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**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 July 4, 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**

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**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.

<u>Class</u>	<u>Outstanding at August 3, 2004</u>
Common Stock, \$0.01 par value	38,740,165

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**PART I - FINANCIAL INFORMATION**

**ITEM 1 – UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS**

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

	<u>July 4, 2004</u>	<u>December 28, 2003</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 13,701	\$ 6,733
Marketable securities	20,656	24,358
Accounts receivable and unbilled contract revenue	1,033	1,613
Deferred contract costs	533	—
Other current assets	1,621	1,777
	<u>37,544</u>	<u>34,481</u>
Total current assets	37,544	34,481
Net property, plant and equipment	21,903	22,600
Net intangible assets	10,576	11,094
Inventory	1,566	1,574
Other assets	1,316	1,323
Restricted cash	450	—
	<u>73,355</u>	<u>71,072</u>
Total assets	\$ 73,355	\$ 71,072
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,264	\$ 2,340
Accrued liabilities	3,409	3,524
Accrued liabilities - Genzyme	3,302	1,924
Deferred contract revenue	1,059	323
Current portion of long-term debt and capital leases	2,221	2,218
Note payable - Genzyme	2,386	—
	<u>14,641</u>	<u>10,329</u>
Total current liabilities	14,641	10,329
Long-term debt and capital leases, net of current portion	8,170	7,769
Note payable – Genzyme	2,387	4,773
Deferred lease obligation	31	40
	<u>25,229</u>	<u>22,911</u>
Total liabilities	25,229	22,911
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; 41,520,253 and 34,749,473 shares issued and 38,700,253 and 31,929,473 shares outstanding at July 4, 2004 and December 28, 2003, respectively	415	347
Capital in excess of par value – common stock	222,440	207,535
Treasury stock, at cost, 2,820,000 shares	(9,545)	(9,545)
Accumulated deficit	(165,014)	(150,179)
Accumulated other comprehensive income	(170)	3
	<u>48,126</u>	<u>48,161</u>
Total shareholders' equity	48,126	48,161
	<u>\$ 73,355</u>	<u>\$ 71,072</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	
	July 4, 2004	June 29, 2003	July 4, 2004	June 29, 2003
<b>Revenues</b>				
Revenue	\$ 1,416	\$ 4,111	\$ 2,463	\$ 5,855
Revenue from related party (Genzyme)	23	—	42	—
	1,439	4,111	2,505	5,855
<b>Costs of revenue and operating expenses:</b>				
Cost of revenue	1,491	3,293	2,563	6,869
Research and development	3,625	4,261	9,065	7,285
Selling, general and administrative	2,421	2,647	5,618	5,340
	7,537	10,201	17,246	19,494
<b>Operating loss</b>	(6,098)	(6,090)	(14,741)	(13,639)
<b>Other income (expense):</b>				
Interest income	125	215	108	507
Interest expense	(332)	(133)	(474)	(269)
Other income	46	—	272	—
	(6,259)	(6,008)	(14,835)	(13,401)
<b>Net loss</b>	(6,259)	(6,008)	(14,835)	(13,401)
<b>Net loss per common share (basic and diluted)</b>	\$ (0.16)	\$ (0.21)	\$ (0.41)	\$ (0.48)
<b>Weighted average number of common shares outstanding (basic and diluted)</b>	38,692	28,058	35,998	27,920
<b>Comprehensive loss:</b>				
Net loss	\$ (6,259)	\$ (6,008)	\$ (14,835)	\$ (13,401)
<b>Other comprehensive income:</b>				
Unrealized change in holding loss on securities available for sale	(157)	(58)	(173)	(93)
<b>Total other comprehensive loss</b>	(157)	(58)	(173)	(93)
<b>Comprehensive loss</b>	\$ (6,416)	\$ (6,066)	\$ (15,008)	\$ (13,494)

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

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

	Six months ended	
	July 4, 2004	June 29, 2003
<b>Cash flows from operating activities:</b>		
Net loss	\$(14,835)	\$(13,401)
Adjustments to reconcile net loss from continuing operations to net cash used in operating activities:		
Depreciation and amortization	1,977	1,516
Stock based compensation	475	—
Amortization of premium (discount) on marketable securities	1,098	(320)
Non-cash common stock issuance to GTC savings and retirement plan	309	172
Inventory write-off	8	—
Changes in assets and liabilities:		
Accounts receivable and unbilled contract revenue	580	(1,665)
Inventory	—	(1,625)
Deferred contract costs	(533)	—
Other assets and liabilities	154	718
Accounts payable	(76)	(877)
Accrued liabilities	(115)	(1,080)
Accrued liabilities – Genzyme	1,378	(973)
Deferred contract revenue	736	(1)
	<u>(8,844)</u>	<u>(17,536)</u>
<b>Net cash used in operating activities</b>		
<b>Cash flows from investing activities:</b>		
Purchase of property, plant and equipment	(762)	(3,094)
Purchase of marketable securities	(14,804)	(15,118)
Redemption of marketable securities	17,235	25,030
Restricted cash	(450)	—
	<u>1,219</u>	<u>6,818</u>
<b>Net cash provided by investing activities</b>		
<b>Cash flows from financing activities:</b>		
Net proceeds from the issuance of common stock, net of offering costs	13,868	—
Net proceeds from long-term debt	10,386	1,624
Repayment of long-term debt	(9,868)	(760)
Repayment of principal on capital leases	(114)	(169)
Net proceeds from employee stock purchase plan	210	363
Net proceeds from the exercise of stock options	111	—
	<u>14,593</u>	<u>1,058</u>
<b>Net cash provided by financing activities</b>		
Net increase (decrease) in cash and cash equivalents	6,968	(9,660)
Cash and cash equivalents at beginning of period	6,733	26,911
	<u>\$ 13,701</u>	<u>\$ 17,251</u>
<b>Cash and cash equivalents at end of period</b>		

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 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 July 4, 2004 and June 29, 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.

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 28, 2003, referred to as the Company's 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 six months ended July 4, 2004 and June 29, 2003 would have been increased to the pro forma amounts indicated below:

	Three Months Ended		Six Months Ended	
	July 4, 2004	June 29, 2003	July 4, 2004	June 29, 2003
Net loss reported	(6,259)	\$ (6,008)	\$(14,835)	\$(13,401)
Add: *	—	—	35	—
Deduct: **	(518)	(605)	(1,388)	(1,378)
<b>Pro Forma net loss</b>	<b>\$ (6,777)</b>	<b>\$ (6,613)</b>	<b>\$(16,188)</b>	<b>\$(14,779)</b>
<b>Earnings per share:</b>				
Basic – as reported (basic and diluted)	\$ (0.16)	\$ (0.21)	\$ (0.41)	\$ (0.48)
Basic – Pro Forma (basic and diluted)	\$ (0.18)	\$ (0.24)	\$ (0.45)	\$ (0.53)

\* 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 assumption: an expected life of five years, expected volatility of 100% for the second quarters of 2004 and 2003 and the six months ended 2004 and 2003, a dividend yield of 0% and a risk-free interest rate of 3.11% for the second quarter of 2004 and the six months ended 2004, and 2.96% for the second quarter of 2003 and the six months ended 2003. The average fair value per share of those options granted during the second quarters of 2004 and 2003 was \$1.38 and \$1.95, respectively. The average fair value per share of those options granted during the first six months of 2004 and 2003 was \$2.70 and \$1.12, 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 quarters of 2004 and 2003 and the six months ended 2004 and 2003, an expected life of three months for the second quarter of 2004 and 2003 and the six months ended 2004 and 2003 and a risk-free interest rate of 0.98% for the second quarter of 2004 and the six months ended 2004 and 1.08% for the second quarter of 2003 and the six months ended 2003. The average fair value of those purchase rights granted during the second quarters of 2004 and 2003 was \$0.86 and \$0.68, respectively. The average fair value of those purchase rights granted during the first six months of 2004 and 2003 was \$0.96 and \$0.65, 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 4.6 million at July 4, 2004 and June 29, 2003, respectively. The increase in potential common shares is a result of warrants issued in connection with the August 1, 2003 private placement and stock option grants. Since the Company was in a net loss position at July 4, 2004 and June 29, 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 July 4, 2004 and December 28, 2003 was finished goods and is 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. Although no specific clinical plans require it to date, 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.

4. Accrued Liabilities:

Accrued liabilities include the following:

	(in thousands)	
	At July 4, 2004	At December 28, 2003
Accrued payroll and benefits	\$ 1,863	\$ 1,714
Accrued bonus	189	727
Other	1,357	1,083
<b>Total accrued expenses</b>	<b>\$ 3,409</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)
	<hr/>
Balance at April 4, 2004	624,000
	<hr/>
Q2 Payments	(233,000)
	<hr/>
Balance at July 4, 2004	\$ 391,000
	<hr/>

5. Intangible Assets:

The Company's intangible assets as of July 4, 2004 and December 28, 2003 consist of:

	Amortization Life	(in thousands)	
		July 4, 2004	December 28, 2003
Marketing rights	15 years	\$ 11,210	\$ 11,210
Accumulated amortization—marketing rights		(2,864)	(2,491)
		<hr/>	<hr/>
Net		8,346	8,719
		<hr/>	<hr/>
Technology licenses	10 years to 15 years	3,379	3,379
Accumulated amortization — technology licenses		(1,149)	(1,004)
		<hr/>	<hr/>
Net		2,230	2,375
		<hr/>	<hr/>
Total intangible assets, net		\$ 10,576	\$ 11,094
		<hr/>	<hr/>

Amortization expense was \$259,000 for the three months ended July 4, 2004 and June 29, 2003, and \$518,000 for the six months ended July 4, 2004 and June 29, 2003.

The estimated aggregate amortization expense for the next five fiscal years is \$1,038,000 per year from 2004 through 2008 and \$5,904,000 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 Agreement 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.

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 GTC'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 contract in excess of revenues recognized to date if the costs incurred are recoverable and the 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 July 4, 2004, the Company had \$533,000 of capitalized costs which are classified as deferred contract costs on the balance sheet.

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 matters cannot be predicted with certainty, the disposition of the matter should not have a material adverse effect on the financial position of the Company.

## **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.

GTC is dependent upon funding from partnering programs, equity financings and proceeds from 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, the Company's 2003 Form 10-K and the information set forth under the heading "Critical Accounting Policies and Estimates" in the Company's 2003 Form 10-K. 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 Note 2 in the Notes to Consolidated Financial Statements included in Item 15 of the Company's 2003 Form 10-K.

## Results of Operations

As the Company generates net losses, the key drivers for the losses are costs of revenue, research and development, 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. As a result of these restructurings, reductions of approximately \$909,000, \$719,000 and \$253,000 were realized in cost of revenue, research and development and selling, general and administrative expenses, respectively, during the second quarter of 2004, totaling approximately \$1.9 million as compared with the second quarter of 2003.

*Three months ended July 4, 2004 and June 29, 2003*

	(\$ in thousands)			
	July 4, 2004	June 29, 2003	\$ Change	% Change
Revenue	\$ 1,416	\$ 4,111	\$(2,695)	(66)%
Revenue from related party (Genzyme)	\$ 23	\$ —	\$ 23	100%
<b>Total Revenue</b>	<b>\$ 1,439</b>	<b>\$ 4,111</b>	<b>\$(2,672)</b>	<b>(65)%</b>
Cost of revenue	\$ 1,491	\$ 3,293	\$(1,802)	(55)%
Research and development	\$ 3,625	\$ 4,261	\$ (636)	(15)%
Selling, general and administrative	\$ 2,421	\$ 2,647	\$ (226)	(9)%

*Revenue.* During the second quarter of 2004, \$1.2 million of the revenues were derived from external development programs, primarily Merrimack Pharmaceuticals and Centocor, and \$234,000 of the revenues were 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. During the second quarter of 2003, \$3.2 million of the revenues were derived from external programs while \$858,000 of the revenues were derived from the malaria program. The 2003 revenues from external programs were primarily derived from the achievement of milestones in connection with programs with Merrimack and Elan. Due to the nature and timing of the Company's milestone-based research and development revenues, the Company expects to see variation in reported revenues 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 \$873,000 in the quarter to \$1.1 million representing revenues deferred to future accounting periods on existing contracts in process.

*Cost of revenue.* In addition to the impact of the restructuring, cost of revenue decreased by approximately \$100,000 due to reductions in direct outside costs as well as \$533,000 of deferred contract costs recorded on the balance sheet which relate to work done on two contracts for which no revenue has been recognized to date. The remaining decrease in

cost of revenue is due to the nature and timing of development activities for the Company's external programs. 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 second quarter 2004 expenses, approximately \$2.1 million were incurred to support the regulatory filing for approval to market ATryn<sup>®</sup> in Europe to treat hereditary antithrombin deficiency, compared with \$2 million in the second quarter of 2003. In the second quarter of 2003, an additional \$1.2 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<sup>®</sup>. Total ATryn<sup>®</sup> spending in the second quarter of 2003, including the capitalized costs, was \$3.2 million. Additionally, in the second quarter of 2004 and 2003, respectively, the Company incurred expenses of \$400,000 and \$500,000 in the development of the rhSA program, \$200,000 and \$700,000 in the development of the malaria program, and \$900,000 and \$1.1 million 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<sup>®</sup> and other programs. Absent a further ATryn<sup>®</sup> clinical trial in 2004, research and development expenses are expected to decline in 2004 as compared with 2003, primarily as a result of the completion of the 2003 ATryn<sup>®</sup> clinical trial for EMEA submission as well as the overall implementation of cost reduction measures.

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

Six months ended July 4, 2004 and June 29, 2003

	(\$ in thousands)			
	July 4, 2004	June 29, 2003	\$ Change	% Change
Revenue	\$ 2,463	\$ 5,855	\$(3,392)	(58)%
Revenue from related party (Genzyme)	\$ 42	\$ —	\$ 42	100%
<b>Total Revenue</b>	<b>\$ 2,505</b>	<b>\$ 5,855</b>	<b>\$(3,350)</b>	<b>(57)%</b>
Cost of revenue	\$ 2,563	\$ 6,869	\$(4,306)	(63)%
Research and development	\$ 9,065	\$ 7,285	\$ 1,780	24%
Selling, general and administrative	\$ 5,618	\$ 5,340	\$ 278	5%
Interest income	\$ 108	\$ 507	\$ (399)	(79)%

*Revenue.* During the first six months of 2004, \$1.7 million of the revenues were derived from external development programs, primarily Merrimack Pharmaceuticals and Centocor, and \$792,000 of the revenues were derived from the malaria program which is funded by the NIAID. During the first six months of 2003, \$4 million of the revenues were derived

from external programs while \$1.9 million of the revenues were derived from the malaria program. The 2003 revenues from external programs were primarily derived from the achievement of milestones in connection with the Merrimack, Elan and Bristol-Myers Squibb programs as well as a license agreement with TransOva Genetics. Due to the nature and timing of the Company's milestone-based research and development revenues, the Company expects to see variation in reported revenues 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 \$736,000 in the first six months to \$1.1 million, representing revenues deferred to future accounting periods on existing contracts in process.

*Cost of revenue and operating expenses.* The expenses for the first six 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 six 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 six months of 2004 was approximately \$600,000 as compared with the first six months of 2003.

*Cost of revenue.* In addition to \$533,000 of deferred contract costs recorded in the balance sheet, which relate to work done on two contracts for which no revenue has been recognized to date, the remaining decrease in cost of revenue is due to the nature and timing of development activities for the Company's external programs. 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 expenses for the first six months of 2004, approximately \$4.3 million was incurred to support the completion of the efficacy study and the preparation for regulatory filing for approval to market ATryn<sup>®</sup> in Europe to treat hereditary antithrombin deficiency, compared with \$3.2 million in the first six months of 2003. In the first six months of 2003, an additional \$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<sup>®</sup>.

Additionally, in the first six months of 2004 and 2003, respectively, the Company incurred expenses of \$900,000 and \$1 million in the development of the rhSA program, \$700,000 and \$900,000 in the development of the malaria program and \$3.2 million and \$2.2 million 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<sup>®</sup> and other programs. Absent a further clinical trial in 2004, research and development expenses are expected to decline in 2004 as compared with 2003, primarily as a result of the completion of the 2003 ATryn<sup>®</sup> clinical trial for EMEA submission as well as the overall implementation of cost reduction measures.

*Selling, General and Administrative Expense.* The increase in selling, general and administrative expenses in the first six months of 2004 is primarily due to \$743,000 of costs associated with the 2004 restructuring, partially offset by \$465,000 in net reductions in all other selling, general and administrative expenses.

*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.

### **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 during the year will be affected by the progress of the regulatory review of ATryn<sup>®</sup>, 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 and clinical testing of the Company's internal products, competitive and technological advances, and regulatory requirements.

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 had cash, cash equivalents and marketable securities of approximately \$34.4 million at July 4, 2004. This amount includes cash and cash equivalents of \$13.7 million. The Company had working capital of \$22.9 million at July 4, 2004 compared to \$24.2 million at December 28, 2003.

### **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 GTC's shelf registration statement previously filed with the Securities and Exchange Commission. 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 \$15.2 million of outstanding long-term debt at July 4, 2004, approximately \$4.6 million is classified as current. Approximately \$9.9 million was related to a term loan with GE Capital, with monthly payments through 2008, approximately \$493,000 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 Agreement 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 six months of 2004 included \$2.4 million in net redemptions of marketable securities in the Company's portfolio, approximately \$1,046,000 in new proceeds from refinancing the SVB debt and \$321,000 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 \$14.8 million) included \$8.8 million used in operations.

Other uses of funds during the period included:

- \$450,000 restricted as a result of refinancing the SVB debt; and
- \$533,000 of deferred contract costs; and
- \$762,000 for capital equipment and further expansion of the transgenic production facility.

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. If the Company does not substantially achieve its partnering revenues or out-licensing arrangements, 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 seek 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.

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**

In the Company's Form 10-K for the year ended December 28, 2003, 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 July 4, 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 4 – SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

At the Annual Meeting of Stockholders held on May 26, 2004, 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>
James A. Geraghty	32,441,517	1,064,521
Robert W. Baldrige	33,158,550	347,488

The directors whose term of office as a director continued after the meeting are Francis J. Bullock, Geoffrey F. Cox, Pamela W. McNamara, Marvin L. Miller and Alan W. Tuck.

To approve the Company's Amended and Restated 2002 Equity Incentive Plan

<u>Total Vote "FOR"</u>	<u>Total Vote "AGAINST"</u>	<u>Total Vote "ABSTAIN"</u>
14,976,025	2,380,065	151,328

### 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 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 Master Security Agreement by and between the Company and General Electric Capital Corporation dated May 26, 2004. Filed as Exhibit 99.1 to the Company's Current Report on Form 8-K filed on May 27, 2004 (File No. 0-21794) (the "May 2004 Form 8-K") and incorporated herein by reference.
- 10.2 Promissory Note made by the Company in favor of General Electric Capital Corporation, dated May 26, 2004. Filed as Exhibit 99.2 to the Company's May 2004 Form 8-K and incorporated herein by reference.
- 10.3 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.
- 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.

(b) Reports on Form 8-K

- 1. On May 5, 2004, the Company filed with the SEC a Current Report on Form 8-K (Item 12) reporting the Company's financial results for the first quarter of 2004.\*
  - 2. On May 27, 2004, the Company filed with the SEC a Current Report on Form 8-K (Items 5 and 7) reporting the refinancing of its credit facility.
- \* Information furnished under Item 12 (2.02) of Form 8-K is not incorporated by reference, is not deemed filed and is not subject to liability under Section 11 of the Securities Act of 1933 or Section 18 of the Securities Exchange Act of 1934.

## 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 9, 2004

GTC BIOTHERAPEUTICS, INC.

By: /s/ John B. Green

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

## EXHIBIT INDEX

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**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 9, 2004

/s/ Geoffrey F. Cox

Geoffrey F. Cox

Chairman of the Board, President and  
Chief Executive Officer

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

I, John B. Green, certify that:

1. I have reviewed this quarterly report on Form 10-Q of GTC Biotherapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 9, 2004

/s/ John B. Green

John B. Green

Senior Vice President,

Chief Financial Officer and Treasurer

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

In connection with the Quarterly Report on Form 10-Q of GTC Biotherapeutics, Inc. (the "Company") for the quarterly period ended July 4, 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: August 9, 2004

/s/ Geoffrey F. Cox

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

Date: August 9, 2004

/s/ John B. Green

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