

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 June 29, 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

____ 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 X No _____

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

Yes X No _____

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 July 30, 2003</u>
Common Stock, \$0.01 par value	28,247,887

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PART I

ITEM 1 – FINANCIAL STATEMENTS

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

	<u>June 29, 2003</u>	<u>December 29, 2002</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 17,251	\$ 26,911
Marketable securities	20,753	30,438
Accounts receivable and unbilled contract revenue	3,844	2,179
Other current assets	1,159	1,932
Total current assets	<u>43,007</u>	<u>61,460</u>
Net property, plant and equipment	23,667	21,701
Net intangible assets	11,611	12,128
Inventory	1,754	-
Other assets	130	84
	<u>\$ 80,169</u>	<u>\$ 95,373</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,571	\$ 4,448
Accounts payable - Genzyme Corporation	1,397	2,370
Accrued expenses	3,362	4,442
Deferred contract revenue	637	638
Current portion of long-term debt and capital leases	2,130	1,880
Total current liabilities	<u>11,097</u>	<u>13,778</u>
Long-term debt and capital leases, net of current portion	13,231	12,786
Deferred lease obligation	28	37
Total liabilities	<u>24,356</u>	<u>26,601</u>
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; 31,067,887 and 30,579,064 shares issued and 28,247,887 and 27,759,064 shares outstanding at June 29, 2003 and December 29, 2002, respectively	311	306
Capital in excess of par value – common stock	198,999	198,469
Treasury stock, at cost, 2,820,000 shares	(9,545)	(9,545)
Accumulated deficit	(134,043)	(120,642)
Accumulated other comprehensive income	91	184
Total shareholders' equity	<u>55,813</u>	<u>68,772</u>
	<u>\$ 80,169</u>	<u>\$ 95,373</u>

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		Six months ended	
	June 29, 2003	June 30, 2002	June 29, 2003	June 30, 2002
Revenue	\$ 4,111	\$ 3,167	\$ 5,855	\$ 7,012
Operating expenses:				
Cost of revenue	3,293	3,924	6,869	8,230
Research and development	4,261	3,068	7,285	5,106
Selling, general and administrative	2,647	3,123	5,340	5,761
	<u>10,201</u>	<u>10,115</u>	<u>19,494</u>	<u>19,097</u>
Operating loss	(6,090)	(6,948)	(13,639)	(12,085)
Other income (expense):				
Interest income	215	559	507	1,179
Interest expense	(133)	(104)	(269)	(153)
	<u>(6,008)</u>	<u>(6,493)</u>	<u>(13,401)</u>	<u>(11,059)</u>
Net loss	\$ <u>(6,008)</u>	\$ <u>(6,493)</u>	\$ <u>(13,401)</u>	\$ <u>(11,059)</u>
Net loss per common share (basic and diluted)	\$ <u>(0.21)</u>	\$ <u>(0.23)</u>	\$ <u>(0.48)</u>	\$ <u>(0.38)</u>
Weighted average number of common shares outstanding (basic and diluted)	<u>28,058</u>	<u>27,916</u>	<u>27,920</u>	<u>29,072</u>
Comprehensive loss:				
Net loss	\$ (6,008)	\$ (6,493)	\$ (13,401)	\$ (11,059)
Other comprehensive income:				
Unrealized change in holding gain (loss) on available for sale securities	(58)	444	(93)	(181)
Total other comprehensive income (loss)	<u>(58)</u>	<u>444</u>	<u>(93)</u>	<u>(181)</u>
Comprehensive loss	<u>\$ (6,066)</u>	<u>\$ (6,049)</u>	<u>\$ (13,494)</u>	<u>\$ (11,240)</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>Six months ended</u>	
	<u>June 29,</u> <u>2003</u>	<u>June 30,</u> <u>2002</u>
Cash flows from operating activities:		
Net loss	\$ (13,401)	\$ (11,059)
Adjustments to reconcile net loss from operations to net cash used in operating activities:		
Depreciation and amortization	1,516	1,121
Amortization of premium/discount on marketable securities	(320)	201
Non-cash common stock issuance to GTC savings and retirement plan	172	234
Provision for doubtful accounts	-	331
Loss on disposal of fixed assets	-	140
Changes in assets and liabilities:		
Accounts receivable and unbilled contract revenue	(1,665)	(1,531)
Inventory	(1,625)	-
Other assets and liabilities	718	(1,580)
Accounts payable	(877)	1,375
Accounts payable – Genzyme Corporation	(973)	638
Accrued expenses	(1,080)	(1,056)
Deferred contract revenue	(1)	(1,493)
Net cash used in operating activities	<u>(17,536)</u>	<u>(12,679)</u>
Cash flows from investing activities:		
Purchase of property, plant and equipment	(3,094)	(2,658)
Purchase of marketable securities	(15,118)	(34,609)
Redemption of marketable securities	25,030	47,297
Net cash provided by investing activities	<u>6,818</u>	<u>10,030</u>
Cash flows from financing activities:		
Proceeds from long-term debt	1,624	9,029
Repayment of long-term debt	(760)	(6,065)
Repayment of principal on capital leases	(169)	(89)
Acquisition of treasury stock from Genzyme Corporation	-	(4,773)
Net proceeds from employee stock purchase plan	363	293
Net proceeds from the exercise of stock options	-	3
Net cash provided by (used in) financing activities	<u>1,058</u>	<u>(1,602)</u>
Net decrease in cash and cash equivalents	<u>(9,660)</u>	<u>(4,251)</u>
Cash and cash equivalents at beginning of period	26,911	26,850
Cash and cash equivalents at end of period	<u>\$ 17,251</u>	<u>\$ 22,599</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 condensed consolidated financial statements should be read in conjunction with the Annual Report on Form 10-K of GTC Biotherapeutics, Inc. (the "Company" or "GTC") 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 accounting principles generally accepted in the United States of America have been condensed or omitted pursuant to Securities and Exchange Commission ("SEC") rules and regulations.

The financial statements for the six months ended June 29, 2003 and June 30, 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 six fiscal months ended June 29, 2003.

Revenue Recognition and Contract Accounting

The Company enters into licensing and development agreements with collaborative partners for the development of production and purification of therapeutic recombinant proteins produced in the milk of transgenic animals. 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 three and six months ended June 29, 2003 and June 30, 2002 would have been increased to the pro forma amounts indicated below:

	Three Months Ended		Six Months Ended	
	June 29, <u>2003</u>	June 30, <u>2002</u>	June 29, <u>2003</u>	June 30, <u>2002</u>
Net loss reported	\$ (6,008)	\$ (6,493)	\$ (13,401)	\$ (11,059)
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	<u>(605)</u>	<u>(635)</u>	<u>(1,378)</u>	<u>(1,747)</u>
Pro Forma net loss	\$ <u>(6,613)</u>	\$ <u>(7,128)</u>	\$ <u>(14,779)</u>	\$ <u>(12,806)</u>
Earnings per share:				
Basic - as reported (basic and diluted)	\$ (0.21)	\$ (0.23)	\$ (0.48)	\$ (0.38)
Basic - pro forma (basic and diluted)	\$ (0.24)	\$ (0.26)	\$ (0.53)	\$ (0.44)

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 100% for the second quarter of 2003 and 95% for the second quarter of 2002, a dividend yield of 0% and a risk-free interest rate of 2.96% for the second quarter of 2003 and 4.47% for the second quarter of 2002. The average fair value of those options granted during the second quarter of 2003 and the second quarter of 2002 was \$1.95 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 100% for the second quarter of 2003 and 95% for the second quarter of 2002, an expected life of five years for the second quarter of 2003 and 2002 and a risk-free interest rate of 1.08% for the second quarter of 2003 and 1.61% for the second quarter of 2002. The average fair value of those purchase rights granted during the second quarter of 2003 and the second quarter of 2002 was \$0.68 and \$0.95, respectively.

Inventories

The Company capitalizes inventory produced for commercial sale, which may result in the capitalization of inventory that has not yet been approved for sale by regulatory authorities such as the FDA. If a product is not approved for sale, it would likely result in the write-off of the inventory and a charge to earnings. When and if capitalized inventory is used for research and development of clinical trials, it will be expensed accordingly at that time. At June 29, 2003, the Company's total inventories consisted of \$1.8 million of finished goods inventory for products that have not yet been approved for sale.

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 3.7 million at June 29, 2003 and June 30, 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 June 29, 2003 and June 30, 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>	June 29, <u>2003</u>	December 29, <u>2002</u>
Asian marketing rights for SMIG	15 years	\$ 11,210	\$ 11,210
Accumulated amortization - marketing rights		<u>(2,117)</u>	<u>(1,744)</u>
Net		<u>9,093</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		<u>(861)</u>	<u>(717)</u>
Net		<u>2,518</u>	<u>2,662</u>
Total intangible assets, net		<u>\$ 11,611</u>	<u>\$ 12,128</u>

Amortization expense was \$259,000 and \$234,000 for the three months ended June 29, 2003 and June 30, 2002, respectively, and \$517,000 and \$467,000 for the six months ended June 29, 2003 and June 30, 2002, respectively.

4. New Accounting Pronouncements:

In November 2002, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. ("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 FIN 45 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, the Company has agreements whereby the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is, or was, serving at its 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 the Company could be required to make under these indemnification agreements is unlimited; however, the Company has a Director and Officer insurance policy that limits its exposure and enables it to recover a portion of any future amounts paid. As a result of its insurance policy coverage, the Company believes the estimated fair value of these indemnification agreements is minimal. All of these indemnification agreements were grandfathered under the provisions of FIN 45 as they were in effect prior to December 31, 2002. The Company has not entered into any new agreements that warrant a liability under FIN 45. Accordingly, the Company has no liabilities recorded for these agreements as of

June 29, 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 FIN 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 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 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 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 provisions of FIN 46 will not have a material effect on the Company's results of operations and financial position.

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 that was put into place to finance capital asset acquisitions, \$1.1 million to refinance previous capital asset acquisitions and \$4 million to finance capital requirements. Approximately \$1 million remains currently available under a revolving line of credit.

In June 2003, the Company entered into a Loan Modification Agreement (the "Modification Agreement") with Silicon Valley Bank. The Modification Agreement established a "2003 Committed Equipment Line" which made an additional \$2,250,000 available to the Company for the financing of capital asset acquisitions. During the second quarter of 2003, \$1,020,000 of this line was drawn down and \$1,230,000 remains available to finance future capital asset acquisitions. All other terms and conditions remain unchanged from the original agreement entered into in March 2002.

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 currently has a majority interest in the joint venture. GTC and Fresenius made available all relevant commercial licenses, manufacturing and marketing rights, and intellectual property to enable the joint venture to

operate worldwide in both the excipient and blood expander markets. 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 Company consolidates the Taurus Joint Venture for financial 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 is being 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 is being supported completely with Federal funds amounting to at least \$4.9 million to be paid through September 2007, a majority of which is to be paid during 2003 and 2004.

8. Merrimack Pharmaceuticals, Inc. ("Merrimack"):

In June 2003, the Company and Merrimack executed a definitive agreement for the clinical production and purification of MM-093. Payment to the Company is substantially dependent upon Merrimack completing further equity financing.

9. Subsequent Event:

On August 1, 2003, the Company issued and sold 3,626,465 shares of common stock at \$2.55 per share in a private placement to institutional investors. The Company also issued warrants to the investors to purchase an aggregate of 906,613 shares of the Company's Common Stock at an exercise price of \$3.30 per share. The Company paid SG Cowen a placement agent fee plus warrants to purchase 54,396 shares of the Company's Common Stock on the same terms as the placement warrants. Net proceeds to the Company, before other expenses, were approximately \$8.6 million.

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

RESULTS OF OPERATIONS

Three months ended June 29, 2003 and June 30, 2002

Total revenues for the three-month period ending June 29, 2003 were \$4.1 million, compared with \$3.2 million for the comparable period in 2002, an increase of \$900,000 or 30%. The 2002 revenues included approximately \$700,000 from Fresenius AG for the recombinant human serum albumin (rhSA) program. The rhSA program was structured into a joint venture in January 2003 which is consolidated for financial reporting purposes in the Company's financial statements. Excluding the 2002 revenues from the rhSA program, for comparison purposes, revenues were \$2.5 million in the second quarter of 2002 compared to \$4.1 million in the second quarter of 2003, an increase of \$1.6 million, or 64%. The second 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 in the second half of 2003 to the extent that GTC attracts partnering revenues in the rhATIII and rhSA programs and new external programs and obtains additional revenues from existing external programs, including the program with Merrimack Pharmaceuticals for clinical production of MM-093.

Operating expenses were \$10.2 million in the current quarter, approximately flat with the \$10.1 million recorded in the second quarter of 2002. GTC spent approximately \$4.3 million on its internal research and development programs in the second quarter of 2003, an increase of approximately \$1.2 million, or 39%, over the comparable 2002 quarter. The 2003 expenses include approximately \$1.9 million to support the 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). Cost of revenue in the second quarter of 2003 was \$3.3 million, compared with \$3.9 million for the comparable period in 2002, a decrease of \$600,000 or 16%. The decrease is due to the nature and timing of development activities on the Company's external programs.

Selling, general and administrative expenses (SG&A) decreased from \$3.1 million in the second quarter of 2002 to \$2.6 million in the corresponding quarter of 2003, a 15% decrease. The change in SG&A was the result of there being no increases in bad debt reserves in 2003 compared to a \$331,000 increase in 2002, as well as a reduction of approximately \$300,000 in legal expenses in 2003 compared to 2002, which were partially offset by increased expenses related to the acquisition of office and laboratory space of approximately \$200,000 to consolidate several functions into a single location.

Interest income decreased to \$215,000 in the second quarter of 2003, from \$559,000 in the second quarter of 2002. The decrease was due to a lower cash balance and to the impact of lower interest rates in 2003.

Interest expense increased to \$133,000 in the second quarter of 2003, from \$104,000 in the second quarter of 2002 due to higher outstanding borrowings in 2003.

Six months ended June 29, 2003 and June 30, 2002

Total revenues for the six-month period ending June 29, 2003 were \$5.9 million, compared with \$7 million for the comparable period in 2002, a decrease of \$1.2 million or 17%. The 2002 revenues included approximately \$1.8 million from Fresenius AG for the rhSA program. The rhSA program was structured as a joint venture in January 2003. Excluding revenues from the rhSA program, for comparison purposes, revenues from the Company's external programs were \$5.2 million in the first six months of 2002 compared with \$5.9 million in the first six months of 2003, a 13% increase. The six-month 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 in the second half of 2003 to the extent that GTC attracts partnering revenues in the rhATIII and rhSA programs and new external programs, and obtains additional revenues from existing external programs.

The cost of revenue and operating expenses were \$19.5 million in the first six months of 2003, compared with \$19.1 million for the comparable period in 2002, an increase of \$400,000 or 2%. GTC spent approximately \$7.3 million on internal research and development programs in the first six months of 2003, an increase of approximately \$2.2 million over the first six months of 2002, or 43%. The 2003 expenses include approximately \$3.2 million to support the ongoing efficacy study for the rhATIII program and preparation for a filing for approval to market rhATIII in Europe to treat HD. Cost of revenue for the first six months of 2003 was \$6.9 million, compared with \$8.2 million for the comparable period in 2002, a decrease of \$1.4 million or 17%, which is in line with the decrease in revenues for the first six months of 2003.

SG&A decreased from \$5.8 million in the first six months of 2002 to \$5.3 million in the first six months of 2003, a 7% decrease. The change in SG&A was the result of there being no increases in bad debt reserves in 2003 compared to a \$331,000 increase in 2002, as well as a reduction of approximately \$400,000 in legal expenses in 2003 compared to 2002, which were partially offset by increased expenses related to the acquisition of office and laboratory space of approximately \$200,000 to consolidate several functions into a single location.

Interest income decreased to \$507,000 in the first six months of 2003, from \$1.2 million in the first six months of 2002. The decrease was due to a lower cash balance and to the impact of lower interest rates in 2003.

Interest expense increased to \$269,000 in the first six months of 2003, from \$153,000 in the first six months of 2002 due to higher outstanding borrowings in 2003.

LIQUIDITY AND CAPITAL RESOURCES

GTC used approximately \$19.3 million of cash in the first six months of 2003, bringing the balance of cash, cash equivalents and marketable securities to \$38 million at June 29, 2003. This amount includes cash and cash equivalents of \$17.3 million.

The principal sources of funds during the period included \$1.6 million in proceeds from long-term debt, \$9.9 million in net redemptions of marketable securities and \$363,000 from the issuance of common stock under various employee stock plans. Uses of funds during the period included \$17.5 million used in operations, of which \$13.4 million was due to the Company's net loss, \$1.6 million was for manufacturing of inventory for rhATIII, \$1.7 million was due to an increase in accounts receivable and unbilled revenues, \$3.1 million for capital equipment and further expansion of the transgenic production facility, of which \$2.6 million was for manufacturing qualification runs for rhATIII and \$929,000 for repayment of long-term debt and capital leases. The rhATIII production is a necessary part of the planned filing for approval in Europe.

GTC had working capital of \$31.9 million at June 29, 2003 compared to \$47.7 million at December 29, 2002.

On August 1, 2003, the Company issued and sold 3,626,465 shares of common stock at \$2.55 per share in a private placement to institutional investors. The Company also issued warrants to the investors to purchase an aggregate of 906,613 shares of the Company's Common Stock at an exercise price of \$3.30 per share. The Company paid SG Cowen a placement agent fee plus warrants to purchase 54,396 shares of the Company's Common Stock on the same terms as the placement warrants. Net proceeds to the Company, before other expenses, were approximately \$8.6 million.

Management believes that existing cash resources plus proceeds from the August 1, 2003 private placement of common stock and warrants and partnering revenue opportunities will be sufficient to fund operations into the second half of 2005. Revenue in 2003 is projected to be between \$15 million and \$20 million with a cash use of between \$20 and \$25 million exclusive of the August 2003 equity financing. The Company's forecasted revenue and cash use for 2003 is dependent upon attracting additional partnering revenues from existing and additional collaborations. Management projects that net operating cash use will decrease in the second half of 2003 based on anticipated partnering payments on the rhATIII and rhSA programs as well as payments for external programs, including the Merrimack program. Additionally, the Company incurred a significant portion of the costs on the Merrimack and ATIII development programs in the first half of 2003, including approximately \$1.6 million for manufacturing inventory for rhATIII and \$2.6 million for manufacturing qualification runs for rhATIII. Revenues from the Merrimack program as well as the collection of the Company's outstanding receivables for the Merrimack program are substantially dependent upon Merrimack completing further equity financing. Revenue recognized year-to-date under the Merrimack program during fiscal 2003 was approximately \$2.8 million. Approximately \$2.4 million was outstanding as a receivable/unbilled at June 29, 2003. The Company believes that collection of the outstanding receivable is reasonably assured; however, if Merrimack does not complete its financing, the Company may not be able to collect the full receivable balance. 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, 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 future revenues, development programs and 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 AND SIGNIFICANT JUDGMENTS

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 June 29, 2003. The Company did not make any changes to such policies during the quarter.

The Company established an inventory policy during 2003 under which the Company values inventories at cost or, if lower, fair value. 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.

The Company capitalizes inventory produced for commercial sale, which may result in the capitalization of inventory that has not yet been approved for sale by regulatory authorities such as the FDA. If a product is not approved for sale, it would likely result in the write-off of the inventory and a charge to earnings. When and if capitalized inventory is used for research and development or clinical trials, it will be expensed accordingly at that time. At June 29, 2003, the Company's total inventories consisted of \$1.8 million of finished goods inventory for products that have not yet been approved for sale.

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 June 29, 2003 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 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

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 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 of 1934, as amended) 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

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

At the Annual Meeting of Stockholders held on May 21, 2003, the Company's stockholders voted as follows:

To elect each of the following nominees to the Board of Directors for a three-year term.

<u>Nominee</u>	<u>Total Vote "FOR"</u>	<u>Total Vote Withheld</u>
Geoffrey F. Cox	24,259,662	156,950
Pamela W. McNamara	24,258,674	157,938
Marvin L. Miller	24,259,660	156,952

To approve the Company's 2003 Employee Stock Purchase Plan

<u>Total Vote "FOR"</u>	<u>Total Vote "AGAINST"</u>	<u>Total Vote "ABSTAIN"</u>
23,972,176	376,946	67,490

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 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 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.
- 10 Agreement Relating to the Production of Clarified Goat Milk Containing Recombinant Human Alpha Fetoprotein by and between the Company and Merrimack Pharmaceuticals, Inc. 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.

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

** Indicates that the exhibit accompanies this report and is not filed as a part of it.

(b) Reports on Form 8-K

On April 23, 2003, the Company filed with the SEC a Current Report on Form 8-K (Items 7 and 9) reporting the Company's financial results for the first quarter of 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: August 4, 2003

GTC BIOTHERAPEUTICS, INC.

By: /s/ John B. Green

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

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 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: August 4, 2003

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

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 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: August 4, 2003

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

EXHIBIT INDEX

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

** Indicates that the exhibit accompanies this report and is not filed as a part of it.

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).
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- 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.

**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 June 29, 2003, 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: August 4, 2003

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

Date: August 4, 2003

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

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request