

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 30, 2003

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	04-3186494
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

175 Crossing Boulevard, Framingham, Massachusetts	01702
(Address of Principal Executive Offices)	(Zip Code)

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

Formerly known as Genzyme Transgenics Corporation.

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 X No \_\_\_\_\_

Indicate by check whether registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes \_\_\_\_\_ No X

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

<u>Class</u>	<u>Outstanding at May 1, 2003</u>
Common Stock, \$0.01 par value	28,057,327

**GTC BIOTHERAPEUTICS, INC.**  
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**PART I**

**ITEM 1 – FINANCIAL STATEMENTS**

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

	<b>March 30, 2003</b>	<b>December 29, 2002</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 26,030	\$ 26,911
Marketable securities	21,796	30,438
Accounts receivable and unbilled contract revenue	2,905	2,179
Other current assets	1,394	1,932
Total current assets	52,125	61,460
Net property, plant and equipment	24,053	21,701
Net intangible assets	11,870	12,128
Other assets	150	84
	\$ 88,198	\$ 95,373
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 6,255	\$ 4,448
Accounts payable - Genzyme Corporation	604	2,370
Accrued expenses	3,961	4,442
Deferred contract revenue	867	638
Current portion of long-term debt and capital leases	1,767	1,880
Total current liabilities	13,454	13,778
Long-term debt and capital leases, net of current portion	13,040	12,786
Deferred lease obligation	32	37
Total liabilities	26,526	26,601
Shareholders' equity:		
Preferred stock, \$.01 par value; 5,000,000 shares authorized; no shares were issued and outstanding	-	-
Common stock, \$.01 par value; 100,000,000 shares authorized; 30,877,682 and 30,579,064 shares issued and 28,057,682 and 27,759,064 shares outstanding at March 30, 2003 and December 29, 2002, respectively	309	306
Capital in excess of par value – common stock	198,794	198,469
Treasury stock, at cost, 2,820,000 shares	(9,545)	(9,545)
Accumulated deficit	(128,035)	(120,642)
Accumulated other comprehensive income	149	184
Total shareholders' equity	61,672	68,772
	\$ 88,198	\$ 95,373

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

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

	<b>Three months ended</b>	
	<b>March 30, 2003</b>	<b>March 31, 2002</b>
Revenue	\$ 1,744	\$ 3,845
Costs of revenue and operating expenses:		
Cost of revenue	3,576	4,091
Research and development	3,024	2,039
Selling, general and administrative	2,693	2,852
	<u>9,293</u>	<u>8,982</u>
Operating loss	(7,549)	(5,137)
Other income (expense):		
Interest income	292	620
Interest expense	(136)	(49)
	<u>(136)</u>	<u>(49)</u>
Net loss	\$ <u>(7,393)</u>	\$ <u>(4,566)</u>
Net loss available per common share (basic and diluted):		
Net loss	\$ <u>(0.27)</u>	\$ <u>(0.15)</u>
Weighted average number of common shares outstanding (basic and diluted)	<u>27,783</u>	<u>30,229</u>
Comprehensive loss:		
Net loss	\$ (7,393)	\$ (4,566)
Other comprehensive loss:		
Unrealized holding loss on available for sale securities	<u>(35)</u>	<u>(626)</u>
Total other comprehensive loss, net of tax	<u>(35)</u>	<u>(626)</u>
Comprehensive loss	\$ <u>(7,428)</u>	\$ <u>(5,192)</u>

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

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

	<u>Three months ended</u>	
	<u>March 30,</u>	<u>March 31,</u>
	<u>2003</u>	<u>2002</u>
Cash flows from operating activities:		
Net loss from continuing operations	\$ (7,393)	\$ (4,566)
Adjustments to reconcile net loss from continuing operations to net cash used in operating activities:		
Depreciation and amortization	747	548
Non-cash interest income (loss) from marketable securities	(51)	314
Common stock issuance to GTC savings and retirement plan	172	234
Loss on disposal of fixed assets	-	138
Changes in assets and liabilities:		
Accounts receivable and unbilled contract revenue	(726)	(221)
Other assets and liabilities	467	(212)
Accounts payable	1,807	(638)
Accounts payable – Genzyme Corporation	(1,766)	(168)
Other accrued expenses	(481)	(275)
Deferred contract revenue	229	(929)
Net cash used in operating activities	<u>(6,995)</u>	<u>(5,775)</u>
Cash flows from investing activities:		
Purchase of property, plant and equipment	(2,841)	(1,376)
Purchase of marketable securities	(4,450)	(26,109)
Redemption of marketable securities	13,108	34,782
Net cash provided by investing activities	<u>5,817</u>	<u>7,297</u>
Cash flows from financing activities:		
Proceeds from long-term debt	584	6,400
Repayment of long-term debt	(330)	(5,778)
Repayment of principal on capital leases	(113)	-
Net proceeds from employee stock purchase plan	156	164
Net proceeds from the exercise of stock options	-	3
Net cash provided by financing activities	<u>297</u>	<u>789</u>
Net increase in cash and cash equivalents	(881)	2,311
Cash and cash equivalents at beginning of period	26,911	26,850
Cash and cash equivalents at end of period	<u>\$ 26,030</u>	<u>\$ 29,161</u>
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	\$ 136	\$ 49

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 condensed consolidated financial statements should be read in conjunction with the Company's Annual Report on Form 10-K for the fiscal year ended December 29, 2002 and the financial statements and footnotes included therein. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to Securities and Exchange Commission rules and regulations.

The financial statements for the three months ended March 30, 2003 and March 31, 2002, are unaudited but include, in the Company's opinion, all adjustments necessary for a fair presentation of the results for the periods presented.

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 Company's Annual Report on Form 10-K for the fiscal year ended December 29, 2002 and updated as necessary in this Form 10-Q for the three fiscal months ended March 30, 2003.

**Revenue Recognition and Contract Accounting**

The Company enters into licensing and development agreements with collaborative partners for the transgenic development in milk of recombinant proteins for therapeutic uses. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon the achievement of certain milestones and royalties on future product sales, if any.

Non-refundable license fees, milestones and collaborative research and development revenues under collaborative agreements, where the Company has continuing involvement, are recognized as revenue over the period of continuing involvement, using the model similar to the one prescribed by Emerging Issues Task Force Issue No. 91-6 (EITF 91-6). Under that model, revenue is recognized for non-refundable license fees, milestones and collaborative research and development using the lesser of non-refundable cash received and milestones met or the result achieved using level of efforts accounting. Under the level of efforts accounting, revenue is based on the cost of effort since the contract's commencement up to the reporting date, divided by the total expected research and development costs from the contract's commencement to the end of the research and development period, multiplied by the total expected contractual payments under the arrangement. Revisions in cost estimates and expected contractual payments as contracts progress have the effect of increasing or decreasing profits in the current period. Payments received in advance of being earned are recorded as deferred revenue. When there are two or more distinct phases embedded into one contract, such as development and commercialization, the contract is considered a multiple element arrangement. When management can conclude as to the fair

value of the related items, up front license fees and milestone payments are recognized over the initial phase of the contract only.

Profits expected to be realized are based on the total contract sales value and the Company's estimates of costs at completion. The sales value is based on achievable milestones and is revised throughout the contract as the Company demonstrates achievement of milestones. The Company's estimates of costs include all costs expected to be incurred to fulfill performance obligations of the contracts. Estimates of total contract costs are reviewed and revised throughout the lives of the contracts, with adjustments to profits resulting from such revisions being recorded on a cumulative basis in the period in which the revisions are made. All revenue recognition estimates are made based upon the current facts and circumstances and are reassessed on at least a quarterly basis. If changes in these estimates or other immaterial adjustments to revenue are identified, the adjustments will be recorded as they become known.

Unbilled contract revenue represents efforts incurred or milestones achieved which had not been billed at the balance sheet date. Deferred contract revenue represents amounts received from customers that exceed the amount of revenue recognized to date.

### Accounting for Employee Equity Plans

The Company applies 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 Statement of Financial Accounting Standards No. 123 ("SFAS 123"), *Accounting for Stock Based Compensation*. 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 quarter ended March 30, 2003 would have been increased to the pro forma amounts indicated below:

	<u>March 30, 2003</u>		<u>March 31, 2002</u>	
	Net Loss Available		Net Loss Available	
	Per Common		Per Common	
	Net Loss	Share	Net Loss	Share
	<u>(in thousands)</u>	<u>(basic and diluted)</u>	<u>(in thousands)</u>	<u>(basic and diluted)</u>
Net income reported	\$ (7,393)	\$(0.27)	\$ (4,566)	\$(0.15)
Deduct: *	( 740 )	( 0.02)	( 1,112)	( 0.04)
Pro Forma net income	\$ (8,133)	\$( 0.29)	\$ (5,678)	\$(0.19)

\*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 assumption: an expected life of five years, expected volatility of 95% for the first quarter of 2003 and the first quarter of 2002, a dividend yield of 0% and a risk-free interest rate of 2.96% for the first quarter of 2003 and 4.47% for the first quarter of 2002. The average fair value of those options granted

during the first quarter of 2003 and the first quarter of 2002 was \$1.06 and \$2.53, 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 95% for the first quarter of 2003 and the first quarter of 2002, an expected life of five years for the first quarter of 2003 and 2002 and a risk-free interest rate of 1.00% for the first quarter of 2003 and 1.61% for the first quarter of 2002. The average fair value of those purchase rights granted during the first quarter of 2003 and the first quarter of 2002 was \$0.60 and \$0.95, 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. Common stock equivalents consisting of warrants and stock options, totaled 4.6 million and 3.6 million at March 30, 2003 and March 31, 2002, respectively. The increase in common stock equivalents is a result of stock option grants. Since the Company was in a net loss position at March 30, 2003 and March 31, 2002, these common stock equivalents were not used to compute diluted loss per share, as the effect would have been antidilutive.

### 3. Intangible Assets:

Intangible assets consist of:

	Amortization <u>Life</u>	March 30 <u>2003</u>	December 29, <u>2002</u>
Asian marketing rights for SMIG	15 years	\$ 11,210	\$ 11,210
Accumulated amortization - marketing rights		(1,931)	(1,744)
Net		<u>9,279</u>	<u>9,466</u>
License agreement with ACT	10 years	1,862	1,862
License agreement with Pharming	15 years	1,517	1,517
Accumulated amortization - license agreements		(789)	(717)
Net		<u>2,590</u>	<u>2,662</u>
Total intangible assets, net		\$ <u>11,869</u>	\$ <u>12,128</u>

Amortization expense was \$259,000 and \$984,000 in Q1 2003 and year end December 29, 2002, respectively.

### 4. New Accounting Pronouncements:

In November 2002, the FASB issued FIN 45, Guarantors Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, an interpretation of FASB Statements No. 5, 57, and 107 and Rescission of FASB Interpretation No. 34. FIN 45 clarifies the requirements of FASB Statement No. 5, Accounting for

Contingencies relating to the guarantors accounting for, and disclosure of, the issuance of certain types of guarantees. For guarantees that fall within the scope of FIN 45, the Interpretation requires that guarantors recognize a liability equal to the fair value of the guarantee upon its issuance. The disclosure provisions of the Interpretation are effective for financial statements of interim or annual periods that end after December 15, 2002. However, the provisions for initial recognition and measurement are effective on a prospective basis for guarantees that are issued or modified after December 31, 2002, irrespective of a guarantor's year-end. As permitted under Delaware law, we have agreements whereby we indemnify our officers and directors for certain events or occurrences while the officer or director is, or was, serving at our request in such capacity. The term of the indemnification period is for the officer's or director's lifetime. The maximum potential amount of future payments we could be required to make under these indemnification agreements is unlimited; however, we have a Director and Officer insurance policy that limits our exposure and enables us to recover a portion of any future amounts paid. As a result of our insurance policy coverage, we believe the estimated fair value of these indemnification agreements is minimal. All of these indemnification agreements were grandfathered under the provisions of FIN No. 45 as they were in effect prior to December 31, 2002. Accordingly, we have no liabilities recorded for these agreements as of March 30, 2003. The Company does not expect the disclosure or measurement provisions of FIN 45 to have a material effect on its results of operations and financial position.

In January 2003, the FASB issued FASB Interpretation No. 46, Consolidation of Variable Interest Entities, to expand upon and strengthen existing accounting guidance that addresses when a company should include in its financial statements the assets, liabilities and activities of another entity. Until now, one company generally has included another entity in its consolidated financial statements only if it controlled the entity through voting interests. FIN No. 46 changes that by requiring a variable interest entity, as defined, to be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity's activities or entitled to receive a majority of the entity's residual returns or both. FIN No. 46 also requires disclosures about variable interest entities that the company is not required to consolidate but in which it has a significant variable interest. The consolidation requirements of FIN No. 46 apply immediately to variable interest entities created after January 31, 2003 and to older entities in the first fiscal year or interim period beginning after June 15, 2003. Certain of the disclosure requirements apply in all financial statements issued after January 31, 2003, regardless of when the variable interest entity was established. The Company does not expect the provisions of FIN 46 to have a material effect on its results of operations and financial position.

Comment:

5. Long-Term Debt:

In March 2002, the Company entered into a five year Loan and Security Agreement (the "Agreement") with Silicon Valley Bank in the amount of \$11.6 million, which was applied as follows: \$5.5 million was used to refinance a prior loan from another bank, \$1.1 million refinanced previous capital asset acquisitions, \$4 million was available to finance future capital requirements, of which the remaining \$584,000 was drawn during the first quarter of 2003 and \$1 million is currently available under a revolving line of credit.

6. Taurus rhSA LLC:

In 2002, Fresenius AG and GTC restructured their relationship for the therapeutic blood expander market into a joint venture, called Taurus rhSA LLC (the "Taurus Joint Venture"), to include the development of rhSA as an excipient under an agreement that became effective January 1, 2003. The Taurus Joint Venture will manage development of rhSA for both the excipient and blood expander markets. GTC has a majority interest in the joint venture. GTC and Fresenius are making available all relevant commercial licenses, manufacturing rights, and intellectual property to enable the joint venture to operate worldwide in both the excipient and blood expander markets. During 2001 and 2002, Fresenius had added to its marketing rights for rhSA in Europe by exercising its option to the marketing rights in North America and Asia, including Japan. These marketing rights are now part of the joint venture. The excipient market is part of an integrated development plan that can also provide entry to the blood expander market. The joint venture structure allows the development of the excipient market with the potential to attract additional marketing or strategic partners that may also assist with the financing of the joint venture. Ownership interests will be adjusted based on future levels of financial participation from existing and new partners. The Taurus Joint Venture is consolidated for reporting purposes.

7. Malaria Vaccine Contract:

The NIAID has approved a proposal to fund development of clinical grade production of MSP-1. The development work will be performed under the existing NIAID Contract No. NO1-A1-05421 managed by Science Applications International Corporation. The scope of work includes developing founder goats that express the MSP-1 antigen in their milk as well as the downstream purification process and final product formulation. The approved scope of work also includes the submittal of an Investigational New Drug application to the FDA. GTC's portion of this project will be supported completely with Federal funds amounting to at least \$4.9 million paid through September 2007, a majority of which is to be paid during 2003 and 2004.

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

### RESULTS OF OPERATIONS

*Three months ended March 30, 2003 and March 31, 2002*

Total revenues for the three-month period ending March 30, 2003 were \$1.7 million, compared with \$3.8 million for the comparable period in 2002, a decrease of \$2.1 million or 55%. The 2002 revenues included approximately \$1.2 million from Fresenius AG for marketing rights in Japan for the recombinant human serum albumin (rhSA) program. Excluding revenues for marketing rights in the rhSA program, for comparison purposes, revenues from the Company's external programs were \$2.6 million in the first quarter of 2002 compared with \$1.7 million in the first quarter of 2003, a 35% decrease. This difference in the quarterly comparison is primarily due to the nature and timing of milestone revenues, as well as the \$1.2 million recognized during 2002 from Fresenius AG. The first quarter 2003 revenues are consistent with GTC's expectations for full year 2003 revenues of \$15 million to \$20 million because revenues are anticipated to increase later in 2003. We expect additional revenue as further work is completed on the MSP-1 Malaria Vaccine program. In addition, we will expect further revenue when Merrimack obtains further financing and we deliver clinical material for the Merrimack MM-093 program.

The cost of revenue and operating expenses was \$9.3 million in the current quarter, approximately 3% higher than the \$9 million recorded in the first quarter of 2002. We spent approximately \$3 million on our internal research and development programs in 2003, an increase of approximately \$1 million over the 2002 quarter, or 48%. The 2003 expenses include support for our ongoing efficacy study for the rhATIII program and preparation for a filing for approval to market rhATIII in Europe to treat hereditary antithrombin deficiency (HD).

Selling, general and administrative (SG&A) expenses decreased from \$2.9 million in the first quarter of 2002 to \$2.7 million in the corresponding quarter of 2003, a 6% decrease from the corresponding quarter. The change in SG&A included lower legal expenses of approximately \$300,000 which were partially offset by the acquisition of office and laboratory space to consolidate several functions into a single location, as well as increased expenses in information technology, regulatory affairs and corporate development.

Interest income decreased to \$292,000 in the first quarter of 2003, from \$620,000 in the first quarter of 2002. The decrease was due to a lower cash balance and the impact of lower interest rates in 2003.

Interest expense increased to \$136,000 in the first quarter of 2003 from \$49,000 in the first quarter of 2002 due to higher outstanding borrowings in 2003.

## **LIQUIDITY AND CAPITAL RESOURCES**

We used approximately \$9.5 million of cash in the first quarter, bringing the balance of cash, cash equivalents and marketable securities to \$47.8 million at March 30, 2003. This amount includes cash and cash equivalents of \$26 million.

The principal sources of funds during the period included \$584,000 in net proceeds from long-term debt, \$8.7 million in net redemptions of marketable securities and \$156,000 from the issuance of Common Stock under various employee stock plans. Uses of funds during the period included \$7 million used in operations, of which \$2 million was for manufacturing qualification runs for rhATIII, \$2.8 million invested in capital equipment and further expansion of the transgenic production facility and \$443,000 for repayment of long-term debt and capital leases. The rhATIII production is a necessary part of our planned filing for approval in Europe.

We had working capital of \$38.7 million at March 30, 2003 compared to \$47.7 million at December 29, 2002.

Management continues to expect that current cash resources and partnering revenue opportunities will be sufficient to fund operations into 2005. Revenue in 2003 is anticipated to be between \$15 million and \$20 million and we expect to use between \$20 and \$25 million in cash. The Company's projected revenue and cash use for 2003 is dependent upon attracting additional partnering revenues from existing and additional collaborations. In addition, the Company and Merrimack have signed an agreement to begin clinical production of Merrimack's MM-093 (formerly named ABI.001), a recombinant human alpha-fetoprotein (rhAFP). Revenues to the Company on this program are substantially dependent upon Merrimack completing a further equity financing. If the Company does not substantially achieve its revenue projections, the Company could be forced to delay, scale back or eliminate one or more of its research and development programs. In addition, from time to time, the Company may seek to raise additional funds from public or private sales of its securities, including equity securities. Should the Company need to raise additional financing in this manner to fund operations, there can be no assurance that additional funding will be available on terms acceptable to the Company, if at all.

Management's current expectations regarding the sufficiency of the Company's cash resources are forward-looking statements, and the Company's cash requirements may vary materially from such expectations. Such forward-looking statements are dependent on several factors, including the ability of the Company to enter into transgenic research and development collaborations in the future and the terms of such collaborations, the results of research and development and preclinical and clinical testing, competitive and technological advances and regulatory requirements.

## **CRITICAL ACCOUNTING POLICIES**

In the Company's Form 10-K for the year ended December 29, 2002, the Company's most critical accounting policies and estimates upon which the Company's financial status depends were identified as those relating to revenue recognition, accrued liabilities, investments, intangible and long-lived assets and income taxes. The Company has reviewed the policies and determined that

such policies remain the Company's most critical accounting policies for the quarter ended March 30, 2003. The Company did not make any changes to such policies during the quarter.

#### **COMMITMENTS AND CONTINGENCIES**

In the Company's Form 10-K for the year ended December 29, 2002, the Company's commitments and contingencies were disclosed in the notes to the consolidated financial statements. The Company has reviewed the commitments and contingencies at March 30, 2003 and noted that there were no material changes or additions.

The Company is 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 29, 2002. 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.* Our chief executive officer and our chief financial officer, after evaluating the effectiveness of our "disclosure controls and procedures" (as defined in the Securities Exchange Act of 1934 Rules 13a-14(c) and 15-d-14(c)) as of a date (the "Evaluation Date") within 90 days before the filing date of this quarterly report, have concluded that, as of the Evaluation Date, our disclosure controls and procedures were adequate and designed to ensure that the information required to be disclosed in the reports filed or submitted by us under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the requisite time periods.

b) *Changes in internal controls.* There were no significant changes in our internal controls or in other factors that could significantly affect our internal controls subsequent to the Evaluation Date.

PART II

**ITEM 6 – EXHIBITS AND REPORTS ON FORM 8-K**

(a) 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 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 GTC'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 with the Commission on June 2, 2000 (File No. 333-38490) and incorporated herein by reference.
3.1.5	Certificate of Vote of Directors Establishing a Series of a Class of Stock of GTC and designating the Series C Junior Participating Cumulative Preferred Stock. Filed as Exhibit 3.1 to 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.
99	Certifications pursuant to 18 U.S.C. Section 1350. Filed herewith.

(b) Reports on Form 8-K

On February 20, 2003, the Company filed a Current Report on Form 8-K (Items 7 and 9) with the SEC reporting the Company's financial results for the full year and for the fourth quarter of 2002.

**GTC BIOTHERAPEUTICS, INC. AND SUBSIDIARY  
FORM 10-Q**

**March 30, 2003**

**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: May 6, 2003

GTC BIOTHERAPEUTICS, INC.

By: /s/ John B. Green

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

## CERTIFICATIONS

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 quarterly 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 quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) Designed such disclosure controls and procedures 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 quarterly report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 6, 2003

/s/Geoffrey F. Cox  
Geoffrey F. Cox  
President, Chief Executive Officer  
and Chairman

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 quarterly 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 quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) Designed such disclosure controls and procedures 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 quarterly report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 6, 2003

/s/John B. Green

John B. Green  
Senior Vice President and  
Chief Financial Officer

## EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
10.1	Management Agreement between the Company and Daniel Woloshen dated as of May 27, 1999. Filed herewith.
10.2	Management Agreement between the Company and Gregory Liposky dated as of June 14, 2000. Filed herewith.
99	Certifications pursuant to 18 U.S.C. Section 1350. Filed herewith.

The following exhibits are incorporated herein by reference:

- 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).
- 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 Company's Annual Report on Form 10-K for the year ended December 28, 1997 (File No. 0-21794).
- 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).
- 3.1.4 Articles of Amendment to the Restated Articles of Organization of the Company filed with the Secretary of the Commonwealth of Massachusetts on June 1, 2000. Filed as Exhibit 4.1.5 to the Company's Registration Statement on Form S-8 filed with the Commission on June 2, 2000 (File No. 333-38490).
- 3.1.5 Certificate of Vote of Directors Establishing a Series of a Class of Stock of the Company 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).
- 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).
- 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.