested is immaterial for 2009 and 2008.

Included within the statements of operations in 2009, 2008 and 2007 are approximately $ 706,000, $660,000 and $847,000 of charges for share-based compensation, which includes both options and restricted stock units.

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		
	January 3, 2010	December 28, 2008	December 30, 2007
Stock Options and Awards:			
Expected life	6.9 years	6.5 years	6 years
Expected volatility	88.44%	87.93%	89.03%
Dividend yield	0%	0%	0%
Risk-free interest rate	2.82%	1.97%	3.80%

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 2009, 2008 and 2007 was $3.55, $3.80 and $10.90, respectively.

As of January 3, 2010, there was approximately $458,000 of total unrecognized compensation costs related to unvested stock options. This cost is expected to be recognized over a weighted average period of 1.48 years.

Shares issued under the Equity Plan, whether for the exercise of stock options or other equity issuances, will be new shares of common stock as authorized under the plan.

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, 75,000 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. In June 2008, the shareholders approved an increase of 100,000 shares under the plan. 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. The stock will be purchased quarterly and each participant can purchase up to 126 shares per quarter, subject to an overall limitation of 6,255 shares that may be sold under the 2003 Purchase Plan in any quarter.

We record the compensation expense related to the 2003 Purchase Plan, however, the amounts are immaterial for the fiscal years ended January 3, 2010, December 28, 2008 and December 30, 2007. Therefore, we do not disclose the weighted average assumptions related to the 2003 Purchase Plan.

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 $331,000, $793,000 and $389,000 for the fiscal years ended January 3, 2010, December 28, 2008 and December 30, 2007, respectively.

NOTE 12. INCOME TAXES

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

	Fiscal Years Ended		
	January 3, 2010	December 28, 2008	December 30, 2007
Federal tax—expense (benefit)	(34.0)%	(34.0)%	(34.0)%
State taxes—net	(7.4)	(5.8)	(5.9)
Research and development tax credits	(1.5)	(1.2)	(1.0)
Mark to Market adjustment	(15.8)	—	—
Other	1.3	1.3	3.9
Change in valuation allowance	57.4	39.7	37.0
Effective tax rate	0%	0%	0%

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 January 3, 2010 and December 28, 2008, respectively, are as follows (dollars in thousands):

	January 3, 2010	December 28, 2008
Deferred tax assets/(liabilities):		
Net operating loss carryforwards	$ 92,000	$ 88,784
Capitalized research and development expenses	19,589	20,507
Tax credits	9,328	8,992
Advance payments	5,911	3,974
Inventory	155	619
Accrued compensation	986	949
Other accruals	442	83
Other	668	185
Depreciation	(542)	(626)
Total gross deferred tax asset	128,537	123,467
Valuation allowance	(128,537)	(123,467)
Net deferred tax asset	$ —	$ —

As of January 3, 2010, we had federal and state net operating losses ("NOLs") of $250 million and $124 million, respectively, and federal and state research and experimentation credit carryforwards of approximately $7.1 million and $3.3 million, respectively, which will expire at various dates starting in 2010 through 2029. We had approximately $22 million of federal net operating losses generated in 1994 and approximately $18.9 million of Massachusetts net operating losses generated in 2004 that expired in 2009. We anticipate that approximately $16 million of federal net operating losses generated between 1995 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 is more likely than not that we will not recognize the benefits of the deferred tax assets. Accordingly, a valuation allowance of approximately $129 million has been established at January 3, 2010.

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 in accordance with Section 382 of the Internal Revenue Code of 1986, or Section 382, as well as similar state provisions. 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. In general an ownership change as defined by Section 382 results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. 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. If we have experienced a change in control as defined by Section 382 at any time since our formation, utilization of our NOL or R&D credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of our stock at the time of the ownership change by the applicable long-term tax-exempt rate, then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOL or R&D carryforwards before utilization.

We have recorded a deferred tax asset of approximately $4.9 million reflecting the benefit of deductions from the exercise of stock options which as 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.

The Company recognizes both accrued interest and penalties related to unrecognized benefits in income tax expense. The Company has not recorded any interest and penalties on any unrecognized tax benefits since its inception.

The tax years 1995 through 2009 remain open to examination by major taxing jurisdictions to which we are subject, which are primarily in the U.S., 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 file income tax returns in the U.S. federal and various state jurisdictions. There are currently no federal or state audits in progress by the Internal Revenue Service or any other jurisdictions for any tax years.

NOTE 13. 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 MAbs using our transgenic production platform. We also entered into a stock and note purchase agreement in September 2006, a note and warrant purchase agreement in December 2008, a redeemable convertible preferred stock agreement in June 2009, which provides for certain ongoing arrangements with LFB, a services agreement in July 2009, a stock purchase agreement in November 2009, and amended and restated promissory note in December 2009 (see Note 3). As of January 3, 2010, LFB owned approximately 65% of our common stock and also held convertible debt, warrants and convertible preferred stock which they can convert and exercise into 12,468,637 shares of our common stock. If the convertible debt is converted, the warrants exercised and the convertible preferred stock converted, LFB would own 28,469,474 shares, or approximately 76.6%. All transactions with LFB are related party transactions and may not be deemed arms-length transactions.

NOTE 14. GEOGRAPHICAL INFORMATION

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

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

	United States	Europe	Israel	Total
2009	$ 2,805	$ 21	$ —	$ 2,826
2008	12,189	4,467	—	16,656
2007	9,485	4,406	5	13,896

Of our long-lived assets, $4.2 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:

	United States	United Kingdom	Total
2009	$ 7,422	$ 5,799	$ 13,221
2008	14,488	5,911	20,399

NOTE 15. UNAUDITED RESULTS OF QUARTERLY OPERATIONS

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2009				
Revenue	$ 198	$ 655	$ 749	$ 1,224
Operating loss	(9,545)	(9,656)	(9,546)	(7,508)[1]
Net loss	(10,354)	(10,757)	(5,054)[2]	(1,689)[3]
Net loss per share—basic and diluted	(1.00)	(1.03)	(0.48)[4]	(0.09)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2008				
Revenue	$ 3,545	$ 9,139[5]	$ 2,929	$ 1,043
Operating loss	(8,197)	(1,825)[6]	(5,831)[7]	(7,353)[8]
Net loss	(8,223)	(2,213)	(6,060)	(6,168)[9]
Net loss per share—basic and diluted	(1.00)	(0.22)	(0.59)	(0.60)

(1) In the fourth quarter of 2009, we recorded a contra expense to research and development of $1.5 million related to a receivable from LFB for funding of a portion of our costs incurred in these joint venture programs during 2009.

(2) In the third quarter of 2009, we recognized $5.3 million of non-cash income, which represents the change in the fair value of the derivative and option components of the July 2009 redeemable convertible preferred financing with LFB (see Note 8).

(3) The third quarter of 2009 net loss per share was adjusted to reflect the dividends accrued related to the July 2009 redeemable convertible preferred financing with LFB (see Note 8).

(4) In the fourth quarter of 2009, we recognized $7.3 million of non-cash income, which represents the change in the fair value of the derivatives and option components of the July 2009 redeemable convertible preferred financing with LFB (see Note 8).

(5) In the second quarter of 2008, we recognized $4.2 million of revenue from product shipments to LEO.

(6) In the second quarter of 2008, we received $3 million of funding from LFB for costs incurred during the first six months of 2008 which was recorded as a contra expense to research and development.

(7) In the third quarter of 2008, we received $1.2 million of funding from the LFB/GTC LLC for costs incurred during the third quarter of 2008.

(8) In the fourth quarter of 2008, we received $900,000 of funding from the LFB/GTC LLC for costs incurred during the fourth quarter of 2008.

(9) In the fourth quarter of 2008, we received $1.5 million from the settlement of arbitration related to the fill/finish process conducted at a U.S. based third party fill/finish contractor during 2007.

NOTE 16. SUBSEQUENT EVENTS

In January 2010, LFB converted the convertible preferred stock it previously purchased in November 2009 under the terms described in the financing agreements approved by our shareholders in July 2009 into a total of 5.3 million shares of common stock.

In February 2010 we issued a secured note payable to LFB in the principal amount of $7,000,000. The secured note is a 4%, 36-month secured note that has a single payment of principal and interest at maturity.

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 12th day of March 2010.

GTC BIOTHERAPEUTICS, INC.

By: /s/ Geoffrey F. Cox
Geoffrey F. Cox
Chairman of the Board, President and Chief Executive Officer

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

Signature	Title	Date
/s/ Geoffrey F. Cox Geoffrey F. Cox	Chairman of the Board, President and Chief Executive Officer (Principal Executive Officer)	March 12, 2010
/s/ John B. Green John B. Green	Chief Financial and Accounting Officer (Principal Financial and Accounting Officer)	March 12, 2010
/s/ Christian Béchon Christian Béchon	Director	March 12, 2010
/s/ Francis J. Bullock Francis J. Bullock	Director	March 12, 2010
/s/ James A. Geraghty James A. Geraghty	Director	March 12, 2010
/s/ William K. Heiden William K. Heiden	Director	March 12, 2010
/s/ Michael J. Landine Michael J. Landine	Director	March 12, 2010
/s/ Pamela W. McNamara Pamela W. McNamara	Director	March 12, 2010
/s/ Bertrand Mérot Bertrand Mérot	Director	March 12, 2010
/s/ Evelyne Nguyen Evelyne Nguyen	Director	March 12, 2010
/s/ Jean-François Prost Jean-François Prost	Director	March 12, 2010
/s/ Alan W. Tuck Alan W. Tuck	Director	March 12, 2010

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EXHIBIT INDEX
to Form 10-K for the Year Ended January 3, 2010

Exhibit No.	Description
3.1.1	Restated Articles of Organization of GTC filed with the Secretary of the Commonwealth of Massachusetts on May 8, 2009. Filed as Exhibit 3.1 to GTC's Quarterly Report on Form 10-Q for the quarter ended March 29, 2009 (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 May 26, 2009. Filed as Exhibit 3.1 to GTC's Current Report on Form 8-K (File No. 0-21794) on May 27, 2009 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 July 30, 2009. Filed as Exhibit 3.1 to GTC's Current Report on Form 8-K (File No. 0-21794) on July 31, 2009 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	Amendment No.1 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.
4.2.2	Amendment No. 2 to Shareholder Rights Agreement, dated as of December 22, 2008, 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 24, 2008 and incorporated by reference herein.
4.2.3	Amendment No. 3 to Shareholder Rights Agreement, dated as of July 30, 2009, 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) on July 31, 2009 and incorporated by reference herein.
4.3	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.
4.4	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.
4.5	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.
4.6	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.
4.7	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.

Exhibit No.	Description
4.8	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 February 8, 2008 and incorporated by reference herein.
4.9	Form of Common Stock Purchase Warrant. Filed as Exhibit 4.1 to GTC's Quarterly Report on Form 10-Q for the quarter ended June 29, 2008 (File No. 0-21794) filed on August 7, 2008 and incorporated by reference herein.
4.10	Form of Common Stock Purchase Warrant. Filed as Exhibit 4.2 to GTC's Quarterly Report on Form 10-Q for the quarter ended June 29, 2008 (File No. 0-21794) filed on August 7, 2008 and incorporated by reference herein.
4.11	Amended and Restated Secured Convertible Note, dated as of December 21, 2009, issued by GTC to LFB Biotechnologies, S.A.S.. Filed herewith.
4.12	Form of Common Stock Purchase Warrant issued to LFB Biotechnologies, S.A.S.U. Included as Exhibit B to the Note and Warrant Purchase Agreement by and between GTC Biotherapeutics, Inc. and LFB Biotechnologies S.A.S.U. dated October 31, 2008, filed as Exhibit 10.1 to GTC's Current Report on Form 8-K filed on November 6, 2008 (File No. 0-21794) 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, 2998. 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.

Exhibit No.	Description
10.10**	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.
10.11**	GTC Amended and Restated 2002 Equity Incentive Plan. Filed as Exhibit 10.1 to GTC's Quarterly Report on Form 10-Q for the quarter ended June 28, 2009 (File No. 0-21794) filed on July 31, 2009 and incorporated by reference herein.
10.12**	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.
10.13	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.
10.14	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.
10.15	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.
10.16**	Second Amended and Restated Employment Agreement, dated as of July 23, 2008, by and between GTC and John B. Green. Filed as Exhibit 10.4 to GTC's Quarterly Report on Form 10-Q for the quarter ending June 29, 2008 (File No. 0-21794) filed on August 7, 2008 and incorporated by reference herein.
10.17**	Amended and Restated Executive Employment Agreement, dated as of July 23, 2008, by and between GTC and Geoffrey F. Cox. Filed as Exhibit 10.3 to GTC's Quarterly Report on Form 10-Q for the quarter ending June 29, 2008 (File No. 0-21794) filed on August 7, 2008 and incorporated by reference herein.
10.18**	Management Agreement, dated as of July 23, 2008 by and between GTC and Harry Meade. Filed as Exhibit 10.5 to GTC's Quarterly Report on Form 10-Q for the quarter ending June 29, 2008 (File No. 0-21794) filed on August 7, 2008 and incorporated by reference herein.
10.19**	Amended and Restated Executive Change in Control Agreement, dated as of July 23, 2008, by and between GTC and Harry M. Meade. Filed as Exhibit 10.8 to GTC's Quarterly Report on Form 10-Q for the quarter ending June 29, 2008 (File No. 0-21794) filed on August 7, 2008 and incorporated by reference herein.
10.20**	Amended and Restated Management Agreement, dated as of July 23, 2008, by and between GTC and Daniel S. Woloshen. Filed as Exhibit 10.7 to GTC's Quarterly Report on Form 10-Q for the quarter ending June 29, 2008 (File No. 0-21794) filed on August 7, 2008 and incorporated by reference herein.
10.21**	Amended and Restated Executive Change in Control Agreement, dated as of July 23, 2008, by and between GTC and Daniel S. Woloshen. Filed as Exhibit 10.10 to GTC's Quarterly Report on Form 10-Q for the quarter ending June 29, 2008 (File No. 0-21794) filed on August 7, 2008 and incorporated by reference herein.
10.22**	Amended and Restated Management Agreement, dated as of July 23, 2008, by and between GTC and Richard A. Scotland. Filed as Exhibit 10.6 to GTC's Quarterly Report on Form 10-Q for the quarter ending June 29, 2008 (File No. 0-21794) filed on August 7, 2008 and incorporated by reference herein.

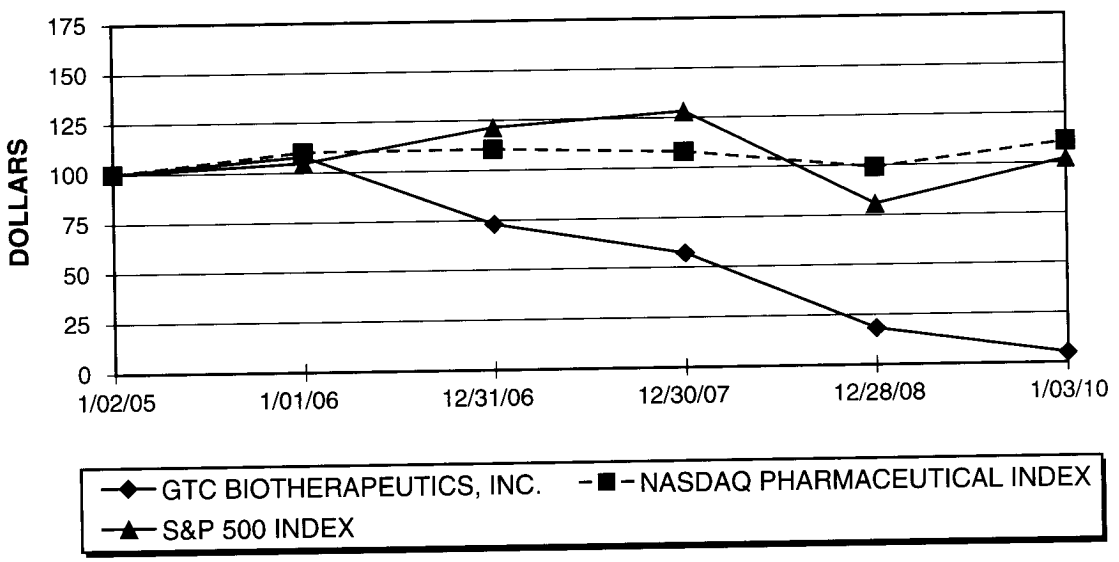
Exhibit No.	Description
10.23**	Amended and Restated Executive Change in Control Agreement, dated as of July 23, 2008, by and between GTC and Richard A. Scotland. Filed as Exhibit 10.9 to GTC's Quarterly Report on Form 10-Q for the quarter ending June 29, 2008 (File No. 0-21794) filed on August 7, 2008 and incorporated by reference herein.
10.24*	Amended and Restated Joint Development and Commercialization Agreement dated June 30, 2008 by and between GTC and LFB Biotechnologies S.A.S.U. Filed as Exhibit 10.11 to GTC's Quarterly Report on Form 10-Q for the quarter ended June 29, 2008 (File No. 0-21794) filed on August 7, 2008 and incorporated by reference herein.
10.25	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.
10.25.1	Amendment No. 1 to Stock and Note Purchase Agreement dated October 18, 2006, by and between GTC and LFB Biotechnologies S.A.S.U. Filed as Exhibit 10.1 to GTC's Quarterly Report on Form 10-Q (File No. 0-21794) for the quarter ended March 30, 2008 filed on May 8, 2008 and incorporated by reference herein.
10.25.2	Amendment No. 2 to Stock and Note Purchase Agreement dated March 25, 2008, by and between GTC and LFB Biotechnologies S.A.S.U. Filed as Exhibit 10.2 to GTC's Quarterly Report on Form 10-Q (File No. 0-21794) for the quarter ended March 30, 2008 filed on May 8, 2008 and incorporated by reference herein.
10.26	Keepwell Agreement dated September 29, 2006, by and between GTC and Laboratories 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.
10.27	Form of Securities Purchase Agreement. Filed as Exhibit 10.2 to GTC's Current Report on Form 8-K (File No. 0-21794) filed on February 8, 2008 and incorporated by reference herein.
10.28*	Acquisition, Licensing, Development and Supply Agreement dated June 22, 2008 by and between GTC, ATIII LLC and Ovation Pharmaceuticals, Inc. Filed as Exhibit 10.1 to GTC's Quarterly Report on Form 10-Q for the quarter ending June 29, 2008 (File No. 0-21794) filed on August 7, 2008 and incorporated by reference herein.
10.29	Note and Warrant Purchase Agreement, dated as of October 31, 2008, by and between GTC and LFB Biotechnologies S.A.S.U., including the form of convertible note attached as Exhibit A thereto and the form of warrant 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 November 6, 2008 and incorporated by reference herein.
10.29.1	Omnibus Amendment to Note and Warrant Purchase Agreement, dated as of December 21, 2009, by and between GTC and LFB Biotechnologies S.A.S. Filed herewith.
10.30	Amended and Restated Security Agreement, dated as of June 18, 2009, by GTC in favor of LFB Biotechnologies S.A.S. Filed as Exhibit 10.2 to GTC's Current Report on Form 8-K (File No. 0-21794) filed on June 19, 2009 and incorporated by reference herein.
10.31	Patent and License Security Agreement, dated as of December 22, 2008, by GTC in favor of LFB Biotechnologies S.A.S.U. Filed as Exhibit 10.2 to GTC's Current Report on Form 8-K (File No. 0-21794) filed on December 24, 2008 and incorporated by reference herein.
10.32	Trademark and License Security Agreement, dated as of December 22, 2008, by GTC in favor of LFB Biotechnologies S.A.S.U. Filed as Exhibit 10.3 to GTC's Current Report on Form 8-K (File No. 0-21794) filed on December 24, 2008 and incorporated by reference herein.

Exhibit No.	Description
10.33**	GTC 2008 Retention Incentive Plan. Filed as Exhibit 10.1 to GTC's Current Report on Form 8-K (File No. 0-21794) filed on July 3, 2008 and incorporated by reference herein.
10.34	Form of nonstatutory stock option award for non-employee directors. Filed as Exhibit 10.1 to GTC's Quarterly Report on Form 10-Q for the quarter ended September 27, 2009 (File No. 0-21794) filed on November 6, 2009 and incorporated by reference herein.
10.35**	Form of nonstatutory stock option award. Filed as Exhibit 10.2 to GTC's Quarterly Report on Form 10-Q for the quarter ended September 27, 2009 (File No. 0-21794) filed on November 6, 2009 and incorporated by reference herein.
10.36**	Form of incentive stock option award. Filed as Exhibit 10.3 to GTC's Quarterly Report on Form 10-Q for the quarter ended September 27, 2009 (File No. 0-21794) filed on November 6, 2009 and incorporated by reference herein.
10.37	Amended and Restated Promissory Note, dated as of December 21, 2009, by GTC in favor of LFB Biotechnologies S.A.S. Filed herewith.
10.38	Loan Agreement, dated as of June 18, 2009, by and between GTC and LFB Biotechnologies S.A.S. Filed as Exhibit 10.1 to GTC's Current Report on Form 8-K (File No. 0-21794) filed on June 19, 2009 and incorporated by reference herein.
10.38.1	Omnibus Amendment to Loan Agreement, dated as of December 21, 2009, by and between GTC and LFB Biotechnologies S.A.S. Filed herewith.
10.39	Securities Purchase Agreement, dated as of June 18, 2009, by and between GTC and LFB Biotechnologies S.A.S. Filed as Exhibit 10.4 to GTC's Current Report on Form 8-K (File No. 0-21794) filed on June 19, 2009 and incorporated by reference herein.
10.40	Amendment to Mortgage Agreement and Fixture Filing, dated as of June 18, 2009 between GTC and LFB Biotechnologies S.A.S. Filed as Exhibit 10.4 to GTC's Quarterly Report on Form 10-Q for the quarter ended June 28, 2009 (File No. 0-21794) filed on July 31, 2009 and incorporated by reference herein.
10.40.1	Second Amendment to Mortgage Agreement and Fixture Filing, dated as of December 21, 2009 between GTC and LFB Biotechnologies S.A.S. Filed herewith.
10.41	Securities Purchase Agreement, dated as of November 2, 2009, by and between GTC and LFB Biotechnologies S.A.S. Filed as Exhibit 10.1 to GTC's Current Report on Form 8-K (File No. 0-21794) filed on November 2, 2009 and incorporated by reference herein.
10.42*	Services Agreement, dated as of July 16, 2009, by and between GTC and LFB Biotechnologies S.A.S. Filed herewith.
10.43*	Atryn Generation I Clinical and Commercial Service Agreement, dated as of June 12, 2009, by and between GTC and LONZA Sales Ltd. Filed herewith.
21	List of Subsidiaries. Filed herewith.
23	Consent of PricewaterhouseCoopers LLP. Filed herewith.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith.
32	Certifications pursuant to 18 U.S.C. Section 1350. Filed herewith.

* 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.

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



Assumes $100 invested on Jan. 02, 2005
Assumes dividend reinvested
Fiscal year ending Jan. 03, 2010

Corporate Information

BOARD OF DIRECTORS

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

Christian Béchon
Chairman and Chief Executive Officer
LFB Biotechnologies, SAS

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

William K. Heiden
Chief Executive Officer
Vitruvian Pharmaceuticals, LLC

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

Pamela W. McNamara
President
Cambridge Consultants, Inc.
Former CEO, CRF, Inc., Arthur D. Little

Bertrand Merot, Ph.D.
Senior Executive Vice-President, COO
LFB Biotechnologies, SAS

Evelyne Nguyen
Chief Financial Officer
SVP Finance and Strategy
LFB SA

Jean François Prost, M.D.
Senior Vice President
Medical & Scientific Affairs
LFB Biotechnologies, SAS

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.

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

Over the Counter Bulletin Board
(OTCBB) Ticker Symbol: GTCB

REPORT ON FORM 10-K

GTC's Annual Report on Form 10-K for the year ended January 3, 2010 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: John Green
or by calling John Green at
(508) 620-9700 x5279

ANNUAL MEETING

The Annual Meeting of Shareholders is scheduled to be held on Wednesday, May 26, 2010 at 2:00 p.m. at the Sheraton Framingham Hotel and Conference Center, 1657 Worcester Rd., Framingham, Massachusetts 01701


GTC
Biotherapeutics