
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 10-Q

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

For the quarterly period ended September 27, 2009

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 Number 0-21794

GTC BIOTHERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Massachusetts
(State or Other Jurisdiction of
Incorporation or Organization)

04-3186494
(I.R.S. Employer
Identification No.)

175 Crossing Boulevard, Framingham, Massachusetts
(Address of Principal Executive Offices)

01702
(Zip Code)

(508) 620-9700
(Registrant's Telephone Number, Including Area Code)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 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 web site 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 whether registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "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 registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding at November 5, 2009
Common Stock, \$0.01 par value	24,741,590

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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 “Risk Factors” in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 28, 2008 as filed with the Securities and Exchange Commission, as supplemented and amended by the “Risk Factors” contained in our Quarterly Reports on Form 10-Q.

The forward-looking statements in this Quarterly Report on Form 10-Q are as of the date of this report. We expressly disclaim any obligation or undertaking to disseminate any updates or revisions to any forward-looking statement contained in this Quarterly Report to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any forward-looking statement is based, except as may be required by law.

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 quarterly period ended September 27, 2009 to prior periods, we have adjusted certain stock amounts and conversion prices of prior periods to accurately reflect the impact of the reverse stock split on our outstanding common stock.

GTC BIOTHERAPEUTICS, INC.
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PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

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

	September 27, 2009	December 28, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 1,753	\$ 11,643
Accounts receivable and unbilled contract revenue	296	287
Inventory	123	863
Other current assets	1,701	962
Total current assets	3,873	13,755
Net property, plant and equipment	12,538	13,396
Intangible assets, net	5,573	6,249
Other assets	835	2,404
Restricted cash	599	4,599
Total assets	<u>\$ 23,418</u>	<u>\$ 40,403</u>
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 6,279	\$ 8,024
Accrued liabilities	6,638	5,962
Short-term deferred contract revenue	6,804	688
Derivative liability	12,330	—
Warrant liability	5,380	—
Current portion of debt and capital leases	439	1,383
Current portion of long-term debt to LFB Biotechnologies, net of debt discount	208	—
Total current liabilities	38,078	16,057
Long-term deferred contract revenue	8,290	9,180
Capital leases, net of current portion	43	6,577
Long-term debt to LFB Biotechnologies, net of debt discount	16,651	12,692
Other long-term liabilities	45	20
Total liabilities	63,107	44,526
Redeemable convertible preferred stock:		
Series E-1 Redeemable Convertible Preferred stock, net of offering costs; redemption amount \$12,000,000; \$.01 par value; 18,000 shares authorized 12,000 shares and 0 shares were issued and outstanding at September 27, 2009 and December 28, 2008, respectively	1,867	—
Series E-2 Redeemable Convertible Preferred stock, redemption amount \$13,500,000; \$.01 par value; 20,250 shares authorized 13,500 shares and 0 shares were issued and outstanding at September 27, 2009 and December 28, 2008, respectively	476	—
Subscription receivable - LFB	(12,750)	—
Total redeemable convertible preferred stock	(10,407)	—
Shareholders' deficit:		
Preferred stock, \$.01 par value; 5,000,000 shares authorized: 15,000 shares were designated as Series D convertible preferred stock; 115 were issued and outstanding at September 27, 2009 and December 28, 2008	—	—
Common stock, \$.01 par value; 210,000,000 shares authorized; 10,444,656 and 10,296,477 shares were issued and outstanding at September 27, 2009 and December 28, 2008, respectively	105	1,029
Capital in excess of par value	298,498	298,963
Accumulated deficit	(327,885)	(304,115)
Total shareholders' deficit	(29,282)	(4,123)
Total liabilities, redeemable convertible preferred stock and shareholders' deficit	<u>\$ 23,418</u>	<u>\$ 40,403</u>

The accompanying notes are an integral part of these financial statements.

GTC BIOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited, dollars in thousands except per share amounts)

	<u>Fiscal three months ended</u>		<u>Fiscal nine months ended</u>	
	<u>September 27, 2009</u>	<u>September 28, 2008</u>	<u>September 27, 2009</u>	<u>September 28, 2008</u>
Revenues:				
Service revenue	\$ 117	\$ 2,866	\$ 755	\$ 11,205
Product revenue	632	63	847	4,408
Total revenue	749	2,929	1,602	15,613
Costs of revenue and operating expenses:				
Cost of service revenue	255	1,123	875	4,165
Cost of product revenue	299	—	315	3,877
Research and development	7,141	5,326	20,914	15,722
Selling, general and administrative	2,600	2,311	8,245	7,702
	10,295	8,760	30,349	31,466
Operating loss	(9,546)	(5,831)	(28,747)	(15,853)
Other income (expense):				
Interest income	—	32	21	180
Interest expense	(695)	(275)	(2,706)	(863)
Other income (expense)	5,331	14	5,411	40
Net loss	<u>\$ (4,910)</u>	<u>\$ (6,060)</u>	<u>\$ (26,021)</u>	<u>\$ (16,496)</u>
Accretion on redeemable convertible preferred stock	(144)	—	(144)	—
Net loss attributable to common stockholders	<u>\$ (5,054)</u>	<u>\$ (6,060)</u>	<u>\$ (26,165)</u>	<u>\$ (16,496)</u>
Net loss per common share (basic and diluted)	<u>\$ (0.48)</u>	<u>\$ (0.59)</u>	<u>\$ (2.51)</u>	<u>\$ (1.71)</u>
Weighted average number of common shares outstanding (basic and diluted)	<u>10,487</u>	<u>10,285</u>	<u>10,445</u>	<u>9,663</u>

The accompanying notes are an integral part of these financial statements.

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

	<u>Fiscal nine months ended</u>	
	<u>September 27, 2009</u>	<u>September 28, 2008</u>
Cash flows from operating activities:		
Net loss from operations	\$ (26,021)	\$ (16,496)
Adjustments to reconcile net loss from operations to net cash used in operating activities:		
Depreciation and amortization	1,642	1,960
Non-cash other income	(5,299)	—
Purchase of in-process research and development	1,250	—
Stock based compensation	610	482
Amortization of premium on marketable securities	—	90
Common stock issuance to GTC savings and retirement plan	793	210
Non-cash interest expense	797	73
Changes in assets and liabilities:		
Accounts receivable and unbilled contract revenue	(9)	(681)
Inventory	740	—
Other assets and liabilities	(18)	116
Accounts payable	(587)	1,148
Accrued liabilities	676	606
Deferred contract revenue	5,226	1,446
Net cash used in operating activities	(20,200)	(11,046)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(171)	(616)
Sale of property, plant and equipment	—	168
Redemption of marketable securities	—	6,600
Net cash (used in) provided by investing activities	(171)	6,152
Cash flows from financing activities:		
Net proceeds from the LFB convertible debt financing, net of offering costs	3,922	—
Net proceeds from the LFB preferred stock financing, net of offering costs	7,474	—
Net proceeds from the issuance of common stock, net of offering costs	—	5,445
Net proceeds from employee stock purchase plan	24	33
Repayment of long-term debt and capital leases	(939)	(889)
Net cash provided by financing activities	10,481	4,589
Net decrease in cash and cash equivalents	(9,890)	(305)
Cash and cash equivalents at beginning of period	11,643	9,075
Cash and cash equivalents at end of period	<u>\$ 1,753</u>	<u>\$ 8,770</u>
Supplemental disclosure of cash flow information:		
Conversion of LFB debt, net of debt discount	\$ 4,512	\$ 1,756
Release of restricted cash for repayment of long-term debt	4,000	—
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	—
Assets purchased under capital lease	159	145
Merrimack preferred stock in consideration for AFP license	1,250	—

The accompanying notes are an integral part of these financial statements.

GTC BIOTHERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Basis of Presentation:

These unaudited consolidated financial statements should be read in conjunction with the Annual Report on Form 10-K of GTC Biotherapeutics, Inc., or GTC, for the fiscal year ended December 28, 2008 (referred to as the 2008 Form 10-K) and the financial statements and footnotes included therein. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted pursuant to Securities and Exchange Commission rules and regulations.

Our significant accounting policies are the same as described in Note 2 to our Notes to Consolidated Financial Statements included in our 2008 Form 10-K. The financial statements for the fiscal nine months and three months ended September 27, 2009 and September 28, 2008, are unaudited but include, in our opinion, all adjustments necessary for a fair presentation of the results for the periods presented. These adjustments are normal and recurring in nature. Comprehensive loss is substantially the same as our net loss.

We are subject to risks common to companies in the biotechnology industry, including, but not limited to, the uncertainties of clinical trials and the regulatory requirements for approval of therapeutic compounds, dependence on existing and new collaborations, the need for additional capital, competitive new technologies, dependence on key personnel, protection of proprietary technology, and compliance with the regulations of the United States Food and Drug Administration and other governmental agencies.

On June 30, 2008, we entered into an additional amendment to the Joint Development and Commercialization Agreement with LFB Biotechnologies, S.A.S., or LFB, a related party, to establish LFB/GTC LLC as a separate legal entity for the joint venture. Our investment in the joint venture is being accounted for at cost based on our ownership percentage and is not being consolidated as we are not the primary beneficiary of the joint venture.

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 since inception and have an accumulated deficit of approximately \$328 million at September 27, 2009. Our recurring losses from operations and limited funds raise substantial doubt about our ability to continue as a going concern. 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. Our primary sources of additional capital raised have been equity financings and debt financings. Management expects that future sources of funding will include sales of equity or debt securities and new or expanded partnering arrangements. Our failure to raise capital as and when needed has had a negative impact on our financial condition and our ability to pursue our business strategies. If no funds are available we would have to sell or liquidate the business. If adequate funds do not become available we may be required to take further steps 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 will dilute ownership of our current equity investors. In July 2009, under an agreement pursuant to which LFB provided a total of \$12.3 million of cash proceeds to us, we granted LFB an option to purchase additional securities. On October 30, 2009 LFB informed us that it was exercising this option, and on November 3, 2009 we issued those additional securities to LFB, providing us an additional \$6.375 million of cash proceeds (see Note 9). In addition, on November 2, 2009 we entered into a Stock Purchase Agreement with LFB pursuant to which we issued shares of our common stock to LFB on November 5, 2009, providing us with an additional \$3.625 million of cash proceeds. Based on our cash balance as of September 27, 2009, as well as the \$10 million in cash we received from the closing of the LFB financing transactions in November 2009 and potential cash receipts from existing programs, we anticipate that we have the ability to continue our operations into the middle of the first quarter of 2010, including normal recurring debt service payments. We are currently engaged in discussions for potential new partnering transactions and plan to bring further financial resources into GTC in the future through some combination of partnering transactions and other debt or equity financing arrangements. 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.

2. 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, consisting of shares issuable upon conversion or exercise of convertible preferred stock, warrants, stock options and stock to be issued under our defined contribution retirement plan, totaled 5.4 million shares and 2.8 million shares at September 27, 2009 and September 28, 2008, respectively. Since we were in a net loss position at September 27, 2009 and September 28, 2008, these potential common shares were not used to compute diluted loss per share, as the effect would

GTC BIOTHERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENT—(Continued)

have been anti-dilutive. We also have two convertible notes payable to LFB. The first convertible note has a current principal balance of \$679,000, net of an unamortized debt discount of \$164,000, 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 is due June 30, 2012 and has a current principal balance of \$12.7 million, net of unamortized debt discount of \$390,000, which may be converted at any time into our common stock at \$3.10 per share at LFB's discretion.

3. Reverse Stock Split:

On May 26, 2009, we filed Articles of Amendment to our Restated Articles of Organization with the Secretary of the Commonwealth of Massachusetts to effect 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.

4. Inventory:

Inventory consists of finished goods at September 27, 2009 and December 28, 2008.

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 or commercial use. Currently, because we have only one customer, 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 September 27, 2009 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., which we received in February 2009. We anticipate our cost of production will be substantially reduced as we move to larger production volumes to support clinical and commercial requirements.

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-offs may be required. Also, if we 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.

5. Business Agreements:

LFB Biotechnologies

In September 2006, we entered into a collaboration agreement with LFB Biotechnologies, or LFB, to develop selected recombinant plasma proteins and MAbs. LFB is a subsidiary of LFB S.A., a vertically integrated plasma fractionation company based in Paris, France that currently markets 19 plasma-derived products in the areas of hemostasis, anesthesia-intensive care and immunology. LFB S.A. is a for-profit company currently 100% owned by the French government. The first program in this collaboration is for the development of a recombinant form of human blood coagulation factor VIIa for the treatment of patients with hemophilia. This collaboration has been established in a separate joint venture entity, and it includes programs to develop a recombinant form of human blood coagulation factor IX and 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®.

Lundbeck Inc. (formerly OVATION Pharmaceuticals)

In June 2008, we entered into a collaboration agreement with Lundbeck Inc., or Lundbeck, to develop and market ATryn® in the United States. The collaboration agreement includes the commercialization of ATryn® in the hereditary antithrombin deficiency, or HD, indication and the further development of ATryn® in acquired antithrombin deficiency indications. Under the agreement, we have received milestone payments to date of \$9 million for the approval of ATryn® for HD in the U.S. of which \$5 million was paid to us in 2008 and \$4 million was paid to us in the first quarter of 2009. We recorded the \$9 million in total milestones received as deferred revenue, which is being recognized as revenue on a straight-line basis over the 20 year life of the agreement. The collaboration anticipates further development of ATryn® in larger market acquired deficiencies, such as the treatment of heparin resistance in patients undergoing surgery requiring cardiopulmonary bypass and the treatment of disseminated intravascular coagulation associated with severe sepsis.

We are responsible for production of ATryn® and currently receive a fixed price for delivery of commercial product to Lundbeck, a royalty on net sales, potential sales-based milestone payments, and payment for product used in clinical trials. In May 2009, Lundbeck launched the sale of ATryn® in the U.S. We have recorded \$847,000 of product revenue and \$43,000 of royalty revenue associated with product shipped to Lundbeck.

GTC BIOTHERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENT—(Continued)

JCOM Co. Ltd (“JCOM”)

In February 2009, we entered into a license and development agreement with JCOM, an affiliate of Dong-A Pharmaceuticals, whereby we granted to JCOM a twelve month 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 for JCOM to make, use, sell, offer for sale and import recombinant human insulin products in these territories. We are in the process of developing appropriate cell lines and demonstrate production of recombinant human insulin products for JCOM. The agreement contemplates the subsequent establishment of a transgenic production system in South Korea. During the first quarter of 2009, we received \$750,000 from JCOM, which was recorded as deferred revenue which will be recognized as revenue when JCOM either exercises its options for Asia and the rest of the world or when the options expire, whichever comes first.

Merrimack

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 known as MM-093, for the treatment of autoimmune diseases as well as Merrimack’s inventory of bulk drug substance. We have also assumed control of the transgenic goats that express rhAFP in their milk, which were originally developed by us for Merrimack and are cared for at our facilities. We intend to further develop rhAFP in autoimmune disease areas such as myasthenia gravis and multiple sclerosis with support from commercial partnering. In consideration for the rights granted us under this agreement we transferred our shares of Merrimack preferred stock, which were issued to us in December 2003 valued at \$1.2 million, back to Merrimack. Since this is not yet an approved product, there are uncertainties around the eventual success of the program and there are no alternative uses, the value of the Merrimack preferred stock was recorded as a non-cash charge of \$1.2 million to in-process research and development expense in the third quarter of 2009.

LEO Pharma A/S (“LEO”)

LEO Pharma informed us in September 2008 of their internal reprioritization and desire to transfer the ATryn® program to us or a third party and subsequently attempted to terminate its 2005 collaboration agreement. We do not believe that LEO had any basis for such termination, and we further believe that LEO is in breach of the agreement. We initiated International Chamber of Commerce (ICC) arbitration proceedings in the fourth quarter of 2008. We have asked the ICC arbitration 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. We had a hearing in the ICC arbitration in the third quarter of 2009 but cannot predict its likely outcome or, in the event of an unfavorable outcome, the potential consequences to us, including cost. We expect a resolution within approximately the next six months and, therefore, the related deferred revenue of approximately \$4.4 million is classified as short-term.

6. Accrued Liabilities:

Accrued liabilities included the following:

	(dollars in thousands)	
	At September 27, 2009	At December 28, 2008
Accrued payroll and benefits	\$ 1,841	\$ 2,456
Accrued bonuses – 2008 ^(a)	1,073	1,254
Accrued bonuses – 2009	1,039	—
Other	2,685	2,252
Total accrued expenses	\$ 6,638	\$ 5,962

^(a) The 2008 bonuses were paid out in shares of common stock during the fourth quarter of 2009.

7. Intangible Assets:

Our intangible assets consist of marketing rights and technology licenses with amortization lives between 9 years and 15 years. Amortization expense was approximately \$225,000 for each of the fiscal three-month periods ended September 27, 2009 and September 28, 2008 and \$676,000 for each of the fiscal nine-month periods ended September 27, 2009 and September 28, 2008.

GTC BIOTHERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENT—(Continued)

The estimated aggregate amortization expense for all our intangible assets over the next five years is as follows:

Three months remaining in 2009	\$ 226,000
2010	\$ 902,000
2011	\$ 902,000
2012	\$ 902,000
2013	\$ 902,000
2014 and thereafter	\$1,739,000

8. Stockholders' Deficit:

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 and 7-year warrants, which were immediately exercisable, to purchase an aggregate of approximately 690,000 shares of our common stock at an exercise price of \$8.70 per share.

In March 2008, LFB converted 1,450 shares of Series D Convertible Preferred Stock into 1,450,000 shares of common stock.

9. Redeemable Convertible Preferred Stock:

On July 30, 2009, our shareholders approved of the issuance of newly-designated Series E-1 and Series E-2 redeemable convertible preferred stock. Upon approval, the \$4.5 million secured convertible note previously issued to LFB converted into 4,500 shares of Series E-1 redeemable convertible preferred stock. As part of the financing agreement entered into with LFB during June 2009, LFB also purchased an additional \$21 million of redeemable convertible preferred stock for cash proceeds of \$8.3 million. The remaining \$12.8 million is subject to an escrow arrangement to secure the future dividends payable on this redeemable convertible preferred stock. LFB had not placed the remaining \$12.8 million into escrow as of September 27, 2009, and is not required to do so until December 15, 2009. The amount has been classified as a subscription receivable on the consolidated balance sheet. In October 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.

The new Series E-1 and Series E-2 redeemable convertible preferred stock ("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. Series E Preferred Stock accrues cumulative dividends as a percentage of the initial stated value 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 43% of the preferred stock that is Series E-1 is \$2.63 per share, representing a total of 4,562,738 shares of common stock for the shares of Series E-1 outstanding at September 27, 2009. The remaining 57% that is Series E-2 is convertible at \$2.2368 per share, based on the volume weighted average market price on July 30, 2009, representing 6,035,408 shares of our common stock for the shares of Series E-2 outstanding at September 27, 2009. The other terms of the Series E-1 redeemable convertible preferred stock are the same as for the Series E-2 redeemable convertible preferred stock. 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. 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 FASB's 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 and 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. For the fiscal three-month period ended September 27, 2009 we recorded approximately \$3.6 million to other income as a result of the change in the fair value of the option. On October 30, 2009, LFB converted all of its then outstanding shares of Series E convertible preferred stock into a total of approximately 10.6 million shares of our common stock.

LFB had the option for six months from the July 31, 2009 closing date of the issuance of Series E Preferred Stock to purchase \$12.75 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. 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 consisting of 43% Series E-1 and 57% Series E-2. Upon exercise of the option, we received an additional \$6.375 million of cash proceeds 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 accordance with FASB's accounting and reporting standards on freestanding

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warrants and other similar instruments on shares that are redeemable, this option to purchase redeemable convertible preferred stock was carried 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 and 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. For the fiscal three-month period ended September 27, 2009 we recorded approximately \$1.7 million to other income as a result of the change in the fair value of the option.

The fair values of the derivative and option calculated using *Level 3* - Unobservable inputs which are inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities, under an accounting standard for fair value measurements of all non financial assets and non financial liabilities.

As of September 27, 2009, on an as converted basis, LFB beneficially owned approximately 70.1% 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 and its option to purchase additional shares of Series E preferred stock.

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, June 29, 2009	\$ —
Issuance of series E units	25,500
Amount allocated to series E derivative	(15,888)
Amount allocated to detachable warrants	(7,120)
Issuance costs	(718)
Net issuance of series E redeemable units	1,774
Accrual of dividends	425
Accretion of series E redeemable convertible preferred stock	144
Subscription receivable	(12,750)
Balance, September 27, 2009	<u>\$ (10,407)</u>

10. Long-Term Debt:

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 (discussed below) the term loan with GE Capital was repaid in full on June 18, 2009.

In December 2006, as part of the second tranche of investment under an agreement with LFB, we issued a \$2.6 million, five-year convertible note to LFB. The note accrues interest at a rate of 2% per annum and will automatically convert into shares of our common stock in conjunction with any future common stock offerings, at the per share offering price of the respective offering, but only to the extent that any conversion does not result in LFB's holdings exceeding 19.9% of our outstanding 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 approximately 200,000 shares of our common stock at the rate of \$8.70 per share. 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 \$19,000 during the third quarter of 2009 and 2008 and \$55,000 and \$73,000 during the first nine months of 2009 and 2008, respectively. Upon the February 2008 partial conversion of the note, approximately \$600,000 of unamortized debt discount was reclassified to additional paid in capital.

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%. The debt may be converted into our common stock at a conversion price of \$3.10 per share at LFB's discretion. Under this agreement we issued to LFB 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 \$2.5 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 \$176,000 during the third quarter of 2009 and \$521,000 during the first nine months of 2009. 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 \$36,000 during the third quarter of 2009 and

\$106,000 during the first nine months of 2009.

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In June 2009 LFB paid off the remaining net principal amount of our term loan with GE Capital for \$3.5 million. 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 interest expense during the second quarter of 2009.

In June 2009, we issued to LFB a \$4.5 million secured convertible note resulting in \$4 million of cash proceeds to us and relieving our payable amount of approximately \$513,000 owed to LFB for their excess funding of costs in our joint venture. The convertible note automatically converted into approximately 4.6 million shares of Series E-1 redeemable convertible preferred stock upon shareholder approval on July 30, 2009.

In July 2009, we entered into a promissory note agreement with Edwards Angell Palmer & Dodge LLP (“EAPD”) in the amount of approximately \$645,000 for amounts then payable to EAPD. The note accrues interest at a rate of 6% per annum with weekly principal and interest payments of approximately \$28,000 through January 8, 2010. The balance of the note was approximately \$423,000 as of September 27, 2009.

At September 27, 2009 and December 28, 2008, the fair values of our debt instruments were as follows:

	(dollars in thousands)	
	At September 27, 2009	At December 28, 2008
GE Capital loan due December 2011 – Paid in full in June 2009	\$ —	\$ 6,379
GE Capital loan due January 2010 – Paid in full in June 2009	—	678
2006 Convertible note to LFB, fixed annual interest of 2%	663	609
2008 Convertible note to LFB, fixed annual interest of 8%	12,644	11,685
2009 Promissory note to LFB, fixed annual interest of 10.8%	3,201	—
EAPD Promissory note, fixed annual interest rate of 6%	415	—

The fair values of our GE Capital loans and our LFB convertible notes and promissory note were calculated using a net present value approach using *Level 3* - Unobservable inputs which are inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities, under an accounting standard for fair value measurements of all non financial assets and non financial liabilities. We used an effective interest rate of 15% in our fair value calculation.

11. Fair Value:

On January 1, 2009, we adopted a newly issued accounting standard for fair value measurements of all non financial assets and non financial liabilities not recognized or disclosed at fair value in the financial statements on a recurring basis. The accounting standard for those assets and liabilities did not have a material impact on our financial position and results of operations. The new accounting standard defines 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. The 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.

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

<u>Description</u>	<u>Fair Value Measure as of September 27, 2009</u>			
	(dollars in thousands)			
	<u>Total</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Money Market Fund	\$ 448	\$ 448	\$ —	\$ —
Warrant Liability	7,121	—	—	7,121
Derivative Liability	15,888	—	—	15,888
Total	<u>\$ 23,457</u>	<u>\$ 448</u>	<u>\$ —</u>	<u>\$ 23,009</u>

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

Given the complex structure of the warrant and derivative liabilities, 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 these instruments. The model utilized assumptions for volatility based on our historical volatility and credit spread based on Standard & Poor's Corporate Ratings criteria.

12. Retention Incentive 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 were eligible to receive awards of restricted stock units issued pursuant to our 2002 Equity Incentive 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.

During the first nine months of 2009 we recorded approximately \$170,000 of compensation expense related to the restricted stock units.

Participants 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. We are accruing this amount on a straight line basis over a 22-month period, resulting in an expense of approximately \$135,000 during the third quarter of 2009 and approximately \$461,000 during the first nine months of 2009. If the payment is made in shares of our common stock, the Retention 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 November 2008, our Compensation Committee approved and adopted a further retention plan, referred to as the Supplemental Retention Plan. The establishment of this retention plan was also a required condition for the closing of the transactions under the Convertible Note and Warrant Purchase Agreement that we entered into with LFB in October 2008. The purposes and administration of the Supplemental Retention Plan, and the eligible participants, are the same as for the original Retention Plan. Eligible participants under the Supplemental Retention Plan received stock options with a term of five years and an exercise price equal to the \$3.10 conversion price of the convertible note and warrants issued to LFB under the Convertible Note and Warrant Purchase Agreement. The stock options will vest in two equal installments on each of September 30, 2009 and June 30, 2010, provided that the recipient remains our employee until these dates.

13. Warrant for Purchase of Common Stock:

In January 2009, we adopted the provisions of Emerging Issues Task Force Issue No. 07-5 "*Determining Whether an Instrument (or an Embedded Feature) is Indexed to an Entity's Own Stock*", which would qualify as a scope exception under previously issued accounting standards. In August 2005, we sold 457,142 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

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placement to institutional investors, which were exercisable on or after February 10, 2006. This warrant was reassessed under the new accounting standard 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 previously issued accounting standard. Therefore, this warrant was determined to be a derivative and was reclassified to a liability and will be marked to market going forward. 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. During the third quarter of 2009 we recorded approximately \$31,000 to other income for the mark-to-market adjustment.

14. New Accounting Pronouncements:

In June 2009, the FASB also issued an amendment to the accounting and disclosure requirements for the consolidation of variable interest entities (VIEs). The elimination of the concept of a QSPE, as discussed above, removes the exception from applying the consolidation guidance within this amendment. 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. Our joint venture with LFB involves the development and commercialization of recombinant plasma proteins and MABs. Our investment in the joint venture is being accounted for at cost based on our ownership percentage and is not being consolidated as we are not the primary beneficiary of the joint venture. We have not determined the effect that the adoption of this Standard will have 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 allow 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. We have not yet determined when we will adopt this update or what the impact will be on our condensed consolidated financial statements.

In August 2009, the FASB issued an amendment that provides clarification that in circumstances in which a quoted price in an active market for the identical liability is not available, a reporting entity is required to measure fair value using one or more of the following methods: 1) a valuation technique that uses a) the quoted price of the identical liability when traded as an asset or b) quoted prices for similar liabilities or similar liabilities when traded as assets and/or 2) a valuation technique that is consistent with the principles of Topic 820 of the Accounting Standards Codification (e.g. an income approach or market approach). The amendment also clarifies that when estimating the fair value of a liability, a reporting entity is not required to adjust to include inputs relating to the existence of transfer restrictions on that liability. The adoption of this standard did not have an impact on our financial position or results of operations; however, this standard may impact us in future periods.

15. Legal Proceedings:

LEO Pharma informed us in September 2008 of their internal reprioritization and desire to transfer the ATryn® program to us or a third party and subsequently attempted to terminate its 2005 collaboration agreement. We do not believe that LEO had any basis for such termination, and we further believe that LEO is in breach of the agreement. We initiated International Chamber of Commerce (ICC) arbitration proceedings in the fourth quarter of 2008. We have 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. A hearing was held in the third quarter before the tribunal of the ICC but we cannot predict its likely outcome or, in the event of an unfavorable outcome, the potential consequences to us, including cost.

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.

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16. Subsequent Events:

On November 3, 2009, LFB exercised its option and purchased \$12.75 million of additional Series E convertible preferred stock under the terms described in the financing arrangements approved by our shareholders in July 2009. The transaction provided \$6.375 million of new cash proceeds to us. In addition, on October 30, 2009 LFB converted the convertible preferred stock it previously purchased under these agreements in July 2009 into a total of approximately 10.6 million shares of common stock. Additionally, LFB purchased \$3.625 million of common stock at the October 30, 2009 market closing price of \$1.07 per share in a transaction that closed on November 5, 2009. The November 5th transaction provided LFB with approximately 3.4 million additional shares of our common stock.

On November 5, 2009, we implemented a restructuring plan to enable us to meet the requirements of key programs and 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.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

Business Overview

We are the leader in the development and production of human therapeutic proteins through transgenic technology that enables animals to produce what is known as a recombinant form of a specified human protein in their milk. Using this technology, we developed the marketed product ATryn[®], a recombinant form of human antithrombin, a blood protein with anticoagulation and anti-inflammatory properties. We also are developing a portfolio of other recombinant blood proteins to treat a range of genetic and acquired blood deficiencies, including hemophilia and other blood coagulation disorders. These blood proteins, also known as plasma proteins, are difficult to produce in other manufacturing systems, and some are currently only available by extraction from human blood. We have also initiated the development of a portfolio of monoclonal antibodies, or MABs, for use as potential follow-on biologics targeted at several large market products. The level and speed of our proprietary products will be dependent upon our financial resources and new partnering arrangements as well as progress made in the legislative process related to follow-on biologics. Our highest priority in our development pipeline behind expanding the usage of ATryn[®] is recombinant human coagulation factor VIIa, referred to as rhFVIIa.

In the second quarter of 2009, the first sales in the U.S. of our first product, ATryn[®], were made by our partner Lundbeck, Inc. (formerly OVATION Pharmaceuticals). We had received United States Food and Drug Administration, or FDA, approval for ATryn[®] in February 2009 for use in patients with hereditary antithrombin deficiency, or HD, undergoing surgery or childbirth in the United States, making ATryn[®] the first transgenically derived therapeutic protein approved by the FDA. ATryn[®] is being marketed in the U.S. under our collaboration agreement with Lundbeck. The collaboration agreement includes the commercialization of ATryn[®] in the HD indication and the further development of ATryn[®] in the acquired antithrombin deficiency indications, or AD. We plan to develop ATryn[®] and several of our other recombinant proteins through strategic collaborations.

In September 2006, we entered into a collaboration agreement with LFB Biotechnologies, 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 has been established in a separate joint venture entity, and it includes programs to develop a recombinant form of human blood coagulation factor IX and 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[®].

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

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.

We have also used our transgenic technology in external programs to produce therapeutic products for our partners. For our external programs, we enter into licensing and development agreements with partners to use our transgenic technology to develop, produce, and purify recombinant forms of therapeutic proteins. Historically, we operated on a service contract basis, generally receiving fees for the development of the production platform and production and purification of the proteins. We currently have two active external programs, one with PharmAthene and another with JCOM. Most of our third quarter 2008 service revenues were derived from our external programs.

We have operated at a net loss since our inception in 1993, and we used \$20.3 million of net cash in our operating cash flows during the first nine months of 2009. Our recurring losses from operations and our limited funds raise substantial doubt about our ability to continue as a going concern. 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 September 27, 2009, as well as the \$10 million in cash we received from the closing of the LFB financing transactions in November 2009 and potential cash receipts from existing programs, we anticipate that we have the ability to continue our operations into the middle of the first quarter of 2010. We expect that future sources of funding will include some combination of sales of equity or debt securities and new or expanded collaboration arrangements. If no funds are available, we would have to sell or liquidate the business. If adequate funds do not become available, we may be required to take further steps 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 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 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.

This discussion and analysis of our financial condition should be read in connection with our consolidated financial statements herein and the accompanying notes thereto, and, our Annual Report on Form 10-K for the fiscal year ended December 28, 2008 (our 2008 Form 10-K), in particular, the information set forth therein under Item 7 – “Management’s Discussion and Analysis of Financial Condition and Results of Operations”.

Results of Operations The key components to our losses are revenue, costs of revenue, and research and development expenses.

Fiscal three months ended September 27, 2009 and September 28, 2008

	(dollars in thousands)			
	September 27, 2009	September 28, 2008	\$ Change	% Change
Revenue	\$ 749	\$ 2,929	\$(2,180)	(74)%
Cost of revenue	\$ 554	\$ 1,123	\$ (569)	(51)%
Research and development expense	\$ 7,141	\$ 5,326	\$ 1,815	34%
Selling, general and administrative	\$ 2,600	\$ 2,311	\$ 289	13%
Other income (expense)	\$ 4,636	\$ (229)	\$ 4,865	2,124%

Revenue. Our revenue for the 2009 quarter was primarily derived from Lundbeck, of which approximately \$461,000 related to the sale of Atryn® product and approximately \$117,000 related to the amortization of milestone payments previously received. During the third quarter of 2008, we derived approximately \$2.7 million of our revenue from our external development programs, of which \$919,000 related to our work with PharmAthene and \$1.5 million related to the Merrimack program, which was completed during the third quarter of 2008. The work on the PharmAthene agreement was substantially completed during the fourth quarter of 2008. 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 it will vary from quarter to quarter.

Cost of revenue. The decrease in cost of revenue was primarily a result of a decrease of approximately \$729,000 on the PharmAthene program as a result of the program being substantially completed as of the end of 2008 partially offset by a \$300,000 increase on the ATryn® program related to sales of ATryn® to Lundbeck in the third quarter of 2009. 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. During 2008, LFB funded their portion and our portion, which was \$1.2 million, of the joint development expenses. The increase in research and development expense was primarily due to the absence of funding from LFB in 2009, a \$1.1 million increase in development costs for the joint development programs with LFB and \$307,000 of additional expense in 2009 (primarily internal resources) on our follow-on biologics programs, all of which was partially offset by a decrease of ATryn® related expenses of approximately \$1.6 million. 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 known as MM-093, for the treatment of autoimmune diseases. In consideration for the rights granted us under this agreement we transferred our shares of Merrimack preferred stock, which were issued to us in December 2003 and recorded on our balance sheet at a value of \$1.2 million, back to Merrimack. The value of the Merrimack preferred stock as recorded at the time of purchase was \$1.2 million, which in the third quarter of 2009 was recorded as a non-cash charge to in-process research and development expense.

Our third quarter 2009 research and development expense included \$2 million related to the ATryn® program as compared to \$3.6 million in the third quarter of 2008. Details of ATryn® related expenses for the respective quarters are as follows:

	(dollars in millions)	
	Fiscal three months ended	
	September 27, 2009	September 28, 2008
ATryn® manufacturing expenses	\$ 1.4	\$ 2.1
EMEA regulatory process expenses	0.3	0.3
U.S. clinical trial and regulatory expenses	0.3	1.2
Total	\$ 2.0	\$ 3.6

Manufacturing costs include costs of producing clinical material in excess of the maximum transfer price to Lundbeck, as well as process development and validation costs for the scale up of the ATryn® manufacturing process.

During the third quarter of 2009, we incurred approximately \$2.3 million of expense on our joint collaboration programs with LFB (FVIIa, FIX, CD20 and AAT). During the third quarter of 2008, we incurred approximately \$1.2 million of expense in support of these same programs in our LFB collaboration, which were charged to the LFB/GTC LLC, in accordance with the terms of the joint venture agreement. During the third quarter of 2008 we were reimbursed approximately \$1.5 million from the LLC, of which approximately \$300,000 was recorded as a payable to the LLC at the end of the third quarter 2008.

We also incurred approximately \$815,000 of expense on other research and development programs during the third quarter of 2009 as compared to \$1.4 million in the third quarter of 2008. This decrease is primarily due to lower expenses incurred on the CD137 program. We cannot estimate the costs to complete our ongoing research and development programs due to significant variability in clinical trial costs and the regulatory approval process.

Selling, general and administrative expense. The increase in SG&A expenses was primarily a result of increased costs related to the LEO arbitration of approximately \$463,000, partially offset by a reduction in other legal costs of approximately \$159,000.

Other income (expense). The increase in other income was primarily due to 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 9).

Fiscal nine months ended September 27, 2009 and September 28, 2008

	(dollars in thousands)			
	September 27, 2009	September 28, 2008	\$ Change	% Change
Revenue	\$ 1,602	\$ 15,613	\$(14,011)	(90)%
Cost of revenue	\$ 1,190	\$ 8,042	\$ (6,852)	(85)%
Research and development expense	\$ 20,914	\$ 15,722	\$ 5,192	33%

	(dollars in thousands)			
	September 27, 2009	September 28, 2008	\$ Change	% Change
Selling, general and administrative	\$ 8,245	\$ 7,702	\$ 543	7%
Other income (expense)	\$ 2,726	\$ (643)	\$ 3,369	524%

Revenue. During the first nine months of 2009, our revenue was primarily derived from Lundbeck, of which approximately \$477,000 related to the sale of ATryn® product and approximately \$243,000 related to the amortization of milestone payments previously received. We also derived approximately \$377,000 of revenue from our external development program with PharmAthene during the first nine months of 2009. During the first nine months of 2008, we derived approximately \$9.6 million of our revenue from our external development programs with Merrimack and PharmAthene, of which \$5.8 million related to PharmAthene, and approximately \$4.2 million from the sale of ATryn® product to LEO Pharma for clinical development and commercial use. We also derived \$550,000 of our revenue related to our exclusive license to Pharming for recombinant fibrinogen. The work on the Merrimack program was completed in the third quarter of 2008 and 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 recently awarded to us from PharmAthene. 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 it will vary from quarter to quarter.

Cost of revenue. The decrease in cost of revenue is primarily a result of a decrease of approximately \$3.8 million on the ATryn® program related to sales of ATryn® for clinical development by LEO in the first nine months of 2008, as well as a decrease of approximately \$2.4 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.

Research and development expense. The increase in research and development expense was primarily due to our bearing our share of the expense of the LFB collaboration programs in 2009 compared to the \$4.1 million assumed by LFB when it fully funded the joint collaboration programs in 2008. There were also \$2.4 million of additional expense in 2009 (primarily internal resources) on our follow-on biologics programs, which were partially offset by a decrease of ATryn® related expenses of approximately \$3.1 million. 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 known as MM-093, for the treatment of autoimmune diseases. In consideration for the rights granted us under this agreement we transferred our shares of Merrimack preferred stock, which were issued to us in December 2003 and recorded on our balance sheet at a value of \$1.2 million, back to Merrimack. The cost of the Merrimack preferred stock as recorded at the time of purchase was \$1.2 million, which in the third quarter of 2009 was recorded as a non-cash charge to in-process research and development expense.

The research and development expense for the first nine months of 2009 included \$9 million related to the ATryn® program as compared to \$12.1 million in the first nine months of 2008. Details of ATryn® related expenses for the respective quarters are as follows:

	(dollars in millions)	
	Fiscal nine months ended	
	September 27, 2009	September 28, 2008
ATryn® manufacturing expenses	\$ 5.8	\$ 6.9
EMEA regulatory process expenses	0.8	0.8
U.S. clinical trial and regulatory expenses	2.4	4.4
Total	\$ 9.0	\$ 12.1

Manufacturing costs include costs of producing clinical material in excess of the maximum transfer price to Lundbeck, as well as process development and validation costs for the scale up of the ATryn® manufacturing process.

During the first nine months of 2009, we incurred approximately \$4.7 million of expense on our joint collaboration programs with LFB (FVIIa, FIX, CD20 and AAT). During the first nine months of 2008, we incurred approximately \$4.3 million of expense in support of the programs in our LFB collaboration (FVIIa, FIX, CD20 and AAT). During the first nine months of 2008 we were reimbursed approximately \$4.5 million of which approximately \$200,000 was recorded as a payable to the LLC at the end of the third quarter 2008.

We also incurred approximately \$2.5 million of expense on other research and development programs during the first nine months of 2009 as compared to \$2.9 million in the first nine months of 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.

Selling, general and administrative expense. The increase in SG&A expenses was primarily a result of increased costs related to the LEO arbitration of approximately \$1.4 million, partially offset by a reduction in other legal costs of approximately \$771,000.

Other income (expense). The increase in other income was primarily due to 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 9).

Liquidity and Capital Resources

Our objective is to finance our business appropriately through a mix of equity financings, partnering payments, receipts from contracts for external programs, grant proceeds, debt financings and interest income earned on our cash and cash equivalents, until such time as product sales and royalties occur and we achieve positive cash flow from operations. We expect that our ability to raise future funds will be affected by our ability to enter into new or expanded partnering arrangements or contracts for external programs, the terms and progress of such arrangements or contracts for external programs and our internal programs, including the transfer of European marketing rights for ATryn® to a new partner, the market launch of ATryn® 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.

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 the third quarter of 2009 and since inception, and we had an accumulated deficit of \$328 million at September 27, 2009. We use our cash primarily to pay salaries, wages and benefits, facility and facility-related costs of farm, laboratory and office space and other outside direct costs such as manufacturing and clinical trial expenses. During the first nine months of 2009 we had a net decrease in cash and marketable securities of \$9.9 million, which reflects \$20.2 million used in operations and \$939,000 used to pay down debt, net of LFB funding of \$4 million. The primary sources of additional capital raised in 2008 and the first nine months of 2009 have been equity financings and debt financings. Based on our cash balance as of September 27, 2009, as well as the \$10 million in cash we received from the closing of the LFB financing transactions in November 2009 and potential cash receipts from existing programs, we anticipate that we have the ability to continue our operations into the middle of the first quarter of 2010. 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 financing. 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. 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 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 \$9.2 million from \$11 million for the first nine months of 2008 to \$20.2 million in the first nine months of 2009. The increase is primarily a result of an increase in our net loss of \$9.5 and the non-cash other income of approximately \$5.3 million related to redeemable convertible preferred stock, partially offset by milestone payments of \$4 million received from Lundbeck and \$750,000 received from JCOM in 2009.

Cash Flows from Investing Activities

There were no significant cash flows provided by or used in investing activities during the first nine months of 2009 as compared to \$7 million provided by investing activities in the first nine months 2008. The decrease is a result of the redemption of all of our short term investments during 2008.

Cash Flows from 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 (market price on the date of the agreement) and 7-year warrants, which were immediately exercisable, to purchase an aggregate of approximately 690,000 shares of our common stock at an exercise price of \$8.70 per share.

In June and July 2009, we received approximately \$12.3 million in proceeds, net of offering costs, from a convertible preferred stock financing with LFB, of which \$4 million was funded in June 2009 in the form of debt that converted into preferred stock in July.

Our \$17.3 million of outstanding long-term debt at September 27, 2009 includes approximately \$12.7 million owed to LFB (net of unamortized discount of approximately \$390,000) on the convertible note that we issued to LFB in December 2008, approximately \$679,000 owed to LFB (net of an unamortized discount of approximately \$164,000) on the convertible note that we issued to LFB in December 2006, approximately \$3.5 million owed to LFB on the term debt promissory note that we issued in June 2009 and approximately \$423,000 on the promissory note to EAPD. Of the \$17.3 million, approximately \$647,000 was classified as current, which reflects the amount due through September 2010 on the convertible note and the term debt promissory note with LFB that we issued in June 2009, the amount due to EAPD on the promissory note as well as for capital leases.

In November 2009, we received an aggregate of \$10 million in gross proceeds from a convertible preferred stock financing with LFB and a common stock financing with LFB.

COMMITMENTS AND CONTINGENCIES

Our commitments and contingencies are disclosed in Note 6 in the Notes to Consolidated Financial Statements included in Item 8 of our 2008 Form 10-K. We have reviewed the commitments and contingencies at September 27, 2009 and noted that there were no material changes or additions.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

There have been no material changes in our market risk since December 28, 2008. Our market risk disclosures are discussed in our 2008 Form 10-K under the heading Item 7A — “Quantitative and Qualitative Disclosures About Market Risk.”

ITEM 4. CONTROLS AND PROCEDURES.

(a) Evaluation 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, or the Exchange Act. 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 quarterly report.

(b) Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) identified in connection with the evaluation of our internal control that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

LEO Pharma informed us in September 2008 of their internal reprioritization and desire to transfer the ATryn® program to us or a third party and subsequently attempted to terminate its 2005 collaboration agreement. We do not believe that LEO had any basis for such termination, and we further believe that LEO is in breach of the agreement. We initiated International Chamber of Commerce (ICC) arbitration proceedings in the fourth quarter of 2008. We have 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. A hearing was held in the third quarter before the tribunal of the ICC but we cannot predict its likely outcome or, in the event of an unfavorable outcome, the potential consequences to us, including cost.

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 1A. RISK FACTORS.

Our Risk Factors, which contain a detailed discussion of certain risks that could materially and adversely affect our business, operating results or financial condition are discussed in our Annual Report on Form 10-K for the fiscal year ended December 28, 2008. Other than discussed below, there have been no material changes to the Risk Factors previously disclosed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 28, 2008. The remaining risk factors included in our Annual Report on Form 10-K for the fiscal year ended December 28, 2008 remain unchanged and are incorporated herein by reference.

The following risk factor, which was included in our 2008 Annual Report on Form 10-K has been amended in its entirety to read as follows:

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

Our common stock is currently listed on the Nasdaq Capital Market, having moved from the Nasdaq Global Market in July 2008. Nasdaq has requirements that a company must meet in order to remain listed on the Nasdaq Capital Market. These requirements include maintaining a minimum closing bid price of \$1.00 per share, which we regained compliance with on June 11, 2009 as a result of a reverse stock split of our outstanding common stock that we effected on May 26, 2009. However, there is no guarantee that the increase in the per share price of our common stock above \$1.00 as a result of the reverse stock split will be able to be maintained over future periods. The market price of our common stock will continue to be based, in part, on our performance and other factors unrelated to the number of shares outstanding.

On June 18, 2009, we received notice from the Listing Qualifications Staff of the Nasdaq Stock Market a staff determination indicating that for ten consecutive trading days the aggregate market value of our common stock had fallen below \$35 million, the minimum level required for continued listing on the Nasdaq Capital Market, as specified by the Marketplace Rule 5550(b)(2). In accordance with Marketplace Rule 5810(c)(3)(C), we had until September 16, 2009 to regain compliance by demonstrating a market value of listed securities of at least \$35 million for at least ten consecutive trading days or for such longer period that Nasdaq may, in its discretion, require. On September 17, 2009, we received notice from the Staff indicating that unless we requested a hearing before the Nasdaq Listing Qualifications Panel, or the Panel, our securities would be subject to delisting from the Nasdaq Capital Market. We have requested and been granted a hearing before the Panel, which request defers any action to the June 2009 staff determination until the Panel renders a decision following the hearing. Our common stock will continue to be listed at least until conclusion of the Panel process. The Panel has the discretion to grant an extension not to exceed 180 days from the date of the delisting notice. However, there can be no assurance that any such extension will be granted or that following the hearing the Panel will grant our request for continued listing.

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

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

A special meeting of our shareholders was held on July 30, 2009. The following represents the results of voting on the proposal submitted to our shareholders:

- (1) To approve the issuance of shares of Series E-1 and Series E-2 10% convertible preferred stock, which are convertible into shares of our common stock, to LFB Biotechnologies, or LFB, pursuant to the securities purchase agreement dated as of June 18, 2009 between GTC and LFB:

<u>Total Vote "For"</u>	<u>Total Vote "Against"</u>	<u>Total Vote Abstaining</u>	<u>Total Broker Non-Votes</u>
5,409,410	339,192	72,036	0

This proposal received a majority of the shares represented in person or by proxy at the special meeting and entitled to vote on this proposal and, therefore, this proposal was approved.

ITEM 6. EXHIBITS.

<u>Exhibit</u>	<u>Description</u>
3.1.1	Restated Articles of Organization of the Company filed with the Secretary of the Commonwealth of Massachusetts on May 8, 2009, filed as Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 29, 2009 (File No. 0-21794) and incorporated herein by reference.
3.1.2	Articles of Amendment to the Restated Articles of Organization of the Company filed with the Secretary of the Commonwealth of Massachusetts on May 26, 2009, filed as Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 0-21794) on May 27, 2009 and incorporated herein by reference.
3.1.3	Articles of Amendment to the Restated Articles of Organization of GTC Biotherapeutics, Inc., filed with the Secretary of the Commonwealth of Massachusetts on July 30, 2009, filed as Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 0-21794) on July 31, 2009 and incorporated herein by reference.
3.2	By-Laws of the Company, as amended, filed as Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended July 4, 1999 (File No. 0-21794) and incorporated herein by reference.
4.1	Third Amendment to Shareholder Rights Agreement dated July 30, 2009 between GTC Biotherapeutics, Inc. and American Stock Transfer and Trust Company, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 0-21794) on July 31, 2009 and incorporated herein by reference.
10.1	Form of Nonstatutory Stock Option Award for Non-Employee Directors. Filed herewith. **
10.2	Form of Nonstatutory Stock Option Award. Filed herewith. **
10.3	Form of Incentive Stock Option Award. Filed herewith. **
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a).
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a).
32	Certifications pursuant to 18 U.S.C. Section 1350.

** Indicates a management contract or compensatory plan.

EXHIBIT INDEX

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32	Certifications pursuant to 18 U.S.C. Section 1350.

** Indicates a management contract or compensatory plan.

GTC BIOTHERAPEUTICS, INC. 2002 EQUITY INCENTIVE PLAN

Form of Nonstatutory Stock Option for Non-Employee Directors Terms And Conditions

1. **Plan Incorporated by Reference.** This Option is issued pursuant to the terms of the Plan and may be amended as provided in the Plan. Capitalized terms used and not otherwise defined in this Option Agreement have the meanings given to them in the Plan. This Option Agreement does not set forth all of the terms and conditions of the Plan, which are incorporated herein by reference. The Committee administers the Plan and its determinations regarding the operation and interpretation of the Plan are final and binding. Copies of the Plan may be obtained upon written request without charge from the Human Resources Department of the Company.
2. **Option Price.** The price to be paid for each share of Common Stock issued upon exercise of the whole or any part of this Option is the option price set forth on the face of this Option Agreement.
3. **Exercisability Schedule.** This Option may be exercised at any time and from time to time up to the number of shares and in accordance with the exercisability schedule set forth on the face of this Option Agreement, but only for the purchase of whole shares. This Option may not be exercised as to any shares after the Expiration Date. This Option may be terminated by the Company before the Expiration Date as permitted herein or by the Plan.
4. **Method of Exercise.** To exercise this Option, the Optionholder shall deliver written notice of exercise to the Company specifying the number of shares with respect to which the Option is being exercised accompanied by payment of the option price for such shares in cash, by certified check or in such other form, including shares of Common Stock of the Company valued at their Fair Market Value on the date of delivery or a payment commitment of a financial or brokerage institution, as the Committee may at the time of exercise approve. Following such notice and payment, the Company will deliver to the Optionholder a certificate representing the number of shares with respect to which the Option is being exercised.
5. **Rights as an Optionholder or Stockholder.** The Optionholder shall not earn the right to exercise or obtain the value of any portion of this Option except as provided in the exercisability schedule and until such time as all the conditions set forth herein and in the Plan that are required to be met in order to exercise this Option have been fully satisfied. No portion of this Option shall be deemed compensation for past services before it has become exercisable in accordance with the exercisability schedule. The Optionholder shall not have any rights in respect of shares as to which the Option shall not have been exercised and payment made as provided above.
6. **No Right to Employment.** Neither the adoption or operation of the Plan nor the grant of this Option confer upon the Optionholder any right to continued employment by the Company or any Affiliate nor shall they interfere with the right of the Company or Affiliate to terminate the
8. **Option Not Transferable.** This Option is not transferable by the Optionholder otherwise than by will or the laws of descent and distribution, and is exercisable, during the Optionholder's lifetime, only by the Optionholder. The naming of a Designated Beneficiary does not constitute a transfer.
9. **Exercise of Option After Cessation of Membership on the Board of Directors.** If the Optionholder's status as a non-employee director, is terminated for any reason other than by disability (within the meaning of section 22(e)(3) of the Code) or death, the Optionholder, during his lifetime, may exercise only the rights that were available to the Optionholder at the time of cessation of membership on the Board of Directors. If such status is terminated as a result of disability or death, such rights may be exercised (including by the Optionholder's Designated Beneficiary after death) only within twelve months from the date of termination. Notwithstanding the foregoing, no rights under this Option may be exercised after the Expiration Date.
10. **Compliance with Securities Laws.** It shall be a condition to the Optionholder's right to purchase shares of Common Stock hereunder that the Company may, in its discretion, require (a) that the shares of Common Stock reserved for issue upon the exercise of this Option shall have been duly listed, upon official notice of issuance, upon any national securities exchange or automated quotation system on which the Company's Common Stock may then be listed or quoted, (b) that either (i) a registration statement under the Securities Act of 1933, as amended, with respect to the shares shall be in effect, or (ii) in the opinion of counsel for the Company, the proposed purchase shall be exempt from registration under that Act and the Optionholder shall have made such undertakings and agreements with the Company as the Company may reasonably require, and (c) that such other steps, if any, as counsel for the Company shall consider necessary to comply with any law applicable to the issue of such shares by the Company shall have been taken by the Company or the Optionholder, or both. The certificates representing the shares purchased under this Option may contain such legends as counsel for the Company shall consider necessary to comply with any applicable law.
11. **Payment of Taxes.** The Optionholder shall pay to the Company, or make provision satisfactory to the Company for payment of, any taxes required by law to be withheld with respect to the exercise of this Option. In the Committee's discretion, such tax obligations may be paid in whole or in part in shares of Common Stock, including shares retained from the exercise of this Option, valued at their Fair Market Value on the date of delivery. The Committee may, in its discretion, require any other taxes imposed on the sale of the shares to be paid by the Optionholder. The Company and its Affiliates may, to the extent permitted by law, deduct any such tax obligations from any payment of any kind otherwise due to the Optionholder.

Optionholder at any time or otherwise to change the terms of the Optionholder's employment.

7. Recapitalization, Mergers, Etc. As provided in the Plan, in the event of a merger, recapitalization or other corporate transaction involving the Company, the Committee may in its discretion take certain actions affecting the Option and the Optionholder's rights hereunder, including without limitation adjusting the number and kind of securities subject to the Option and the option price, providing for another entity to assume the Option, providing for a cash payment in lieu of issuing shares, and terminating the Option.

GTC BIOTHERAPEUTICS, INC. 2002 EQUITY INCENTIVE PLAN

Form of Nonstatutory Stock Option Terms And Conditions

1. **Plan Incorporated by Reference.** This Option is issued pursuant to the terms of the Plan and may be amended as provided in the Plan. Capitalized terms used and not otherwise defined in this Option Agreement have the meanings given to them in the Plan. This Option Agreement does not set forth all of the terms and conditions of the Plan, which are incorporated herein by reference. The Committee administers the Plan and its determinations regarding the operation and interpretation of the Plan are final and binding. Copies of the Plan may be obtained upon written request without charge from the Human Resources Department of the Company.
2. **Option Price.** The price to be paid for each share of Common Stock issued upon exercise of the whole or any part of this Option is the option price set forth on the face of this Option Agreement.
3. **Exercisability Schedule.** This Option may be exercised at any time and from time to time up to the number of shares and in accordance with the exercisability schedule set forth on the face of this Option Agreement, but only for the purchase of whole shares. This Option may not be exercised as to any shares after the Expiration Date. This Option may be terminated by the Company before the Expiration Date as permitted herein or by the Plan.
4. **Method of Exercise.** To exercise this Option, the Optionholder shall deliver written notice of exercise to the Company specifying the number of shares with respect to which the Option is being exercised accompanied by payment of the option price for such shares in cash, by certified check or in such other form, including shares of Common Stock of the Company valued at their Fair Market Value on the date of delivery or a payment commitment of a financial or brokerage institution, as the Committee may at the time of exercise approve. Following such notice and payment, the Company will deliver to the Optionholder a certificate representing the number of shares with respect to which the Option is being exercised.
5. **Rights as an Optionholder or Stockholder.** The Optionholder shall not earn the right to exercise or obtain the value of any portion of this Option except as provided in the exercisability schedule and until such time as all the conditions set forth herein and in the Plan that are required to be met in order to exercise this Option have been fully satisfied. No portion of this Option shall be deemed compensation for past services before it has become exercisable in accordance with the exercisability schedule. The Optionholder shall not have any rights in respect of shares as to which the Option shall not have been exercised and payment made as provided above.
6. **No Right to Employment.** Neither the adoption or operation of the Plan nor the grant of this Option confer upon the Optionholder any right to continued employment by the
8. **Option Not Transferable.** This Option is not transferable by the Optionholder otherwise than by will or the laws of descent and distribution, and is exercisable, during the Optionholder's lifetime, only by the Optionholder. The naming of a Designated Beneficiary does not constitute a transfer.
9. **Exercise of Option After Termination of Employment or Engagement.** If the Optionholder's status as an employee or consultant of (a) the Company, (b) an Affiliate, or (c) a corporation (or parent or subsidiary corporation of such corporation) issuing or assuming a stock option in a transaction to which section 424(a) of the Code applies, is terminated for any reason other than by disability (within the meaning of section 22(e)(3) of the Code) or death, the Optionholder may exercise only the rights that were available to the Optionholder at the time of such termination and only within three months from the date of termination. If such status is terminated as a result of disability or death, such rights may be exercised (including by the Optionholder's Designated Beneficiary after death) only within twelve months from the date of termination. Notwithstanding the foregoing, no rights under this Option may be exercised after the Expiration Date.
10. **Compliance with Securities Laws.** It shall be a condition to the Optionholder's right to purchase shares of Common Stock hereunder that the Company may, in its discretion, require (a) that the shares of Common Stock reserved for issue upon the exercise of this Option shall have been duly listed, upon official notice of issuance, upon any national securities exchange or automated quotation system on which the Company's Common Stock may then be listed or quoted, (b) that either (i) a registration statement under the Securities Act of 1933, as amended, with respect to the shares shall be in effect, or (ii) in the opinion of counsel for the Company, the proposed purchase shall be exempt from registration under that Act and the Optionholder shall have made such undertakings and agreements with the Company as the Company may reasonably require, and (c) that such other steps, if any, as counsel for the Company shall consider necessary to comply with any law applicable to the issue of such shares by the Company shall have been taken by the Company or the Optionholder, or both. The certificates representing the shares purchased under this Option may contain such legends as counsel for the Company shall consider necessary to comply with any applicable law.
11. **Payment of Taxes.** The Optionholder shall pay to the Company, or make provision satisfactory to the Company for payment of, any taxes required by law to be withheld with respect to the exercise of this Option. In the Committee's discretion, such tax obligations may be paid in whole or in part in shares of Common Stock, including shares retained from the exercise of this Option, valued at their Fair Market Value on the date of delivery. The Committee may, in its

Company or any Affiliate nor shall they interfere with the right of the Company or Affiliate to terminate the Optionholder at any time or otherwise to change the terms of the Optionholder's employment.

7. Recapitalization, Mergers, Etc. As provided in the Plan, in the event of a merger, recapitalization or other corporate transaction involving the Company, the Committee may in its discretion take certain actions affecting the Option and the Optionholder's rights hereunder, including without limitation adjusting the number and kind of securities subject to the Option and the option price, providing for another entity to assume the Option, providing for a cash payment in lieu of issuing shares, and terminating the Option.

discretion, require any other taxes imposed on the sale of the shares to be paid by the Optionholder. The Company and its Affiliates may, to the extent permitted by law, deduct any such tax obligations from any payment of any kind otherwise due to the Optionholder.

GTC BIOTHERAPEUTICS, INC. 2002 EQUITY INCENTIVE PLAN

Form of Incentive Stock Option Terms And Conditions

1. **Plan Incorporated by Reference.** This Option is issued pursuant to the terms of the Plan and may be amended as provided in the Plan. Capitalized terms used and not otherwise defined in this Option Agreement have the meanings given to them in the Plan. This Option Agreement does not set forth all of the terms and conditions of the Plan, which are incorporated herein by reference. The Committee administers the Plan and its determinations regarding the operation and interpretation of the Plan are final and binding. Copies of the Plan may be obtained upon written request without charge from the Human Resources Department of the Company.

2. **Option Price.** The price to be paid for each share of Common Stock issued upon exercise of the whole or any part of this Option is the option price set forth on the face of this Option Agreement.

3. **Exercisability Schedule.** This Option may be exercised at any time and from time to time up to the number of shares and in accordance with the exercisability schedule set forth on the face of this Option Agreement, but only for the purchase of whole shares. This Option may not be exercised as to any shares after the Expiration Date. This Option may be terminated by the Company before the Expiration Date as permitted herein or by the Plan.

4. **Method of Exercise.** To exercise this Option, the Optionholder shall deliver written notice of exercise to the Company specifying the number of shares with respect to which the Option is being exercised accompanied by payment of the option price for such shares in cash, by certified check or in such other form, including shares of Common Stock of the Company valued at their Fair Market Value on the date of delivery or a payment commitment of a financial or brokerage institution, as the Committee may at the time of exercise approve. Following such notice and payment, the Company will deliver to the Optionholder a certificate representing the number of shares with respect to which the Option is being exercised.

5. **Rights as an Optionholder or Stockholder.** The Optionholder shall not earn the right to exercise or obtain the value of any portion of this Option except as provided in the exercisability schedule and until such time as all the conditions set forth herein and in the Plan that are required to be met in order to exercise this Option have been fully satisfied. No portion of this Option shall be deemed compensation for past services before it has become exercisable in accordance with the exercisability schedule. The Optionholder shall not have any rights in respect of shares as to which the Option shall not have been exercised and payment made as provided above.

6. **No Right to Employment.** Neither the adoption or operation of the Plan nor the grant of this Option confer upon the Optionholder any right to continued employment by the

8. **Option Not Transferable.** This Option is not transferable by the Optionholder otherwise than by will or the laws of descent and distribution, and is exercisable, during the Optionholder's lifetime, only by the Optionholder. The naming of a Designated Beneficiary does not constitute a transfer.

9. **Exercise of Option After Termination of Employment.** If the Optionholder's employment with (a) the Company, (b) an Affiliate, or (c) a corporation (or parent or subsidiary corporation of such corporation) issuing or assuming a stock option in a transaction to which section 424(a) of the Code applies, is terminated for any reason other than by disability (within the meaning of section 22(e)(3) of the Code) or death, the Optionholder may exercise only the rights that were exercisable by the Optionholder at the time of such termination and only within three months from the date of termination. If Optionholder's employment is terminated as a result of disability or death, such rights may be exercised (including by the Optionholder's Designated Beneficiary after death) only within twelve months from the date of termination. Notwithstanding the foregoing, no rights under this Option may be exercised after the Expiration Date.

10. **Compliance with Securities Laws.** It shall be a condition to the Optionholder's right to purchase shares of Common Stock hereunder that the Company may, in its discretion, require (a) that the shares of Common Stock reserved for issue upon the exercise of this Option shall have been duly listed, upon official notice of issuance, upon any national securities exchange or automated quotation system on which the Company's Common Stock may then be listed or quoted, (b) that either (i) a registration statement under the Securities Act of 1933, as amended, with respect to the shares shall be in effect, or (ii) in the opinion of counsel for the Company, the proposed purchase shall be exempt from registration under that Act and the Optionholder shall have made such undertakings and agreements with the Company as the Company may reasonably require, and (c) that such other steps, if any, as counsel for the Company shall consider necessary to comply with any law applicable to the issue of such shares by the Company shall have been taken by the Company or the Optionholder, or both. The certificates representing the shares purchased under this Option may contain such legends as counsel for the Company shall consider necessary to comply with any applicable law.

11. **Optionholder's Tax Treatment.** This Option is intended to be treated as an incentive stock option under section 422 of the Code. However, incentive stock option treatment requires compliance with a number of factors, and the Company gives no assurance that this Option will, in fact, be treated as an incentive stock option.

12. **Notice of Sale of Shares Required.** The Optionholder agrees to notify the Company in writing within 30 days of the sale or other disposition of any shares purchased upon

Company or any Affiliate nor shall they interfere with the right of the Company or Affiliate to terminate the Optionholder at any time or otherwise to change the terms of the Optionholder's employment.

7. Recapitalization, Mergers, Etc. As provided in the Plan, in the event of a merger, recapitalization or other corporate transaction involving the Company, the Committee may in its discretion take certain actions affecting the Option and the Optionholder's rights hereunder, including without limitation adjusting the number and kind of securities subject to the Option and the option price, providing for another entity to assume the Option, providing for a cash payment in lieu of issuing shares, and terminating the Option.

exercise of this Option if such sale or other disposition occurs within two years of the date of the grant of this Option or within one year after such purchase.

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Geoffrey F. Cox, certify that:

1. I have reviewed this quarterly report on Form 10-Q of GTC Biotherapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2009

/s/ Geoffrey F. Cox

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

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John B. Green, certify that:

1. I have reviewed this quarterly report on Form 10-Q of GTC Biotherapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2009

/s/ John B. Green

John B. Green
Senior Vice President,
Chief Financial Officer and Treasurer

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of GTC Biotherapeutics, Inc. (the "Company") for the quarterly period ended September 27, 2009, as filed with the Securities and Exchange Commission on the date hereof, (the "Report"), each of the undersigned hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 6, 2009

/s/ Geoffrey F. Cox

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

Date: November 6, 2009

/s/ John B. Green

John B. Green
Senior Vice President,
Chief Financial Officer and Treasurer