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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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## FORM 10-Q

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

For the quarterly period ended April 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**

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

Indicate by check whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

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

Yes  No

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

Class	Outstanding at May 6, 2004
Common Stock, \$0.01 par value	38,694,971

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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)**

	April 4, 2004	December 28, 2003
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 20,583	\$ 6,733
Marketable securities	17,429	24,358
Accounts receivable and unbilled contract revenue	1,630	1,613
Other current assets	1,744	1,777
Total current assets	41,386	34,481
Net property, plant and equipment	22,274	22,600
Net intangible assets	10,835	11,094
Inventory	1,574	1,574
Other assets	1,361	1,323
	<u>\$ 77,430</u>	<u>\$ 71,072</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 2,527	\$ 2,340
Accrued liabilities	3,181	3,524
Accrued liabilities -Genzyme	2,689	1,924
Deferred contract revenue	186	323
Current portion of long-term debt and capital leases	2,220	2,218
Note payable - Genzyme	2,386	—
Total current liabilities	13,189	10,329
Long-term debt and capital leases, net of current portion	7,392	7,769
Note payable – Genzyme	2,387	4,773
Deferred lease obligation	37	40
Total liabilities	23,005	22,911
<b>Shareholders' equity:</b>		
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; 41,462,702 and 34,749,473 shares issued and 38,642,702 and 31,929,473 shares outstanding at April 4, 2004 and December 28, 2003, respectively	415	347
Capital in excess of par value - common stock	222,323	207,535
Treasury stock, at cost, 2,820,000 shares	(9,545)	(9,545)
Accumulated deficit	(158,755)	(150,179)
Accumulated other comprehensive income	(13)	3
Total shareholders' equity	54,425	48,161
	<u>\$ 77,430</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**	
	April 4, 2004	March 30, 2003
<b>Revenues:</b>		
Revenue	\$ 1,047	\$ 1,744
Revenue from related party	19	—
	<u>1,066</u>	<u>1,744</u>
<b>Costs of revenue and operating expenses:</b>		
Cost of revenue	1,072	3,576
Research and development	5,440	3,024
Selling, general and administrative	3,197	2,693
	<u>9,709</u>	<u>9,293</u>
Operating loss	(8,643)	(7,549)
<b>Other income (expense):</b>		
Interest income	(17)	292
Interest expense	(142)	(136)
Other income	226	—
	<u>226</u>	<u>—</u>
Net loss	<u>\$ (8,576)</u>	<u>\$ (7,393)</u>
Net loss per common share (basic and diluted)	<u>\$ (0.26)</u>	<u>\$ (0.27)</u>
Weighted average number of common shares outstanding (basic and diluted)	<u>33,496</u>	<u>27,783</u>
<b>Comprehensive loss:</b>		
Net loss	\$ (8,576)	\$ (7,393)
<b>Other comprehensive income:</b>		
Unrealized change in holding loss on available for sale securities	(16)	(35)
Total other comprehensive loss	(16)	(35)
Comprehensive loss	<u>\$ (8,592)</u>	<u>\$ (7,428)</u>

\*\*Three months ended April 4, 2004 includes 14 weeks and the three months ended March 30, 2003 includes 13 weeks.

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

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

	Three months ended **	
	April 4, 2004	March 30, 2003
<b>Cash flows from operating activities:</b>		
Net loss	\$ (8,576)	\$ (7,393)
Adjustments to reconcile net loss from continuing operations to net cash used in operating activities:		
Depreciation and amortization	955	747
Stock based compensation	475	—
Non-cash interest income (loss) from marketable securities	31	(51)
Non-cash common stock issuance to GTC savings and retirement plan	309	172
Changes in assets and liabilities:		
Accounts receivable and unbilled contract revenue	(17)	(726)
Other assets and liabilities	(8)	467
Accounts payable	187	1,807
Accounts payable – Genzyme	765	(1,766)
Other accrued liabilities	(343)	(481)
Deferred contract revenue	(137)	229
Net cash used in operating activities	(6,359)	(6,995)
<b>Cash flows from investing activities:</b>		
Purchase of property, plant and equipment	(370)	(2,841)
Purchase of marketable securities	(6,538)	(4,450)
Redemption of marketable securities	13,420	13,108
Net cash provided by investing activities	6,512	5,817
<b>Cash flows from financing activities:</b>		
Net proceeds from issuance of common stock, net of offering costs	13,868	—
Net proceeds from long-term debt	386	584
Repayment of long-term debt	(695)	(330)
Repayment of principal on capital leases	(66)	(113)
Net proceeds from employee stock purchase plan	116	156
Net proceeds from the exercise of stock options	88	—
Net cash provided by financing activities	13,697	297
Net increase (decrease) in cash and cash equivalents	13,850	(881)
Cash and cash equivalents at beginning of period	6,733	26,911
Cash and cash equivalents at end of period	<u>\$ 20,583</u>	<u>\$ 26,030</u>

\*\*Three months ended April 4, 2004 includes 14 weeks and the three months ended March 30, 2003 includes 13 weeks.

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 three months ended April 4, 2004 and March 30, 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 quarter ended April 4, 2004 and March 30, 2003 would have been increased to the pro forma amounts indicated below:

	April 4, 2004		March 30, 2003	
	Net Loss (in thousands)	Net Loss Available Per Common Share (basic and diluted)	Net Loss (in thousands)	Net Loss Available Per Common Share (basic and diluted)
Net loss reported	\$ (8,576)	\$ (0.26)	\$ (7,393)	\$ (0.27)
Add: *	35	—	—	—
Deduct: **	(870)	(0.02)	(740)	(0.02)
Pro forma net loss	\$ (9,411)	\$ (0.28)	\$ (8,133)	\$ (0.29)

\* 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 first quarter of 2004 and 95% for the first quarter of 2003, a dividend yield of 0% and a risk-free interest rate of 3.11% for the first quarter of 2004 and 2.96% for the first quarter of 2003. The average fair value of those options granted during the first quarter of 2004 and the first quarter of 2003 was \$2.88 and \$1.06, 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 first quarter of 2004 and 95% for the first quarter of 2003, an expected life of five years for the first quarter of 2004 and 2003 and a risk-free interest rate of 0.98% for the first quarter of 2004 and 1.00% for the first quarter of 2003. The average fair value of those purchase rights granted during the first quarter of 2004 and the first quarter of 2002 was \$1.05 and \$0.60, 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 5.6 million and 4.6 million at April 4, 2004 and March 30, 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 April 4, 2004 and March 30, 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 all of the

inventory on hand at April 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 the 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 April 4, 2004	At December 28, 2003
Accrued payroll and benefits	\$ 1,863	\$ 1,714
Accrued bonus	110	727
Other	1,208	1,083
Total accrued expenses	<u>\$ 3,181</u>	<u>\$ 3,524</u>

In 2003, there were 22 employees terminated as a result of a restructuring during the third quarter. This restructuring included employees from all departments located at both the Company's Framingham and central Massachusetts locations.

In February 2004, the Company announced a restructuring of its organization to control costs and to support its focus on clinical development and commercialization of its internal pipeline of proprietary products and its portfolio of external programs. Under the February 2004 restructuring plan, headcount was reduced by approximately 20% from 159 to 127 full time equivalent employees. Approximately \$743,000 and \$200,000 of the costs associated with the 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		<u>(437,000)</u>
Balance at April 4, 2004	\$	<u>624,000</u>

5. Intangible Assets:

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

	<u>Amortization Life</u>	(in thousands)	
		<u>April 4, 2004</u>	<u>December 28, 2003</u>
Marketing rights	15 years	\$ 11,210	\$ 11,210
Accumulated amortization—marketing rights		(2,678)	(2,491)
Net		<u>8,532</u>	<u>8,719</u>
Technology licenses	10 years to 15 years	3,379	3,379
Accumulated amortization — technology licenses		(1,076)	(1,004)
Net		<u>2,303</u>	<u>2,375</u>
Total intangible assets, net		<u>\$ 10,835</u>	<u>\$ 11,094</u>

Amortization expense was \$259,000 for the three months ended April 4, 2004 and March 30, 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 March 2002, the Company entered into a five year Loan and Security Agreement with Silicon Valley Bank, or SVB, in the amount of \$11.6 million, of which \$5.5 million was used to refinance an existing term loan, \$1.1 million refinanced previous capital asset acquisitions, \$4 million was available to finance future capital requirements, and \$1 million is available under a revolving line of credit at April 4, 2004. As a requirement under a facility lease, the Company also has a standby letter of credit in the amount of \$249,360 with SVB. Interest on the SVB debt instruments accrues at the prime rate, which was 4% at April 4, 2004.

In June 2003, the Company entered into a Loan Modification Agreement (the "Modification Agreement") with SVB. The Modification Agreement established a "2003 Committed Equipment Line" which made an additional \$2.25 million available to the Company for the

financing of capital asset acquisitions. During the first quarter of 2004, \$386,000 was drawn down and \$359,000 remained available for future capital asset acquisitions at April 4, 2004. All other terms and conditions remain unchanged from the original agreement entered into in March 2002.

In January 2004, the Company entered into an additional Loan Modification Agreement (the "Additional Modification Agreement") with SVB. This Additional Modification Agreement amended the terms of the 2003 Committed Equipment Line to extend the availability of the unused portion of the 2003 Committed Equipment Line to June 30, 2004 from December 31, 2003. The Additional Modification Agreement also reduced from \$25 million to \$18.2 million the amount the Company must maintain as unrestricted cash and marketable securities before the Company is required to provide cash collateral for the outstanding obligation to SVB, which was approximately \$9.3 million at April 4, 2004. In addition, the Additional Modification Agreement requires the Company to provide SVB with evidence that the Company has submitted to the European Medicines Evaluation Agency, or EMEA, a market approval application for ATryn<sup>®</sup> which was submitted by the Company on January 26, 2004. All other terms and conditions remain unchanged from the original agreement entered into in March 2002.

In April 2004, the Company entered into a third Loan Modification Agreement with SVB, which extended the revolving maturity date for the revolving line of credit from March 24, 2004 to March 24, 2005.

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 effective 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.

8. 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. 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 royalties on future product sales, if any.

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. To date, revenue from licensing and development agreements with collaborative partners has been more than offset by the related costs, which has further contributed to the Company's net loss in the first quarters of 2004 and 2003.

Three months ended April 4, 2004 and March 30, 2003

	(\$ in thousands)			
	<u>April 4, 2004</u>	<u>March 30, 2003</u>	<u>\$ Change</u>	<u>% Change</u>
Revenue	\$ 1,047	\$ 1,744	\$ (697)	(40)%
Revenue from related party	\$ 19	\$ —	\$ 19	100%
Total Revenue	\$ 1,066	\$ 1,744	\$ (678)	(39)%
Cost of revenue	\$ 1,072	\$ 3,576	\$ (2,504)	(70)%
Research and development	\$ 5,440	\$ 3,024	\$ 2,416	80%
Selling, general and administrative	\$ 3,197	\$ 2,693	\$ 504	19%
Interest income	\$ (17)	\$ 292	\$ (309)	(106)%

*Revenue.* During the first quarter of 2004, \$508,000 of the revenues were derived from external development programs with Merrimack Pharmaceuticals and Centocor and \$558,000 of the revenues were derived from the malaria program which is funded by the National Institute of Health, or NIH. During the first quarter of 2003, \$754,000 of the revenues were derived from external programs while \$990,000 of the revenues were derived from the malaria program. In 2003, revenues were primarily derived from the achievement of milestones in connection with the Merrimack and Bristol-Myers Squibb programs. 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.

*Cost of revenues and research and development expense.* First quarter 2004 expenses included a \$943,000 charge associated with the corporate restructuring that was implemented in February 2004 as well as an additional week of expenses due to the fact that it was a 14 week quarter. The impact of the additional week of operating expenses was approximately \$600,000. Of the first quarter 2004 expenses, approximately \$3.2 million was incurred to support the completion of the efficacy study and the preparation for regulatory filing for approval to market ATryn® in Europe to treat hereditary antithrombin deficiency, an increase of \$1.5 million over the first quarter of 2003. Additionally, the Company incurred expenses

of \$792,000 and \$2.4 million in the development of the rhSA program in the first quarter of 2004 and 2003, respectively, and \$700,000 and \$345,000 in the development of the malaria program in the first quarter of 2004 and 2003, respectively. Research and development expenses going forward are expected to fluctuate based on a number of factors, including the timing and status of clinical development activities for ATryn® and other programs. Absent a further ATryn® clinical trial, research and development expenses are expected to decline in 2004 as compared with 2003, primarily as a result of the completion of the ATryn® clinical trial as well as the overall implementation of cost reduction measures. If the FDA approves a trial protocol for ATryn®, the Company's research and development spending may increase versus the current planned expenditures. The 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.

In September 2003, the Company implemented an initial restructuring plan and in February 2004, the Company implemented a further restructuring. As a result of these restructurings, headcount was reduced by approximately 30%. This resulted in a restructuring charge of \$943,000 in the first quarter of 2004. The Company also renegotiated some research agreements with outside contractors. On an annualized basis, these changes are expected to reduce the Company's operating expenses by approximately \$8 million. The Company expects to achieve the full benefit of these reductions starting in the second quarter of 2004.

Approximately \$743,000 and \$200,000, respectively, of the costs associated with the restructuring are included in selling, general and administrative expense and research and development expense.

*Selling, General and Administrative Expense.* The increase of approximately \$504,000 in selling, general and administrative expenses is primarily due to the corporate restructuring charge.

*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 SVB investments during 2003.

### **Liquidity and Capital Resources**

The Company's objective is to appropriately finance its business 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®, the ability of the Company to enter into new transgenic research and development collaborations and 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.

Historically, the Company has used its cash for a mix of activities focused on enhancing product development and program execution, and development and expansion of operational capabilities. In 2003 and the first quarter of 2004, the Company used its cash primarily for the general operation of GTC's business.

The Company had cash, cash equivalents and marketable securities of approximately \$38 million at April 4, 2004. This amount includes cash and cash equivalents of \$20.6 million. The Company had working capital of \$28.2 million at April 4, 2004 compared to \$24.2 million at December 28, 2003.

#### ***Q1 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 effective 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 \$14.4 million of outstanding long-term debt at April 4, 2004, approximately \$4.6 million is classified as current. Approximately \$9.1 million was related to a term loan and an equipment line of credit with Silicon Valley Bank, or SVB, with monthly payments through 2008, approximately \$542,000 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. The Company had approximately \$359,000 available at April 4, 2004 under a Committed Equipment Line with SVB and \$1 million was currently available under a revolving line of credit with SVB.

In January 2004, the Company entered into a Loan Modification Agreement with SVB. This Modification Agreement reduced from \$25 million to \$18.2 million the amount the Company must maintain as unrestricted cash and marketable securities before the Company is required to provide cash collateral for the outstanding obligation to SVB, which was approximately \$9.3 million at April 4, 2004. The Company has never paid a cash dividend on its Common Stock and currently expects that future earnings will be retained for use in its business.

In April 2004, the Company entered into a third Loan Modification Agreement with SVB, which extended the revolving maturity date for the revolving line of credit from March 24, 2004 to March 24, 2005.

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

Other sources of funds during the first quarter of 2004 included \$386,000 in proceeds from long-term debt, \$6.9 million in net redemptions of marketable securities in the Company's

portfolio and \$204,000 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 \$8.6 million) included \$6.4 million used in operations.

Other uses of funds during the period included:

- \$343,000 decrease in accrued expenses as a result of the 2003 bonus payout, which was paid in GTC common stock.
- \$370,000 for capital equipment and further expansion of the transgenic production facility.
- \$761,000 for the repayment of long-term debt and capital leases.

Management believes that existing cash resources and potential future cash compensation 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 cannot use all of its cash to fund operations as a result of a condition in the Additional Modification Agreement with SVB. Under this Agreement, if the Company's cash and marketable securities drop below \$18.2 million, the Company is required to provide cash collateral for the outstanding obligation to SVB, which was approximately \$9.3 million at April 4, 2004.

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 April 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 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.
10.1	Loan Modification Agreement by and between the Company and Silicon Valley Bank dated January 25, 2004. Filed herewith.
10.2	Loan Modification Agreement by and between the Company and Silicon Valley Bank dated April 7, 2004. 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.

(b) Reports on Form 8-K

1. On March 3, 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 March 16, 2004, the Company filed with the SEC a Current Report on Form 8-K (Items 5 and 7) reporting the Company's registered direct offering.

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\* Information furnished under Item 12 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: May 10, 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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32	Certifications pursuant to 18 U.S.C. Section 1350.

The following exhibits are incorporated herein by reference:

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