



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

**FORM 10-Q**

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

For the quarterly period ended October 3, 2004

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)

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

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

Indicate by check 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 whether registrant is an accelerated filer (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, 2004
Common Stock, \$0.01 par value	38,793,559



### NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements, including statements regarding GTC's collaborations and the Company's future cash requirements. The words or phrases "will likely result," "are expected to," "will continue," "is anticipated," "estimate," "project," "believes," "expects", or similar expressions are intended to identify "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934 and Section 27A of the Securities Act of 1933, as amended, as enacted by the Private Securities Litigation Reform Act of 1995. Statements that are not historical facts are based on current expectations, beliefs, assumptions, estimates, forecasts and projections for GTC's business and the industry and markets related to its 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 the Company's future cash requirements include, without limitation, regulatory review of the Company's ATryn<sup>®</sup> product, the ability of the Company to enter into transgenic research and development collaborations in the future and the terms of such collaborations, the results of research and development and preclinical and clinical testing of the Company's internal product, competitive and technological advances and regulatory requirements.

For a further description of these and other risks and uncertainties, the Company encourages you to read carefully the portion of the Annual Report on Form 10-K for the fiscal year ended December 28, 2003 of the Company under the caption "Factors Affecting Future Operations and Results" in Item 7 — Management's Discussion and Analysis of Financial Condition and Results of Operations filed with the Securities and Exchange Commission on March 8, 2004.

The forward-looking statements contained in this Quarterly Report on Form 10-Q speak only as of the date of this report. GTC expressly disclaims 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 its 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.



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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)

	October 3, 2004	December 28, 2003
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 9,222	\$ 6,733
Marketable securities	20,583	24,358
Accounts receivable and unbilled contract revenue	424	1,613
Deferred contract costs	992	—
Other current assets	1,750	1,777
<b>Total current assets</b>	<b>32,971</b>	<b>34,481</b>
Net property, plant and equipment	21,269	22,600
Net intangible assets	10,318	11,094
Inventory	1,393	1,574
Other assets	1,362	1,323
Restricted cash	450	—
<b>Total assets</b>	<b>\$ 67,763</b>	<b>\$ 71,072</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,837	\$ 2,340
Accrued liabilities	2,995	3,524
Accrued liabilities - Genzyme	4,133	1,924
Deferred contract revenue	2,066	323
Note payable – Genzyme	2,386	—
Current portion of long-term debt and capital leases	2,442	2,218
<b>Total current liabilities</b>	<b>16,859</b>	<b>10,329</b>
Note payable, net of current portion – Genzyme	2,387	4,773
Long-term debt and capital leases, net of current portion	7,372	7,769
Deferred lease obligation	27	40
<b>Total liabilities</b>	<b>26,645</b>	<b>22,911</b>
Shareholders' equity:		
Preferred stock, \$.01 par value; 5,000,000 shares authorized; no shares were issued and outstanding	—	—
Common stock, \$.01 par value; 100,000,000 shares authorized; 41,575,826 and 34,749,473 shares issued and 38,755,826 and 31,929,473 shares outstanding at October 3, 2004 and December 28, 2003, respectively	415	347
Capital in excess of par value – common stock	222,533	207,535
Treasury stock, at cost, 2,820,000 shares	(9,545)	(9,545)
Accumulated deficit	(172,164)	(150,179)
Accumulated other comprehensive income (loss)	(121)	3
<b>Total shareholders' equity</b>	<b>41,118</b>	<b>48,161</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 67,763</b>	<b>\$ 71,072</b>

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



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

	Three months ended		Nine months ended	
	October 3, 2004	September 28, 2003	October 3, 2004	September 28, 2003
<b>Revenues</b>				
Revenue	\$ 920	\$ 2,164	\$ 3,383	\$ 8,019
Revenue from related party (Genzyme)	4	—	46	—
	<u>924</u>	<u>2,164</u>	<u>3,429</u>	<u>8,019</u>
<b>Costs of revenue and operating expenses:</b>				
Cost of revenue	1,182	2,369	3,745	9,238
Research and development	4,561	4,804	13,626	12,089
Selling, general and administrative	2,194	2,893	7,812	8,233
	<u>7,937</u>	<u>10,066</u>	<u>25,183</u>	<u>29,560</u>
Operating loss	(7,013)	(7,902)	(21,754)	(21,541)
<b>Other income (expense):</b>				
Interest income	111	344	219	851
Interest expense	(271)	(129)	(745)	(398)
Other income	23	81	295	81
	<u>23</u>	<u>81</u>	<u>295</u>	<u>81</u>
Net loss	\$ (7,150)	\$ (7,606)	\$ (21,985)	\$ (21,007)
Net loss per common share (basic and diluted)	\$ (0.18)	\$ (0.25)	\$ (0.60)	\$ (0.73)
Weighted average number of common shares outstanding (basic and diluted)	<u>38,751</u>	<u>30,480</u>	<u>36,894</u>	<u>28,726</u>
<b>Comprehensive loss:</b>				
Net loss	\$ (7,150)	\$ (7,606)	\$ (21,985)	\$ (21,007)
<b>Other comprehensive income (loss):</b>				
Unrealized change in holding gain (loss) on securities available for sale	49	75	(124)	(18)
	<u>49</u>	<u>75</u>	<u>(124)</u>	<u>(18)</u>
Total other comprehensive income (loss)	49	75	(124)	(18)
Comprehensive loss	\$ (7,101)	\$ (7,531)	\$ (22,109)	\$ (21,025)

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



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

	Nine months ended	
	October 3, 2004	September 28, 2003
<b>Cash flows from operating activities:</b>		
Net loss	\$(21,985)	\$ (21,007)
Adjustments to reconcile net loss from continuing operations to net cash used in operating activities:		
Depreciation and amortization	3,041	2,514
Stock based compensation	475	—
Amortization of premium (discount) on marketable securities	1,220	(113)
Non-cash common stock issuance to GTC savings and retirement plan	313	172
Inventory write-off	181	—
Changes in assets and liabilities:		
Accounts receivable and unbilled contract revenue	1,189	(1,892)
Inventory	—	(2,038)
Deferred contract costs	(992)	—
Other assets and liabilities	(25)	(121)
Accounts payable	497	2
Accrued liabilities	(529)	(755)
Accrued liabilities – Genzyme	2,209	(1,625)
Deferred contract revenue	1,743	(159)
Net cash used in operating activities	<u>(12,663)</u>	<u>(25,022)</u>
<b>Cash flows from investing activities:</b>		
Purchase of property, plant and equipment	(1,160)	(2,965)
Sale of property, plant and equipment	226	—
Purchase of marketable securities	(14,804)	(21,968)
Redemption of marketable securities	17,235	25,880
Restricted cash	(450)	—
Net cash provided by investing activities	<u>1,047</u>	<u>947</u>
<b>Cash flows from financing activities:</b>		
Proceeds from the issuance of common stock, net of offering costs	13,868	8,541
Net proceeds from long-term debt	10,386	1,901
Repayment of long-term debt	(10,395)	(1,241)
Repayment of principal on capital leases	(164)	(228)
Net proceeds from employee stock purchase plan	291	475
Net proceeds from the exercise of stock options	119	2
Net cash provided by financing activities	<u>14,105</u>	<u>9,450</u>
Net increase (decrease) in cash and cash equivalents	2,489	(14,625)
Cash and cash equivalents at beginning of period	6,733	26,911
Cash and cash equivalents at end of period	<u>\$ 9,222</u>	<u>\$ 12,286</u>

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., referred to as GTC or the Company, for the fiscal year ended December 28, 2003 (2003 Form 10-K), which was filed with the Securities and Exchange Commission (SEC) on March 8, 2004 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 SEC rules and regulations.

The financial statements for the nine months ended October 3, 2004 and September 28, 2003, are unaudited but include, in the Company's opinion, all adjustments necessary for a fair presentation of the results for the periods presented. The Company recorded an adjustment of \$155,000 to reduce interest income during the first quarter of 2004, which related to activity during 2003.

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, the uncertainties of clinical trials and regulatory requirements for approval of therapeutic compounds, the need for additional capital, competitive new technologies, dependence on key personnel, protection of proprietary technology, and compliance with the United States Food and Drug Administration (FDA) and other government regulations. The Company's consolidated financial statements have been presented on the basis that it is a going concern, which contemplates the continuity of business, realization of assets and the satisfaction of liabilities in the ordinary course of business. The Company has incurred losses from operations since inception and has an accumulated deficit of \$172.2 million at October 3, 2004. Based on the current rate of cash utilization, management believes that existing cash resources and potential future cash payments from new partnering and licensing programs will be sufficient to fund operations through 2005. The primary sources of additional capital raised in 2002, 2003 and 2004 have been equity and debt, and management expects that future sources of funds may include new or expanded partnering arrangements, or the sale of equity or debt-related instruments. However, there can be no assurance that the Company will be able to raise needed capital on terms that are acceptable to the Company, or at all. If the Company does not obtain an adequate amount of additional financing, the Company will be required to curtail operating expenses or take other steps that could adversely impact the Company's ability to grow and commercialize its products.

2. Accounting Policies:

The accounting policies underlying the quarterly financial statements are those set forth in Note 2 of the financial statements included in the 2003 Form 10-K. There have been no material changes in the accounting policies that are set forth in Note 2 of the financial statements included in the Company's 2003 Form 10-K.

**Accounting for Employee Equity Plans**

In December 2002, the Financial Accounting Standards Board issued FASB No. 148 (SFAS 148), Accounting for Stock Based Compensation – Transition and Disclosure. SFAS 148, which was effective for fiscal years ending after December 15, 2002, amends Statement of Accounting Standards No. 123 (SFAS 123), Accounting for Stock Based Compensation and provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based compensation. In addition, SFAS 148 amends the disclosure requirements of SFAS 123 regardless of the accounting method used to account for stock-based compensation. The Company continues to apply APB Opinion 25 and related interpretations in accounting for its employee equity plans. Accordingly, no compensation cost has been recognized for options granted to employees with exercise prices equal to or greater than the fair market value at the grant date. The Company applies the disclosure only provisions of SFAS 148. If the compensation cost for the Company's stock-based compensation plans to employees had been determined based on the fair value at the grant dates as calculated in accordance with SFAS 123, the Company's net loss and loss per share for the three and nine months ended October 3, 2004 and September 28, 2003 would have been increased to the pro forma amounts indicated below:

	Three Months Ended		Nine Months Ended	
	October 3, 2004	September 28, 2003	October 3, 2004	September 28, 2003
	(dollars in thousands except per share amounts)			
Net loss reported	\$ (7,150)	\$ (7,606)	\$ (21,985)	\$ (21,007)
Add: *	—	—	35	—
Deduct: **	(417)	(547)	(1,805)	(1,904)
Pro Forma net loss	\$ (7,567)	\$ (8,153)	\$ (23,755)	\$ (22,911)
Earnings per share:				



Basic – as reported (basic and diluted)	\$ (0.18)	\$ (0.25)	\$ (0.60)	\$ (0.73)
Basic – Pro Forma (basic and diluted)	\$ (0.20)	\$ (0.27)	\$ (0.64)	\$ (0.80)

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

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



The fair value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions: an expected life of five years, expected volatility of 100% for the third quarters of 2004 and 2003 and the nine months ended October 3, 2004 and September 28, 2003, a dividend yield of 0% and a risk-free interest rate of 3.11% for the third quarter of 2004 and the nine months ended October 3, 2004, and 2.96% for the third quarter of 2003 and the nine months ended September 28, 2003. The average fair value per share of those options granted during the third quarters of 2004 and 2003 was \$1.34 and \$2.73, respectively. The average fair value per share of those options granted during the nine months ended October 3, 2004 and September 28, 2003 was \$2.66 and \$1.21, respectively.

The fair value of the employees' purchase rights was estimated using the Black-Scholes model with the following weighted-average assumptions: a dividend yield of 0%, expected volatility of 100% for the third quarters of 2004 and 2003 and the nine months ended October 3, 2004 and September 28, 2003, an expected life of three months for the third quarter of 2004 and 2003 and the nine months ended October 3, 2004 and September 28, 2003 and a risk-free interest rate of 1.39% for the third quarter of 2004 and the nine months ended 2004 and 0.84% for the third quarter of 2003 and the nine months ended 2003. The average fair value of those purchase rights granted during the third quarters of 2004 and 2003 was \$0.58 and \$1.12, respectively. The average fair value of those purchase rights granted during the nine months ended October 3, 2004 and September 28, 2003 was \$0.81 and \$0.70, respectively.

### **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 warrants and stock options, totaled 5.4 million and 5.5 million at October 3, 2004 and September 28, 2003, respectively. Since the Company was in a net loss position at October 3, 2004 and September 28, 2003, these potential common shares were not used to compute diluted loss per share, as the effect would have been antidilutive.

### 3. Inventory:

The Company carries inventory at the lower of cost or market using the first-in, first-out method. The Company capitalizes inventory produced for commercial sale, and the entire inventory on hand at October 3, 2004 and December 28, 2003 was finished goods related to ATryn<sup>®</sup>, which has not yet been approved for commercial sale. The Company expects that all of the capitalized inventory will be sold commercially in Europe, provided the Company receives marketing approval. If, at any time, the Company believes that marketing approval of ATryn<sup>®</sup> is no longer probable, the Company will charge the inventory to expense. It is possible that the Company could use some of the capitalized inventory for additional clinical trials and, if so, the Company would expense the inventory when it was designated for use in such a clinical trial. The Company determines cost using the first-in, first-out method. The Company analyzes its inventory levels quarterly and will write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value, and inventory in excess of expected requirements. Expired inventory will be disposed of and the related costs will be written off. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required. In the third quarter of 2004, the Company recorded a charge of approximately \$173,000 to research and development to reflect usage of inventory for development purposes.



4. Accrued Liabilities:

Accrued liabilities include the following:

	At October 3, 2004	At December 28, 2003
	(in thousands)	
Accrued payroll and benefits	\$ 1,537	\$ 1,714
Accrued bonus	356	727
Other	1,102	1,083
<b>Total accrued liabilities</b>	<b>\$ 2,995</b>	<b>\$ 3,524</b>

In 2003, 22 employees were terminated as a result of a restructuring during the third quarter. In February 2004, the Company completed a further restructuring in which headcount was further reduced by approximately 20% from 159 to 127 full time equivalent employees. The accrued expenses for these restructurings are reflected in "other" in the table above. Approximately \$743,000 and \$200,000 of the costs associated with the 2004 restructuring are included in selling, general and administrative expense and research and development expenses, respectively. Payments related to the restructuring will be completed in the third quarter of 2005.

Following is a summary of accrued severance:

Balance at December 28, 2003	\$ 118,000
Q1 2004 Restructuring Accrual	943,000
Q1 2004 Payments	(437,000)
Balance at April 4, 2004	624,000
Q2 Payments	(233,000)
Balance at July 4, 2004	391,000
Q3 Payments	(143,000)
Balance at October 3, 2004	<b>\$ 248,000</b>

5. Intangible Assets:

The Company's intangible assets as of October 3, 2004 and December 28, 2003 consisted of:

	Amortization Life	October 3, 2004	December 28, 2003
		(in thousands)	
Marketing rights	15 years	\$ 11,210	\$ 11,210
Accumulated amortization—marketing rights		(3,051)	(2,491)
Net		8,159	8,719
Technology licenses	10 years to 15 years	3,379	3,379
Accumulated amortization — technology licenses		(1,220)	(1,004)
Net		2,159	2,375
<b>Total intangible assets, net</b>		<b>\$ 10,318</b>	<b>\$ 11,094</b>

Amortization expense was \$259,000 for the three months ended October 3, 2004 and September 28, 2003, and \$776,000 for the nine months ended October 3, 2004 and September 28, 2003.

The estimated aggregate amortization expense for the next five fiscal years is \$1,035,000 per year from 2004 through 2008 and \$5,966,000 for 2009 and thereafter.

6. Long-Term Debt:

In May 2004, the Company entered into a four year loan agreement with General Electric Capital Corporation, or GE Capital, in



the amount of \$10 million with a 9.94% interest rate and monthly payments of approximately \$253,000, which was used to refinance the Company's outstanding loan with Silicon Valley Bank, or SVB. Collateral for the loan includes all existing and future acquired assets of the Company, excluding intellectual property. As a result of this refinancing, the Company was no longer required to maintain \$18.2 million as unrestricted cash and marketable securities before it would be required to provide cash collateral for the loan. In connection with the refinancing, the Company was required to provide \$450,000 of cash collateral for its two outstanding stand-by letters of credit which appears as restricted cash on the balance sheet.

7. Financing:

In March 2004, the Company sold 6,395,298 shares of its common stock at \$2.35 per share in a registered direct offering to institutional investors. These shares were issued under the Company's shelf registration statement previously filed with the SEC. SG Cowen Securities, lead agent, and Rodman & Renshaw, LLC acted as placement agents for the offering and the Company paid a placement agent fee for their services. Proceeds to the Company, net of offering costs of approximately \$1.2 million, were approximately \$13.9 million.

8. Deferred Contract Costs:

The Company defers direct costs incurred under a binding purchase order in excess of revenues recognized to date if the costs incurred are recoverable and the pending contract is not a loss contract. The deferred costs include direct labor, direct materials and overhead. Deferred costs are limited to the non-refundable cash received under the contract plus amounts receivable for work performed or milestones achieved as of the balance sheet date. As of October 3, 2004, the Company had \$992,000 of capitalized costs which are classified as deferred contract costs on the balance sheet. The deferred contract costs are related to one pending contract for which ongoing work is being performed under terms and conditions that have not been finalized by a formal arrangement and for which the Company has not recognized any revenue.

9. Commitments and Contingencies:

On November 13, 2001, two employees of one of the Company's former subsidiaries filed an action in the Court of Common Pleas for Philadelphia County in Pennsylvania against the Company seeking damages, declaratory relief and certification of a class action relating primarily to their Company stock options. The claims arise as a result of the Company's sale of Primedica Corporation to Charles River Laboratories International, Inc. in February 2001, which the Company believes resulted in the termination of Primedica employees' status as employees of the Company or its affiliates and termination of their options. The plaintiffs contend that the sale of Primedica to Charles River did not constitute a termination of their employment with the Company or its affiliates for purposes of the Company's equity incentive plan and, therefore, that the Company breached its contractual obligations to them and other Primedica employees who had not exercised their stock options. The complaint demands damages in excess of \$5 million, plus interest. GTC has filed an answer denying all material allegations in the complaint, and is vigorously defending the case and objecting to certification of the claims as a class action. The Company believes that it has meritorious defenses and that, although the ultimate outcome of the matter cannot be predicted with certainty, the disposition of the matter should not have a material adverse effect on the financial position, results of operations or cash flows of the Company.

In July 2004, the Company entered into a three year lease agreement with GE Capital, which allows the Company to finance up to \$1.4 million of laboratory, office and computer equipment. During the third quarter of 2004, the Company utilized \$226,000 through a sale lease-back transaction which is being accounted for as an operating lease. The Company has \$1.2 million available to finance future equipment purchases.



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

### Business Overview

GTC Biotherapeutics, Inc., referred to as GTC or the Company, is a leader in the development, production, and commercialization of human therapeutic proteins in the milk of animals, principally goats and cattle. Using a technology known as transgenics, GTC inserts protein-specific DNA into the animal to enable it to produce that specific human protein in its milk. The protein is then purified from the milk under pharmaceutical manufacturing conditions to obtain the therapeutic product, which is typically administered by injection or infusion. A significant focus of the Company's product development pipeline is on commercializing recombinant forms of therapeutic human plasma proteins, including the lead program, ATryn<sup>®</sup>. GTC's technology enables recombinant forms of human plasma proteins that are otherwise difficult to express at practical levels in traditional production technologies.

GTC is dependent upon funding from collaborations and proceeds from equity financings and short and long-term debt to finance operations. The Company enters into licensing and development agreements with collaborative partners for the development, production and purification of therapeutic recombinant proteins produced transgenically. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon the achievement of certain milestones and, in some cases, royalties on future product sales.

This discussion and analysis of our financial condition should be read in connection with the Company's consolidated financial statements and accompanying notes thereto in the Company's 2003 Form 10-K, including without limitation the information set forth under the heading "Critical Accounting Policies and Estimates." The key value drivers for the Company remain substantially the same as those described in Management's Discussion and Analysis of Financial Condition and Results of Operations set forth in the Company's 2003 Form 10-K.

### Critical Accounting Policies and Estimates

The preparation of consolidated financial statements requires that the Company make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. The Company's accounting policies are summarized in Note 2 in the Notes to Consolidated Financial Statements included in Item 15 of the Company's 2003 Form 10-K. On an on-going basis, the Company evaluates its estimates, including those related to revenue recognition, investments, intangible and long-lived assets, income taxes, accrued expenses, financing operations, and contingencies and litigation. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes in the critical accounting policies that are set forth in Management's Discussion and Analysis of Financial Condition and Results of Operations included in Item 7 of the Company's 2003 Form 10-K.

### Results of Operations

As a Company that has not yet launched a commercial product, the key components to the Company's losses are costs of revenue, research and development expenses, and selling, general and administrative expenses. In September 2003, the Company implemented an initial restructuring plan followed by a further restructuring in February 2004. As part of these actions, headcount was reduced by approximately 30% and the Company also renegotiated certain research agreements with outside contractors. These restructurings resulted in a \$1.7 million reduction of expense in the third quarter of 2004 as compared with the same quarter of 2003, including reductions of \$600,000 in cost of revenue, \$331,000 in research and development and \$815,000 in selling, general and administrative expenses.



**Three months ended October 3, 2004 and September 28, 2003**

	October 3, 2004	September 28, 2003	\$ Change	% Change
	(\$ in thousands)			
Revenue	\$ 924	\$ 2,164	\$(1,240)	(57)%
Cost of revenue	\$ 1,182	\$ 2,369	\$(1,187)	(50)%
Research and development	\$ 4,561	\$ 4,804	\$ (243)	(5)%
Selling, general and administrative	\$ 2,194	\$ 2,893	\$ (699)	(24)%

*Revenue.* During the third quarter of 2004, \$848,000 of the revenue was derived from external development programs, primarily the programs with Merrimack Pharmaceuticals and Nexia Biotechnologies, and \$76,000 of the revenue was derived from the malaria program which is funded by the National Institute of Allergy and Infectious Diseases, or NIAID, a part of the National Institutes of Health, or NIH. The decrease in revenue derived from the malaria program is primarily a result of the timing of activities on the program. During the third quarter of 2003, \$1.6 million of the revenue was derived from external programs while \$565,000 of the revenue was derived from the malaria program. The 2003 revenue from external programs was primarily derived from the achievement of milestones in connection with the Merrimack program. Due to the nature and timing of the Company's milestone-based research and development revenue, the Company expects to see variation in reported revenue on a quarter to quarter basis. Deferred contract revenue, which is not included in the statement of operations but is reflected on the balance sheet, has increased by \$1 million in the quarter to \$2.1 million representing revenue deferred to future accounting periods on existing contracts in process.

*Cost of revenue.* The decrease in cost of revenue is primarily the result of a decrease in revenue due to the stage of development on external programs for which revenue is being recognized as well as the cost reductions from the restructurings. In addition, deferred contract costs, which are recorded on the balance sheet, have increased by \$505,000 in the quarter to \$992,000 representing work done on one pending contract for which no revenue has been recognized to date. The level of expenses on the Company's external programs will continue to fluctuate depending upon the stage of development of these individual contracts.

*Research and development expense.* Of the third quarter 2004 expenses, approximately \$3 million were incurred to support the regulatory filing for approval to market ATryn® in Europe to treat hereditary antithrombin deficiency, compared with \$2.2 million in the third quarter of 2003. The Company incurred expenses of \$500,000 in both the third quarters of 2004 and 2003 in the development of the recombinant human albumin, or rhA, program. Additionally, in the third quarters of 2004 and 2003, the Company incurred expenses of \$100,000 and \$700,000, respectively, in the development of the malaria program, and \$1 million and \$1.4 million, respectively, in the development of other internal programs. Research and development expenses going forward are expected to fluctuate based on a number of factors, including the timing and status of clinical development activities for ATryn® and other programs. During the fourth quarter of 2004, the Company plans to submit an amendment to its Investigational New Drug (IND) application to the Food and Drug Administration (FDA) to define the clinical protocol for ATryn® in the United States in the HD indication. The results of this clinical study, in conjunction with the data provided to the European Medicines Agency (EMA), are anticipated to form the basis for a filing for market approval in the U.S.

*Selling, General and Administrative Expense.* Expenses for the third quarter of 2004 decreased compared with the third quarter of 2003 due to lower headcount which resulted from the 2003 and 2004 restructurings.

**Nine months ended October 3, 2004 and September 28, 2003**

	(\$ in thousands)			
	October 3, 2004	September 28, 2003	\$ Change	% Change
Revenue	\$ 3,383	\$ 8,019	\$(4,636)	(58)%
Revenue from related party (Genzyme)	\$ 46	\$ —	\$ 46	—
Total Revenue	\$ 3,429	\$ 8,019	\$(4,590)	(57)%
Cost of revenue	\$ 3,745	\$ 9,238	\$(5,493)	(59)%
Research and development	\$ 13,626	\$ 12,089	\$ 1,537	13%
Selling, general and administrative	\$ 7,812	\$ 8,233	\$ (421)	(5)%
Interest income	\$ 219	\$ 851	\$ (632)	(74)%

*Revenue.* During the first nine months of 2004, \$2.5 million of the revenue was derived from external development programs, primarily the programs with Merrimack and Centocor, and \$868,000 of the revenue was derived from the malaria program which is funded by the NIAID. During the first nine months of 2003, \$5.6 million of the revenue was derived from external programs while \$2.4 million of the revenue was derived from the malaria program. The decrease in revenue derived from the malaria program is primarily a result of the timing of activities on the program. The 2003 revenue from external programs was





primarily derived from the achievement of milestones in connection with the Merrimack, Elan and Bristol-Myers Squibb programs. Due to the nature and timing of the Company's milestone-based research and development revenue, the Company expects to see variation in reported revenue on a quarter- to-quarter basis. Deferred contract revenue, which is not included in the statement of operations but is reflected on the balance sheet, has increased by \$1.7 million in the first nine months of 2004 to \$2.1 million, representing revenue deferred to future accounting periods on existing contracts in process.

*Cost of revenue and operating expenses.* The expenses for the first nine months of 2004 included a \$943,000 charge associated with the corporate restructuring that was implemented in February 2004, of which approximately \$743,000 and \$200,000, respectively, are included in selling, general and administrative expense and research and development expense. The first nine months of 2004 also include an additional week of expenses due to the fact that the first quarter was a 14 week fiscal quarter. The impact of the additional week of operating expenses in the first nine months of 2004 was approximately \$600,000 as compared with the first nine months of 2003.

*Cost of revenue.* The decrease in cost of revenue is primarily the result of a decrease in revenue due to the stage of development on external programs for which revenue is being recognized as well as the reduction from the restructurings. In addition, deferred contract costs, which are recorded on the balance sheet, have increased to \$992,000 in the first nine months of 2004, representing work done on one pending contract for which no revenue has been recognized to date. The level of expenses on the Company's external programs will continue to fluctuate depending upon the stage of development of these individual contracts.

*Research and development expense.* The increase in research and development is primarily a result of the increase in expenses incurred to support the regulatory filing for approval to market ATryn® in Europe to treat hereditary antithrombin deficiency to \$7.3 million in the first nine months of 2004 as compared with \$5.4 million in the first nine months of 2003. In the first nine months of 2003, \$3 million was capitalized in connection with the FDA and EMEA approval process for the manufacturing equipment to be used for the bulk production of ATryn®.

Additionally, in the first nine months of 2004 and 2003, the Company incurred expenses of \$1.4 million and \$1.5 million, respectively, in the development of the rhA program, \$800,000 and \$1.6 million, respectively, in the development of the malaria program and \$4.1 million and \$3.6 million, respectively, in the development of other internal programs. Research and development expenses going forward are expected to fluctuate based on a number of factors, including the timing and status of clinical development activities for ATryn® and other programs. During the fourth quarter of 2004, the Company plans to submit an amendment to its IND application to the FDA to define the clinical protocol for ATryn® in the United States in the HD indication. The results of this clinical study, in conjunction with the data provided to the EMEA, are anticipated to form the basis for a filing for market approval in the U.S.

*Selling, General and Administrative Expense.* The decrease in selling, general and administrative expenses in the first nine months of 2004, of approximately \$1.2 million, reflects lower expenses throughout all areas of selling, general and administrative, primarily a result of the restructurings. This is offset by \$743,000 of costs associated with the 2004 restructuring.

*Interest Income.* The decrease in interest income is primarily the result of an adjustment of \$155,000 recorded in the first quarter of 2004 related to interest income on the Company's investments during 2003, as well as lower average cash and marketable securities balances in 2004.

### Liquidity and Capital Resources

The Company's objective is to finance its business appropriately through a mix of equity financings, collaboration and grant revenue, debt financings and interest income earned on its cash and cash equivalents. The Company's ability to raise future funds will be affected by the progress of clinical trials and the regulatory review of ATryn®, the ability of the Company to enter into new or expanded transgenic research and development collaborations, the terms of such collaborations, the results of research and development and preclinical testing of the Company's other internal product candidates, competitive and technological advances.

The Company uses its cash for a mix of activities focused on enhancing product development and program execution and development and expansion of operational capabilities, which consist primarily of salaries and wages, facility and facility-related costs for office and laboratory space and other outside direct costs. The Company anticipates utilizing approximately \$20 million of cash in 2005 which includes supporting the launch of ATryn® in Europe and the HD clinical trial in the U.S. After a successful launch of this product in mid-2005, and on the basis of a supportive ATryn® partnering agreement, the Company may manufacture additional product to supply clinical studies for larger markets. This additional manufacturing may increase the Company's total net cash utilization in 2005 to \$25 million.



The Company had cash, cash equivalents and marketable securities of approximately \$29.8 million at October 3, 2004. This amount includes cash and cash equivalents of \$9.2 million. The Company had working capital of \$16.1 million at October 3, 2004 compared to \$24.2 million at December 28, 2003.

The Company has incurred losses from operations since inception and has an accumulated deficit of \$172.2 million at October 3, 2004. Based on the current rate of cash utilization, management believes that existing cash resources and potential future cash payments from new partnering and licensing programs will be sufficient to fund operations through 2005. The primary sources of additional capital raised in 2002, 2003 and 2004 have been equity and debt, and management expects that future sources of funds may include new or expanded partnering arrangements, or the sale of equity or debt-related instruments. However, there can be no assurance that the Company will be able to raise needed capital on terms that are acceptable to the Company, or at all. If the Company does not obtain an adequate amount of additional financing, the Company will be required to curtail operating expenses or take other steps that could adversely impact the Company's ability to grow and commercialize products. Any future sales of common stock will proportionally reduce the ownership interest of the Company's current shareholders and may have an adverse impact on the price of the Company's common stock.

#### ***2004 Financing Activities***

In March 2004, the Company sold 6,395,298 shares of its common stock at \$2.35 per share in a registered direct offering to institutional investors. These shares were issued under the Company's shelf registration statement previously filed with the SEC. SG Cowen Securities, lead agent, and Rodman & Renshaw, LLC acted as placement agents for the offering and the Company paid a placement agent fee for their services. Proceeds to the Company, net of offering costs of approximately \$1.2 million, were approximately \$13.9 million.

#### ***Credit Facility***

Of the Company's \$14.6 million of outstanding long-term debt at October 3, 2004, approximately \$4.8 million is classified as current. Approximately \$9.4 million was related to a term loan from GE Capital, with monthly payments through 2008, approximately \$443,000 was related to capital leases with monthly payments through 2006 and approximately \$4.8 million was related to a promissory note payable to Genzyme with two equal payments of \$2.4 million each due April 3, 2005 and April 3, 2006.

In May 2004, the Company entered into a four year loan agreement with GE Capital, in the amount of \$10 million with a 9.94% interest rate and monthly payments of approximately \$253,000, which was used to refinance the Company's outstanding loan with SVB. Collateral for the loan includes all existing and future acquired assets of the Company, excluding intellectual property. As a result of this refinancing, the Company is no longer required to maintain \$18.2 million as unrestricted cash and marketable securities before it would be required to provide cash collateral for the loan. In connection with the refinancing, the Company was required to provide \$450,000 of cash collateral for its two outstanding stand-by letters of credit, which appears as restricted cash on the balance sheet

#### ***Other Sources of Funds***

Other sources of funds during the first nine months of 2004 included \$2.4 million in net redemptions of marketable securities in the Company's portfolio, approximately \$1 million in new proceeds from refinancing the SVB debt, and \$410,000 from the issuance of common stock under various employee stock plans.

#### ***Other Uses of Funds***

Uses of funds during the period (in which the Company recognized a net loss of \$22 million) included \$12.7 million used in operations.

Other uses of funds during the period included:

- \$450,000 restricted as a result of refinancing the SVB debt; and
- \$992,000 of deferred contract costs; and
- \$934,000 for capital equipment and further expansion of the transgenic production facility.



The Company has entered into transactions with related parties in the normal course of business. The terms of these transactions are considered to be at arms-length.

**COMMITMENTS AND CONTINGENCIES**

The Company's commitments and contingencies are disclosed in Note 9 of this Form 10-Q as well as in the Company's 2003 Form 10-K in the notes to the consolidated financial statements. The Company has reviewed the commitments and contingencies at October 3, 2004 and noted that there were no material changes or additions.

The Company is a party to license agreements for certain technologies. Certain of these agreements contain provisions for future royalties to be paid on commercial sales of products developed from the licensed technologies. Currently the amounts payable under these agreements and any resulting commitments on the Company's behalf are unknown and are not able to be estimated since the level of future sales, if any, is uncertain.



### ITEM 3 - QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes in the Company's market risk since December 28, 2003. The Company's market risk disclosures are discussed in its Annual Report on 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

The Company's management, with the participation of its principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of its disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, the "Exchange Act") as of the end of the period covered by this quarterly report. Based on this evaluation, the principal executive officer and the principal financial officer concluded that the Company's disclosure controls and procedures were effective and designed to ensure that the information required to be disclosed in the reports filed or submitted by it under the Exchange Act is recorded, processed, summarized and reported within the requisite time periods.

#### (b) Changes in Internal Control over Financial Reporting

There was no change in the Company's 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 the Company's internal control that occurred during its last fiscal quarter that has materially affected, or is reasonably likely to materially affect, its internal control over financial reporting.

**PART II - OTHER INFORMATION****ITEM 6 – EXHIBITS**

## 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 December 27, 1993. Filed as Exhibit 3.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 1993 (File No. 0-21794) and incorporated herein by reference.
3.1.2	Articles of Amendment to the Restated Articles of Organization filed with the Secretary of the Commonwealth of Massachusetts on October 3, 1994. Filed as Exhibit 3.1.2 to the Company's Annual Report on Form 10-K for the year ended December 28, 1997 (File No. 0-21794) and incorporated herein by reference.
3.1.3	Articles of Amendment to the Restated Articles of Organization filed with the Secretary of Commonwealth of Massachusetts on June 26, 1997. Filed as Exhibit 3 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 29, 1997 (File No. 0-21794) and incorporated herein by reference.
3.1.4	Articles of Amendment to the Restated Articles of Organization of the Company filed with the Secretary of the Commonwealth of Massachusetts on June 1, 2000. Filed as Exhibit 4.1.5 to the Company's Registration Statement on Form S-8 filed on June 2, 2000 (File No. 333-38490) and incorporated herein by reference.
3.1.5	Certificate of Vote of Directors Establishing a Series of a Class of Stock of GTC and designating the Series C Junior Participating Cumulative Preferred Stock. Filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 1, 2001 (File No. 0-21794) and incorporated herein by reference.
3.1.6	Articles of Amendment to the Restated Articles of Organization of the Company filed with the Secretary of the Commonwealth of Massachusetts on May 31, 2002. Filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 3, 2002 (File No. 0-21794) and incorporated herein by reference.
3.2	By-Laws of the Company, as amended. Filed as Exhibit 3.1 to the Company's Form 10-Q for the quarter ended July 4, 1999 (File No. 000-21794) and incorporated herein by reference.
10.1	The Company's 2002 Equity Incentive Plan, as amended and restated. Filed as Exhibit 99.1 to the Company's Registration Statement on Form S-8 filed on August 4, 2004 (File No. 333-117923) and incorporated herein by reference.
10.2.1	Executive Change in Control Agreement, dated as of August 16, 2004, by and between GTC Biotherapeutics, Inc. and Daniel S. Woloshen. Filed herewith.
10.2.2	Executive Change in Control Agreement, dated as of August 16, 2004, by and between GTC Biotherapeutics, Inc. and Gregory F. Liposky. Filed herewith.
10.2.3	Executive Change in Control Agreement, dated as of August 16, 2004, by and between GTC Biotherapeutics, Inc. and Harry M. Meade, Ph.D. Filed herewith.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a). Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a). Filed herewith.
32	Certifications pursuant to 18 U.S.C. Section 1350. Filed herewith.



### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 10, 2004

GTC BIOTHERAPEUTICS, INC.

By: /s/ John B. Green

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John B. Green  
Senior Vice President,  
Chief Financial Officer and Treasurer  
(Principal Financial and Accounting Officer)

**EXHIBIT INDEX**

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The following exhibits are incorporated herein by reference:

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**Exhibit 10.2.1**

**EXECUTIVE CHANGE IN CONTROL AGREEMENT**

This Executive Change in Control Agreement (this "Agreement") is dated as of August 16, 2004 by and between GTC Biotherapeutics, Inc. (the "Company"), a Massachusetts corporation with its principal executive offices at 175 Crossing Boulevard, 4th Floor, Suite 410, Framingham, MA 01702-9322; and Daniel S. Woloshen ("Executive").

Executive is employed by the Company and the Company and Executive desire to arrange for certain provisions applicable in the event of termination of Executive's employment after a Change in Control of the Company, as provided herein.

Accordingly, the parties hereto agree as follows:

**ARTICLE 1  
TERMINATION FOLLOWING CHANGE IN CONTROL**

1.1 Termination of Employment Following Change in Control. If a Change in Control of the Company shall have occurred, Executive shall be entitled to the benefits provided in Section 1.2 hereof upon the subsequent termination of Executive's employment within twelve (12) months after the effective date of such Change in Control, unless such termination is (a) because of Executive's death or Retirement, (b) by the Company for Cause or (c) by Executive other than for Good Reason. For purposes of this Agreement:

(a) "Cause" shall mean (i) Executive's breach of any material duty or obligation hereunder after written notice of such breach has been given to the Executive by the Board of Directors or Chief Executive Officer of the Company and such breach shall have continued for thirty (30) days after receipt of such notice, or intentional or grossly negligent conduct that is materially injurious to GTC, as determined in good faith by GTC's Board of Directors, or (ii) willful failure to follow the reasonable directions of GTC's Board of Directors or Chief Executive Officer after written notice of such failure has been given to the Executive and such failure shall have continued for thirty (30) days after receipt of such notice.

(b) "Change in Control of the Company" shall mean:

(i) the acquisition (A) by any "person" (as such term is defined in Section 3(a)(9) of the Securities Exchange Act of 1934) from any party of an amount of the Company's Common Stock so that it holds or controls 50% or more of the Company's Common Stock;

(ii) a merger or similar combination after which 50% or more of the voting stock of the surviving corporation is held by persons who were not stockholders of the Company immediately prior to such merger or combination;

(iii) the election by the stockholders of the Company of 50% or more of the directors of the Company other than pursuant to nomination by the Company's independent directors; or



(iv) the sale by the Company of all or substantially all of its assets or business.

(c) "Good Reason" shall mean any of the following:

(i) any change in the duties assigned to Executive, without Executive's express written consent, that represents a material diminution of Executive's duties and responsibilities with the Company in effect immediately prior to the Change in Control; provided, however, that a mere change in Executive's title or reporting relationships shall not constitute "Good Reason";

(ii) a reduction by the Company in Executive's Base Salary as in effect on the date hereof or as the same may be increased from time to time, except as otherwise agreed by Executive;

(iii) the Company requiring Executive to be based anywhere other than within sixty (60) miles of Executive's office location immediately prior to the Change in Control, except for required travel on the Company's business to an extent substantially consistent with Executive's business travel obligations in the twelve (12) months immediately prior to the Change in Control, without Executive's express written consent; or

(iv) the failure by the Company to obtain the assumption of the agreement to perform this Agreement by any successor as contemplated in Section 3.4 hereof.

(d) "Retirement" shall mean termination of Executive's employment in accordance with the Company's retirement policy, including early retirement, generally applicable to its salaried employees.

**1.2 Payments Upon Termination Without Cause, For Good Reason, Following Change in Control.** If, within twelve (12) months after a Change in Control of the Company, Executive's employment is terminated (a) by the Company or its successor in interest other than for Cause or Retirement or (b) by Executive for a Good Reason which has not been cured within ten (10) days after Executive has given notice thereof to the Company, then Executive shall be entitled to the benefits provided below:

(a) **Back Salary Payment.** The Company shall pay Executive any unpaid Base Salary accrued through the date of termination at the rate in effect at the time notice of termination is given, plus credit for any vacation earned but not taken and the amount, if any, and any bonus awarded for the past fiscal year which has not yet been paid to Executive;

(b) **Severance Payment.** The Company shall pay Executive an aggregate severance amount (the "Severance Amount") equal to (i) twelve (12) months of Base Salary in effect on the date of termination and (ii) an amount equal to Executive's incentive bonus most recently paid to him, pro rated on the basis of the number of days that have elapsed between the beginning of the bonus period in which such termination occurs and the date of termination, which Severance Amount shall be payable in substantially equal monthly installments over the twelve (12)-month period following the date of termination;



(c) Continuation of Benefits. The Company shall maintain in full force and effect, for Executive's continued benefit until the earlier of (a) the end of the 12<sup>th</sup> calendar month following the date of termination of employment or (b) Executive's commencement of full time employment with a new employer, all life insurance, medical, health and accident insurance, and disability plans, programs or arrangements in which Executive was entitled to participate immediately prior to the date of termination, provided that Executive's continued participation is possible under the general terms and provisions of such plans and programs. In the event that Executive's participation in any such plan or program is barred, the Company shall arrange to provide Executive with benefits substantially similar to those which Executive was entitled to receive under such plans and programs at its expense; and

(d) Accelerated Vesting of Stock Options. Any stock options to purchase Common Stock of the Company then held by Executive on the date of termination which are then subject to vesting shall, notwithstanding any contrary provision in this Agreement or the Plan pursuant to which such options had been granted, become fully vested and exercisable on the date of termination.

1.3 Limitation on Benefit Payments. In the event that any payment or benefit received or to be received by Executive in connection with a Change in Control or the termination of Executive's employment (whether pursuant to the terms of this Agreement or any other plan, arrangement or agreement with the Company, any person whose actions result in a Change in Control or any person affiliated with the Company or such person) (collectively "Parachute Payments") would not be deductible (in whole or part) as a result of section 280G of the Internal Revenue Code of 1986, as amended (the "Code") by the Company, an affiliate or other person making such payment or providing such benefit, the Parachute Payments shall be reduced until no portion of the Parachute Payments is not deductible. For purposes of this limitation,

(a) no portion of the Parachute Payments the receipt or enjoyment of which Executive shall have effectively waived in writing prior to the date of payment of the Parachute Payments shall be taken into account,

(b) no portion of the Parachute Payments shall be taken into account which in the opinion of tax counsel selected by the Company's independent auditors serving as such immediately prior to the Change in Control does not constitute a "parachute payment" within the meaning of section 280G(b)(2) of the Code,

(c) the Parachute Payments shall be reduced only to the extent necessary so that the Parachute Payments (other than those referred to in clauses (a) or (b)) in their entirety constitute reasonable compensation for services actually rendered within the meaning of section 280G(b)(4) of the Code or are otherwise not subject to disallowance as deductions, in the opinion of the tax counsel referred to in clause (b),

(d) the value of any non-cash benefit or any deferred payment or benefit included in the Parachute Payments shall be determined by the Company's independent auditors based on Sections 280G and 4999 of the Code and on proposed or final regulations for applying those Code Sections, or on substantial authority within the meaning of Section 6662 of the Code, and

(e) if any portion of the Parachute Payments are determined not to be deductible by reason of section 280G of the Code, then to the extent reasonably practicable and permitted by applicable law, the Company shall consult with Executive prior to reducing any particular Parachute Payments to afford Executive the opportunity to waive other Parachute Payments.



Except to the extent prohibited by applicable law, the Company shall honor Executive's preferences with respect to the order of waiver of Parachute Payments to the extent that written notice of such preferences is received by the Company prior to the Change in Control.

**ARTICLE 2  
CONFIDENTIAL INFORMATION AND NON-COMPETITION**

2.1 Confidential Information. As a condition to the Company's obligations hereunder, Executive shall continue to be bound by the confidentiality and non-competition agreement pertaining to the intellectual property and confidential information of the Company and the non-competition provision set forth in the Management Agreement (the "Severance Agreement") between the Company and Executive. The obligations of Executive under this Article 2 and the agreements referenced in this paragraph shall survive termination of this Agreement for any reason.

**ARTICLE 3  
TERM AND TERMINATION**

3.1 Term of Agreement. If a Change in Control should occur while Executive is still an employee of the Company, then this Agreement shall continue in effect for a term from the date of such Change in Control for so long as Executive remains an employee of the Company, but in no event for more than twelve (12) months following such Change in Control. If Executive's employment is terminated by the Company without Cause prior to a Change in Control, this Agreement shall expire upon the date that Executive's employment is terminated.

3.2 Termination. This Agreement may be terminated by the Company at any time prior to a Change in Control upon twelve month's written notice to Executive.

3.3 Effect of Expiration or Termination. The termination or expiration of the term of this Agreement shall not adversely affect Executive's rights under this Agreement that have accrued prior to any such termination or expiration.

**ARTICLE 4  
MISCELLANEOUS**

4.1 No Conflicting Commitments. During the period of Executive's full time employment with the Company, Executive will not undertake any commitments which might materially impair Executive's performance of his duties as a full time Executive of the Company.

4.2 Taxes. The Company may withhold from any amounts payable under this Agreement such federal, state, local or foreign taxes as shall be required to be withheld pursuant to any applicable law or regulation.



4.3 Effect on Employment Status. This Agreement does not entitle Executive to remain in the employ of the Company for any minimum or prescribed period or term, and it does not modify the at-will status of Executive's employment.

4.4 Release. The payment of the compensation and the provision of the benefits to Executive set forth in Article 2 are contingent upon Executive's execution and delivery of a release of claims against the Company in a form reasonably acceptable to the Company and Executive.

4.5 Exclusion of Other Benefits. In the event that compensation and benefits are due to Executive hereunder after a termination of Executive's Employment upon a Change in Control, such compensation and benefits shall be in lieu of any other compensation or benefit for which Executive would be eligible under any severance pay plan or policy of the Company, unless the Company has expressly provided that it shall be so payable in addition to the compensation and benefits due under this Agreement.

4.6 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and all of which together shall be deemed to be one and the same instrument.

4.7 Binding Effect. This Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective lawful successors and assigns and upon Executive's heirs and personal representatives.

4.8 Assignment. This Agreement may not be assigned, in whole or in part, by any party without the prior written consent of the other party, except that the Company may, without the consent of Executive, assign its rights and obligations under this Agreement to any corporation, firm or other business entity with or into which the Company may merge or consolidate, or to which the Company may sell or transfer all or substantially all of its assets, or of which 50% or more of the equity investment and of the voting control is owned, directly or indirectly, by, or is under common ownership with, the Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company to expressly assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform it if no such succession had taken place. Failure of the Company to obtain such assumption and agreement prior to or in conjunction with the effectiveness of any such succession shall be a breach of this Agreement and shall entitle the Executive to compensation from the Company or its successor in the same amount and on the same terms as he would be entitled to hereunder if he terminated his employment for Good Reason following a Change in Control, except that for purposes of implementing the foregoing, the date on which any such succession becomes effective shall be deemed the Date of Termination. After any such assignment by the Company, the Company shall be discharged from all further liability hereunder and such assignee shall have all the rights and obligations of the Company under this Agreement.

4.9 Entire Agreement. This Agreement is the entire agreement of the parties with respect to the subject matter hereof and supersedes any prior agreement or understanding thereto. In the event of any conflict between this Agreement and the Severance Agreement, this Agreement shall control.



4.10 Notices. All notices, requests, demands and other communications to be given pursuant to this Agreement shall be in writing and shall be deemed to have been duly given if delivered by hand or mailed by registered or certified mail, return receipt requested, postage prepaid, as follows:

If to the Company, to:

GTC Biotherapeutics, Inc.  
175 Crossing Boulevard  
4th Floor, Suite 410  
Framingham, MA 01702-9322  
Attention: Chief Executive Officer

with a copy to:

Nathaniel S. Gardiner, Esq.  
Palmer & Dodge LLP  
111 Huntington Avenue  
Boston, Massachusetts 02199-7613

If to Executive, at his then current address on the payroll records of the Company; or such other address as either party hereto shall have designated by notice in writing to the other party.

4.11 Amendments. This Agreement may be amended, supplemented or otherwise modified at any time, but only by an instrument in writing signed by the parties hereto.

4.12 Governing Law. This Agreement and the legal relations among the parties hereto shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, without regard to its conflict of law provisions.

4.13 Severability. In case any provision hereof shall, for any reason, be held to be invalid or unenforceable in any respect, such invalidity or unenforceability shall not affect any other provision hereof, and this Agreement shall be construed as if such invalid or unenforceable provision had not been included herein. If any provision hereof shall, for any reason, be held by a court to be excessively broad as to duration, geographical scope, activity or subject matter, it shall be construed by limiting and reducing it to make it enforceable to the extent compatible with applicable law as then in effect.

4.14 Survival. Articles 1 and 2 shall survive the termination of this Agreement for the periods of time indicated therein or indefinitely if no period of time is indicated.

[Remainder of page intentionally left blank.]



IN WITNESS WHEREOF, the undersigned have duly executed and delivered this Agreement as of the date first above written.

EXECUTIVE:

/s/ Daniel S. Woloshen

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Daniel S. Woloshen  
Sr. Vice President and General Counsel

COMPANY:

GTC BIOTHERAPEUTICS, INC.

By: /s/ Geoffrey F. Cox

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Geoffrey F. Cox  
President and Chief Executive Officer



**Exhibit 10.2.2**

**EXECUTIVE CHANGE IN CONTROL AGREEMENT**

This Executive Change in Control Agreement (this "Agreement") is dated as of August 16, 2004 by and between GTC Biotherapeutics, Inc. (the "Company"), a Massachusetts corporation with its principal executive offices at 175 Crossing Boulevard, 4th Floor, Suite 410, Framingham, MA 01702-9322; and Gregory F. Liposky ("Executive").

Executive is employed by the Company and the Company and Executive desire to arrange for certain provisions applicable in the event of termination of Executive's employment after a Change in Control of the Company, as provided herein.

Accordingly, the parties hereto agree as follows:

**ARTICLE 1  
TERMINATION FOLLOWING CHANGE IN CONTROL**

1.1 Termination of Employment Following Change in Control. If a Change in Control of the Company shall have occurred, Executive shall be entitled to the benefits provided in Section 1.2 hereof upon the subsequent termination of Executive's employment within twelve (12) months after the effective date of such Change in Control, unless such termination is (a) because of Executive's death or Retirement, (b) by the Company for Cause or (c) by Executive other than for Good Reason. For purposes of this Agreement:

(a) "Cause" shall mean (i) Executive's breach of any material duty or obligation hereunder after written notice of such breach has been given to the Executive by the Board of Directors or Chief Executive Officer of the Company and such breach shall have continued for thirty (30) days after receipt of such notice, or intentional or grossly negligent conduct that is materially injurious to GTC, as determined in good faith by GTC's Board of Directors, or (ii) willful failure to follow the reasonable directions of GTC's Board of Directors or Chief Executive Officer after written notice of such failure has been given to the Executive and such failure shall have continued for thirty (30) days after receipt of such notice.

(b) "Change in Control of the Company" shall mean:

(i) the acquisition (A) by any "person" (as such term is defined in Section 3(a)(9) of the Securities Exchange Act of 1934) from any party of an amount of the Company's Common Stock so that it holds or controls 50% or more of the Company's Common Stock;

(ii) a merger or similar combination after which 50% or more of the voting stock of the surviving corporation is held by persons who were not stockholders of the Company immediately prior to such merger or combination;

(iii) the election by the stockholders of the Company of 50% or more of the directors of the Company other than pursuant to nomination by the Company's independent directors; or



(iv) the sale by the Company of all or substantially all of its assets or business.

(c) "Good Reason" shall mean any of the following:

(i) any change in the duties assigned to Executive, without Executive's express written consent, that represents a material diminution of Executive's duties and responsibilities with the Company in effect immediately prior to the Change in Control; provided, however, that a mere change in Executive's title or reporting relationships shall not constitute "Good Reason";

(ii) a reduction by the Company in Executive's Base Salary as in effect on the date hereof or as the same may be increased from time to time, except as otherwise agreed by Executive;

(iii) the Company requiring Executive to be based anywhere other than within sixty (60) miles of Executive's office location immediately prior to the Change in Control, except for required travel on the Company's business to an extent substantially consistent with Executive's business travel obligations in the twelve (12) months immediately prior to the Change in Control, without Executive's express written consent; or

(iv) the failure by the Company to obtain the assumption of the agreement to perform this Agreement by any successor as contemplated in Section 3.4 hereof.

(d) "Retirement" shall mean termination of Executive's employment in accordance with the Company's retirement policy, including early retirement, generally applicable to its salaried employees.

**1.2 Payments Upon Termination Without Cause, For Good Reason, Following Change in Control.** If, within twelve (12) months after a Change in Control of the Company, Executive's employment is terminated (a) by the Company or its successor in interest other than for Cause or Retirement or (b) by Executive for a Good Reason which has not been cured within ten (10) days after Executive has given notice thereof to the Company, then Executive shall be entitled to the benefits provided below:

(a) **Back Salary Payment.** The Company shall pay Executive any unpaid Base Salary accrued through the date of termination at the rate in effect at the time notice of termination is given, plus credit for any vacation earned but not taken and the amount, if any, and any bonus awarded for the past fiscal year which has not yet been paid to Executive;

(b) **Severance Payment.** The Company shall pay Executive an aggregate severance amount (the "Severance Amount") equal to (i) twelve (12) months of Base Salary in effect on the date of termination and (ii) an amount equal to Executive's incentive bonus most recently paid to him, pro rated on the basis of the number of days that have elapsed between the beginning of the bonus period in which such termination occurs and the date of termination, which Severance Amount shall be payable in substantially equal monthly installments over the twelve (12)-month period following the date of termination;



(c) Continuation of Benefits. The Company shall maintain in full force and effect, for Executive's continued benefit until the earlier of (a) the end of the 12<sup>th</sup> calendar month following the date of termination of employment or (b) Executive's commencement of full time employment with a new employer, all life insurance, medical, health and accident insurance, and disability plans, programs or arrangements in which Executive was entitled to participate immediately prior to the date of termination, provided that Executive's continued participation is possible under the general terms and provisions of such plans and programs. In the event that Executive's participation in any such plan or program is barred, the Company shall arrange to provide Executive with benefits substantially similar to those which Executive was entitled to receive under such plans and programs at its expense; and

(d) Accelerated Vesting of Stock Options. Any stock options to purchase Common Stock of the Company then held by Executive on the date of termination which are then subject to vesting shall, notwithstanding any contrary provision in this Agreement or the Plan pursuant to which such options had been granted, become fully vested and exercisable on the date of termination.

1.3 Limitation on Benefit Payments. In the event that any payment or benefit received or to be received by Executive in connection with a Change in Control or the termination of Executive's employment (whether pursuant to the terms of this Agreement or any other plan, arrangement or agreement with the Company, any person whose actions result in a Change in Control or any person affiliated with the Company or such person) (collectively "Parachute Payments") would not be deductible (in whole or part) as a result of section 280G of the Internal Revenue Code of 1986, as amended (the "Code") by the Company, an affiliate or other person making such payment or providing such benefit, the Parachute Payments shall be reduced until no portion of the Parachute Payments is not deductible. For purposes of this limitation,

(a) no portion of the Parachute Payments the receipt or enjoyment of which Executive shall have effectively waived in writing prior to the date of payment of the Parachute Payments shall be taken into account,

(b) no portion of the Parachute Payments shall be taken into account which in the opinion of tax counsel selected by the Company's independent auditors serving as such immediately prior to the Change in Control does not constitute a "parachute payment" within the meaning of section 280G(b)(2) of the Code,

(c) the Parachute Payments shall be reduced only to the extent necessary so that the Parachute Payments (other than those referred to in clauses (a) or (b)) in their entirety constitute reasonable compensation for services actually rendered within the meaning of section 280G(b)(4) of the Code or are otherwise not subject to disallowance as deductions, in the opinion of the tax counsel referred to in clause (b),

(d) the value of any non-cash benefit or any deferred payment or benefit included in the Parachute Payments shall be determined by the Company's independent auditors based on Sections 280G and 4999 of the Code and on proposed or final regulations for applying those Code Sections, or on substantial authority within the meaning of Section 6662 of the Code, and

(e) if any portion of the Parachute Payments are determined not to be deductible by reason of section 280G of the Code, then to the extent reasonably practicable and permitted by applicable law, the Company shall consult with Executive prior to reducing any particular Parachute Payments to afford Executive the opportunity to waive other Parachute Payments.



Except to the extent prohibited by applicable law, the Company shall honor Executive's preferences with respect to the order of waiver of Parachute Payments to the extent that written notice of such preferences is received by the Company prior to the Change in Control.

**ARTICLE 2  
CONFIDENTIAL INFORMATION AND NON-COMPETITION**

2.1 Confidential Information. As a condition to the Company's obligations hereunder, Executive shall continue to be bound by the confidentiality and non-competition agreement pertaining to the intellectual property and confidential information of the Company and the non-competition provision set forth in the Management Agreement (the "Severance Agreement") between the Company and Executive. The obligations of Executive under this Article 2 and the agreements referenced in this paragraph shall survive termination of this Agreement for any reason.

**ARTICLE 3  
TERM AND TERMINATION**

3.1 Term of Agreement. If a Change in Control should occur while Executive is still an employee of the Company, then this Agreement shall continue in effect for a term from the date of such Change in Control for so long as Executive remains an employee of the Company, but in no event for more than twelve (12) months following such Change in Control. If Executive's employment is terminated by the Company without Cause prior to a Change in Control, this Agreement shall expire upon the date that Executive's employment is terminated.

3.2 Termination. This Agreement may be terminated by the Company at any time prior to a Change in Control upon twelve month's written notice to Executive.

3.3 Effect of Expiration or Termination. The termination or expiration of the term of this Agreement shall not adversely affect Executive's rights under this Agreement that have accrued prior to any such termination or expiration.

**ARTICLE 4 MISCELLANEOUS**

4.1 No Conflicting Commitments. During the period of Executive's full time employment with the Company, Executive will not undertake any commitments which might materially impair Executive's performance of his duties as a full time Executive of the Company.

4.2 Taxes. The Company may withhold from any amounts payable under this Agreement such federal, state, local or foreign taxes as shall be required to be withheld pursuant to any applicable law or regulation.



4.3 Effect on Employment Status. This Agreement does not entitle Executive to remain in the employ of the Company for any minimum or prescribed period or term, and it does not modify the at-will status of Executive's employment.

4.4 Release. The payment of the compensation and the provision of the benefits to Executive set forth in Article 2 are contingent upon Executive's execution and delivery of a release of claims against the Company in a form reasonably acceptable to the Company and Executive.

4.5 Exclusion of Other Benefits. In the event that compensation and benefits are due to Executive hereunder after a termination of Executive's Employment upon a Change in Control, such compensation and benefits shall be in lieu of any other compensation or benefit for which Executive would be eligible under any severance pay plan or policy of the Company, unless the Company has expressly provided that it shall be so payable in addition to the compensation and benefits due under this Agreement.

4.6 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and all of which together shall be deemed to be one and the same instrument.

4.7 Binding Effect. This Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective lawful successors and assigns and upon Executive's heirs and personal representatives.

4.8 Assignment. This Agreement may not be assigned, in whole or in part, by any party without the prior written consent of the other party, except that the Company may, without the consent of Executive, assign its rights and obligations under this Agreement to any corporation, firm or other business entity with or into which the Company may merge or consolidate, or to which the Company may sell or transfer all or substantially all of its assets, or of which 50% or more of the equity investment and of the voting control is owned, directly or indirectly, by, or is under common ownership with, the Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company to expressly assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform it if no such succession had taken place. Failure of the Company to obtain such assumption and agreement prior to or in conjunction with the effectiveness of any such succession shall be a breach of this Agreement and shall entitle the Executive to compensation from the Company or its successor in the same amount and on the same terms as he would be entitled to hereunder if he terminated his employment for Good Reason following a Change in Control, except that for purposes of implementing the foregoing, the date on which any such succession becomes effective shall be deemed the Date of Termination. After any such assignment by the Company, the Company shall be discharged from all further liability hereunder and such assignee shall have all the rights and obligations of the Company under this Agreement.

4.9 Entire Agreement. This Agreement is the entire agreement of the parties with respect to the subject matter hereof and supersedes any prior agreement or understanding thereto. In the event of any conflict between this Agreement and the Severance Agreement, this Agreement shall control.



4.10 Notices. All notices, requests, demands and other communications to be given pursuant to this Agreement shall be in writing and shall be deemed to have been duly given if delivered by hand or mailed by registered or certified mail, return receipt requested, postage prepaid, as follows:

If to the Company, to:

GTC Biotherapeutics, Inc.  
175 Crossing Boulevard  
4th Floor, Suite 410  
Framingham, MA 01702-9322  
Attention: Chief Executive Officer

with a copy to:

Nathaniel S. Gardiner, Esq.  
Palmer & Dodge LLP  
111 Huntington Avenue  
Boston, Massachusetts 02199-7613

If to Executive, at his then current address on the payroll records of the Company; or such other address as either party hereto shall have designated by notice in writing to the other party.

4.11 Amendments. This Agreement may be amended, supplemented or otherwise modified at any time, but only by an instrument in writing signed by the parties hereto.

4.12 Governing Law. This Agreement and the legal relations among the parties hereto shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, without regard to its conflict of law provisions.

4.13 Severability. In case any provision hereof shall, for any reason, be held to be invalid or unenforceable in any respect, such invalidity or unenforceability shall not affect any other provision hereof, and this Agreement shall be construed as if such invalid or unenforceable provision had not been included herein. If any provision hereof shall, for any reason, be held by a court to be excessively broad as to duration, geographical scope, activity or subject matter, it shall be construed by limiting and reducing it to make it enforceable to the extent compatible with applicable law as then in effect.

4.14 Survival. Articles 1 and 2 shall survive the termination of this Agreement for the periods of time indicated therein or indefinitely if no period of time is indicated.

[Remainder of page intentionally left blank.]



IN WITNESS WHEREOF, the undersigned have duly executed and delivered this Agreement as of the date first above written.

EXECUTIVE:

/s/ Gregory F. Liposky

\_\_\_\_\_  
Gregory F. Liposky  
Sr. Vice President, Operations

COMPANY:

GTC BIOTHERAPEUTICS, INC.

By: /s/ Geoffrey F. Cox

\_\_\_\_\_  
Geoffrey F. Cox  
President and Chief Executive Officer



**Exhibit 10.2.3**

**EXECUTIVE CHANGE IN CONTROL AGREEMENT**

This Executive Change in Control Agreement (this "Agreement") is dated as of August 16, 2004 by and between GTC Biotherapeutics, Inc. (the "Company"), a Massachusetts corporation with its principal executive offices at 175 Crossing Boulevard, 4th Floor, Suite 410, Framingham, MA 01702-9322; and Harry M. Meade, Ph.D. ("Executive").

Executive is employed by the Company and the Company and Executive desire to arrange for certain provisions applicable in the event of termination of Executive's employment after a Change in Control of the Company, as provided herein.

Accordingly, the parties hereto agree as follows:

**ARTICLE 1  
TERMINATION FOLLOWING CHANGE IN CONTROL**

1.1 Termination of Employment Following Change in Control. If a Change in Control of the Company shall have occurred, Executive shall be entitled to the benefits provided in Section 1.2 hereof upon the subsequent termination of Executive's employment within twelve (12) months after the effective date of such Change in Control, unless such termination is (a) because of Executive's death or Retirement, (b) by the Company for Cause or (c) by Executive other than for Good Reason. For purposes of this Agreement:

(a) "Cause" shall mean (i) Executive's breach of any material duty or obligation hereunder after written notice of such breach has been given to the Executive by the Board of Directors or Chief Executive Officer of the Company and such breach shall have continued for thirty (30) days after receipt of such notice, or intentional or grossly negligent conduct that is materially injurious to GTC, as determined in good faith by GTC's Board of Directors, or (ii) willful failure to follow the reasonable directions of GTC's Board of Directors or Chief Executive Officer after written notice of such failure has been given to the Executive and such failure shall have continued for thirty (30) days after receipt of such notice.

(b) "Change in Control of the Company" shall mean:

(i) the acquisition (A) by any "person" (as such term is defined in Section 3(a)(9) of the Securities Exchange Act of 1934) from any party of an amount of the Company's Common Stock so that it holds or controls 50% or more of the Company's Common Stock;

(ii) a merger or similar combination after which 50% or more of the voting stock of the surviving corporation is held by persons who were not stockholders of the Company immediately prior to such merger or combination;

(iii) the election by the stockholders of the Company of 50% or more of the directors of the Company other than pursuant to nomination by the Company's independent directors; or



(iv) the sale by the Company of all or substantially all of its assets or business.

(c) "Good Reason" shall mean any of the following:

(i) any change in the duties assigned to Executive, without Executive's express written consent, that represents a material diminution of Executive's duties and responsibilities with the Company in effect immediately prior to the Change in Control; provided, however, that a mere change in Executive's title or reporting relationships shall not constitute "Good Reason";

(ii) a reduction by the Company in Executive's Base Salary as in effect on the date hereof or as the same may be increased from time to time, except as otherwise agreed by Executive;

(iii) the Company requiring Executive to be based anywhere other than within sixty (60) miles of Executive's office location immediately prior to the Change in Control, except for required travel on the Company's business to an extent substantially consistent with Executive's business travel obligations in the twelve (12) months immediately prior to the Change in Control, without Executive's express written consent; or

(iv) the failure by the Company to obtain the assumption of the agreement to perform this Agreement by any successor as contemplated in Section 3.4 hereof.

(d) "Retirement" shall mean termination of Executive's employment in accordance with the Company's retirement policy, including early retirement, generally applicable to its salaried employees.

**1.2 Payments Upon Termination Without Cause, For Good Reason, Following Change in Control.** If, within twelve (12) months after a Change in Control of the Company, Executive's employment is terminated (a) by the Company or its successor in interest other than for Cause or Retirement or (b) by Executive for a Good Reason which has not been cured within ten (10) days after Executive has given notice thereof to the Company, then Executive shall be entitled to the benefits provided below:

(a) **Back Salary Payment.** The Company shall pay Executive any unpaid Base Salary accrued through the date of termination at the rate in effect at the time notice of termination is given, plus credit for any vacation earned but not taken and the amount, if any, and any bonus awarded for the past fiscal year which has not yet been paid to Executive;

(b) **Severance Payment.** The Company shall pay Executive an aggregate severance amount (the "Severance Amount") equal to (i) twelve (12) months of Base Salary in effect on the date of termination and (ii) an amount equal to Executive's incentive bonus most recently paid to him, pro rated on the basis of the number of days that have elapsed between the beginning of the bonus period in which such termination occurs and the date of termination, which Severance Amount shall be payable in substantially equal monthly installments over the twelve (12)-month period following the date of termination;



(c) Continuation of Benefits. The Company shall maintain in full force and effect, for Executive's continued benefit until the earlier of (a) the end of the 12<sup>th</sup> calendar month following the date of termination of employment or (b) Executive's commencement of full time employment with a new employer, all life insurance, medical, health and accident insurance, and disability plans, programs or arrangements in which Executive was entitled to participate immediately prior to the date of termination, provided that Executive's continued participation is possible under the general terms and provisions of such plans and programs. In the event that Executive's participation in any such plan or program is barred, the Company shall arrange to provide Executive with benefits substantially similar to those which Executive was entitled to receive under such plans and programs at its expense; and

(d) Accelerated Vesting of Stock Options. Any stock options to purchase Common Stock of the Company then held by Executive on the date of termination which are then subject to vesting shall, notwithstanding any contrary provision in this Agreement or the Plan pursuant to which such options had been granted, become fully vested and exercisable on the date of termination.

1.3 Limitation on Benefit Payments. In the event that any payment or benefit received or to be received by Executive in connection with a Change in Control or the termination of Executive's employment (whether pursuant to the terms of this Agreement or any other plan, arrangement or agreement with the Company, any person whose actions result in a Change in Control or any person affiliated with the Company or such person) (collectively "Parachute Payments") would not be deductible (in whole or part) as a result of section 280G of the Internal Revenue Code of 1986, as amended (the "Code") by the Company, an affiliate or other person making such payment or providing such benefit, the Parachute Payments shall be reduced until no portion of the Parachute Payments is not deductible. For purposes of this limitation,

(a) no portion of the Parachute Payments the receipt or enjoyment of which Executive shall have effectively waived in writing prior to the date of payment of the Parachute Payments shall be taken into account,

(b) no portion of the Parachute Payments shall be taken into account which in the opinion of tax counsel selected by the Company's independent auditors serving as such immediately prior to the Change in Control does not constitute a "parachute payment" within the meaning of section 280G(b)(2) of the Code,

(c) the Parachute Payments shall be reduced only to the extent necessary so that the Parachute Payments (other than those referred to in clauses (a) or (b)) in their entirety constitute reasonable compensation for services actually rendered within the meaning of section 280G(b)(4) of the Code or are otherwise not subject to disallowance as deductions, in the opinion of the tax counsel referred to in clause (b),

(d) the value of any non-cash benefit or any deferred payment or benefit included in the Parachute Payments shall be determined by the Company's independent auditors based on Sections 280G and 4999 of the Code and on proposed or final regulations for applying those Code Sections, or on substantial authority within the meaning of Section 6662 of the Code, and

(e) if any portion of the Parachute Payments are determined not to be deductible by reason of section 280G of the Code, then to the extent reasonably practicable and permitted by applicable law, the Company shall consult with Executive prior to reducing any particular Parachute Payments to afford Executive the opportunity to waive other Parachute Payments.



Except to the extent prohibited by applicable law, the Company shall honor Executive's preferences with respect to the order of waiver of Parachute Payments to the extent that written notice of such preferences is received by the Company prior to the Change in Control.

**ARTICLE 2  
CONFIDENTIAL INFORMATION AND NON-COMPETITION**

2.1 Confidential Information. As a condition to the Company's obligations hereunder, Executive shall continue to be bound by the confidentiality and non-competition agreement pertaining to the intellectual property and confidential information of the Company and the non-competition provision set forth in the Management Agreement (the "Severance Agreement") between the Company and Executive. The obligations of Executive under this Article 2 and the agreements referenced in this paragraph shall survive termination of this Agreement for any reason.

**ARTICLE 3  
TERM AND TERMINATION**

3.1 Term of Agreement. If a Change in Control should occur while Executive is still an employee of the Company, then this Agreement shall continue in effect for a term from the date of such Change in Control for so long as Executive remains an employee of the Company, but in no event for more than twelve (12) months following such Change in Control. If Executive's employment is terminated by the Company without Cause prior to a Change in Control, this Agreement shall expire upon the date that Executive's employment is terminated.

3.2 Termination. This Agreement may be terminated by the Company at any time prior to a Change in Control upon twelve month's written notice to Executive.

3.3 Effect of Expiration or Termination. The termination or expiration of the term of this Agreement shall not adversely affect Executive's rights under this Agreement that have accrued prior to any such termination or expiration.

**ARTICLE 4  
MISCELLANEOUS**

4.1 No Conflicting Commitments. During the period of Executive's full time employment with the Company, Executive will not undertake any commitments which might materially impair Executive's performance of his duties as a full time Executive of the Company.

4.2 Taxes. The Company may withhold from any amounts payable under this Agreement such federal, state, local or foreign taxes as shall be required to be withheld pursuant to any applicable law or regulation.



4.3 Effect on Employment Status. This Agreement does not entitle Executive to remain in the employ of the Company for any minimum or prescribed period or term, and it does not modify the at-will status of Executive's employment.

4.4 Release. The payment of the compensation and the provision of the benefits to Executive set forth in Article 2 are contingent upon Executive's execution and delivery of a release of claims against the Company in a form reasonably acceptable to the Company and Executive.

4.5 Exclusion of Other Benefits. In the event that compensation and benefits are due to Executive hereunder after a termination of Executive's Employment upon a Change in Control, such compensation and benefits shall be in lieu of any other compensation or benefit for which Executive would be eligible under any severance pay plan or policy of the Company, unless the Company has expressly provided that it shall be so payable in addition to the compensation and benefits due under this Agreement.

4.6 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and all of which together shall be deemed to be one and the same instrument.

4.7 Binding Effect. This Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective lawful successors and assigns and upon Executive's heirs and personal representatives.

4.8 Assignment. This Agreement may not be assigned, in whole or in part, by any party without the prior written consent of the other party, except that the Company may, without the consent of Executive, assign its rights and obligations under this Agreement to any corporation, firm or other business entity with or into which the Company may merge or consolidate, or to which the Company may sell or transfer all or substantially all of its assets, or of which 50% or more of the equity investment and of the voting control is owned, directly or indirectly, by, or is under common ownership with, the Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company to expressly assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform it if no such succession had taken place. Failure of the Company to obtain such assumption and agreement prior to or in conjunction with the effectiveness of any such succession shall be a breach of this Agreement and shall entitle the Executive to compensation from the Company or its successor in the same amount and on the same terms as he would be entitled to hereunder if he terminated his employment for Good Reason following a Change in Control, except that for purposes of implementing the foregoing, the date on which any such succession becomes effective shall be deemed the Date of Termination. After any such assignment by the Company, the Company shall be discharged from all further liability hereunder and such assignee shall have all the rights and obligations of the Company under this Agreement.

4.9 Entire Agreement. This Agreement is the entire agreement of the parties with respect to the subject matter hereof and supersedes any prior agreement or understanding thereto. In the event of any conflict between this Agreement and the Severance Agreement, this Agreement shall control.



4.10 Notices. All notices, requests, demands and other communications to be given pursuant to this Agreement shall be in writing and shall be deemed to have been duly given if delivered by hand or mailed by registered or certified mail, return receipt requested, postage prepaid, as follows:

If to the Company, to:

GTC Biotherapeutics, Inc.  
175 Crossing Boulevard  
4th Floor, Suite 410  
Framingham, MA 01702-9322  
Attention: Chief Executive Officer

with a copy to:

Nathaniel S. Gardiner, Esq.  
Palmer & Dodge LLP  
111 Huntington Avenue  
Boston, Massachusetts 02199-7613

If to Executive, at his then current address on the payroll records of the Company; or such other address as either party hereto shall have designated by notice in writing to the other party.

4.11 Amendments. This Agreement may be amended, supplemented or otherwise modified at any time, but only by an instrument in writing signed by the parties hereto.

4.12 Governing Law. This Agreement and the legal relations among the parties hereto shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, without regard to its conflict of law provisions.

4.13 Severability. In case any provision hereof shall, for any reason, be held to be invalid or unenforceable in any respect, such invalidity or unenforceability shall not affect any other provision hereof, and this Agreement shall be construed as if such invalid or unenforceable provision had not been included herein. If any provision hereof shall, for any reason, be held by a court to be excessively broad as to duration, geographical scope, activity or subject matter, it shall be construed by limiting and reducing it to make it enforceable to the extent compatible with applicable law as then in effect.

4.14 Survival. Articles 1 and 2 shall survive the termination of this Agreement for the periods of time indicated therein or indefinitely if no period of time is indicated.

[Remainder of page intentionally left blank.]



IN WITNESS WHEREOF, the undersigned have duly executed and delivered this Agreement as of the date first above written.

EXECUTIVE:

/s/ Harry M. Meade, Ph.D.

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Harry M. Meade, Ph.D.  
Sr. Vice President, Research and Development

COMPANY:

GTC BIOTHERAPEUTICS, INC.

By: /s/ Geoffrey F. Cox

\_\_\_\_\_  
Geoffrey F. Cox  
President and Chief Executive Officer



**Exhibit 31.1**

**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)) for the registrant and we 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) 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
  - (c) 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 10, 2004

/s/ Geoffrey F. Cox

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



**Exhibit 31.2**

**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)) for the registrant and we 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) 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
  - (c) 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 10, 2004

/s/ John B. Green

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



**Exhibit 32**

**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 October 3, 2004, 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 10, 2004

/s/ Geoffrey F. Cox

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

Date: November 10, 2004

/s/ John B. Green

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