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

FORM 10-Q

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

For the quarterly period ended April 3, 2005

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

Common Stock, \$0.01 par value

Outstanding at May 9, 2005

46,841,994

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements regarding our prospects for clinical trials, regulatory approval, and collaborations for our internal and external programs and our future cash requirements. The word or phrase “will likely result”, “are expected to”, “will continue”, “is anticipated”, “estimate”, “project”, “believes”, or similar expressions are intended to identify “forward-looking statements” within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of Securities Act of 1933, as amended, as enacted by the Private Securities Litigation Reform Act of 1995. Statements that are not historical facts are based on current expectations, beliefs, assumptions, estimates, forecasts and projections for our business and the industry and markets related to our business. The statements contained in this report are not guarantees of future performance and involve certain risks, uncertainties, and assumptions which are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed in such forward-looking statements. Important factors which may affect future revenues, research and development programs, clinical trials and collaborations and our future cash requirements include, without limitation, clinical development and regulatory review of our ATryn® product, potential arrangements for commercialization and development of additional markets for ATryn®, our ability to enter into transgenic research and development collaborations in the future and the terms of such collaborations, the results of research and development and preclinical testing of our internal products, competitive and technological advances and regulatory requirements.

For a further description of these and other risks and uncertainties, we encourage you to read carefully the portion of our Annual Report on Form 10-K for the fiscal year ended January 2, 2005 (the “2004 Form 10-K”) under the caption “Note Regarding Forward-Looking Statements” in Part I of the 2004 Form 10-K, as filed with the Securities and Exchange Commission on March 15, 2005.

The forward-looking statements in this Quarterly Report on Form 10-Q speak as of the date of this report. We expressly disclaim any obligation or undertaking to disseminate any updates or revisions to any forward-looking statement contained in this Quarterly Report to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any forward-looking statement is based, except as may be required by law.

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PART I - FINANCIAL INFORMATION

ITEM 1 –FINANCIAL STATEMENTS

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

	<u>April 3, 2005</u>	<u>January 2, 2005</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 10,966	\$ 1,835
Marketable securities	16,835	20,446
Accounts receivable and unbilled contract revenue	317	725
Inventory	251	466
Other current assets	1,447	1,479
	<u>29,816</u>	<u>24,951</u>
Total current assets		
Net property, plant and equipment	18,702	20,279
Net intangible assets	9,800	10,059
Other assets	1,570	1,562
Restricted cash	450	450
	<u>\$ 60,338</u>	<u>\$ 57,301</u>
Total assets		
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,485	\$ 2,391
Accrued liabilities	2,817	3,517
Accrued liabilities - Genzyme	2,114	2,806
Deferred contract revenue	1,727	733
Current portion of long-term debt and capital leases	3,053	2,479
Note payable - Genzyme	2,386	2,386
	<u>14,582</u>	<u>14,312</u>
Total current liabilities		
Long-term debt and capital leases, net of current portion	7,810	6,926
Note payable – Genzyme	2,387	2,387
Deferred lease obligation	21	23
	<u>24,800</u>	<u>23,648</u>
Total liabilities		
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; 49,484,013 and 41,619,974 shares issued and 46,664,013 and 38,799,974 shares outstanding at April 3, 2005 and January 2, 2005, respectively	495	416
Capital in excess of par value – common stock	232,421	222,590
Treasury stock, at cost, 2,820,000 shares	(9,545)	(9,545)
Accumulated deficit	(187,705)	(179,672)
Accumulated other comprehensive loss	(128)	(136)
	<u>35,538</u>	<u>33,653</u>
Total shareholders' equity		
Total liabilities and shareholders' equity	<u>\$ 60,338</u>	<u>\$ 57,301</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 3, 2005	April 4, 2004
Revenues:		
Revenue	\$ 1,322	\$ 1,047
Revenue from related party - Genzyme	—	19
	<u>1,322</u>	<u>1,066</u>
Costs of revenue and operating expenses:		
Cost of revenue	1,373	1,072
Research and development	5,417	5,538
Selling, general and administrative	2,395	3,099
	<u>9,185</u>	<u>9,709</u>
Operating loss	(7,863)	(8,643)
Other income (expense):		
Interest income	121	(17)
Interest expense	(340)	(142)
Other income	49	226
	<u>—</u>	<u>—</u>
Net loss	\$ (8,033)	\$ (8,576)
	<u>—</u>	<u>—</u>
Net loss per common share (basic and diluted)	\$ (0.18)	\$ (0.26)
	<u>—</u>	<u>—</u>
Weighted average number of common shares outstanding (basic and diluted)	44,837	33,496
	<u>—</u>	<u>—</u>
Comprehensive loss:		
Net loss	\$ (8,033)	\$ (8,576)
Other comprehensive income:		
Unrealized change in holding gain (loss) on available for sale securities	8	(16)
	<u>8</u>	<u>(16)</u>
Total other comprehensive gain/(loss)	8	(16)
	<u>—</u>	<u>—</u>
Comprehensive loss	\$ (8,025)	\$ (8,592)
	<u>—</u>	<u>—</u>

* Three months ended April 3, 2005 includes 13 weeks and the three months ended April 4, 2004 includes 14 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 3, 2005	April 4, 2004
Cash flows from operating activities:		
Net loss from operations	\$ (8,033)	\$ (8,576)
Adjustments to reconcile net loss from operations to net cash used in operating activities:		
Depreciation and amortization	1,150	955
Stock based compensation	—	35
Amortization of premium (discount) on marketable securities	(193)	31
Common stock issuance to GTC savings and retirement plan	—	309
Inventory write down	419	—
Gain on sale of fixed asset	(37)	—
Changes in assets and liabilities:		
Accounts receivable and unbilled contract revenue	408	(17)
Inventory	(204)	—
Other assets and liabilities	22	(8)
Accounts payable	94	187
Accrued liabilities	(561)	97
Accrued liabilities – Genzyme	(692)	765
Deferred contract revenue	994	(137)
Net cash used in operating activities	(6,633)	(6,359)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(240)	(370)
Sales of property, plant and equipment	570	—
Purchase of marketable securities	(5,938)	(15,538)
Redemption of marketable securities	9,750	13,420
Net cash provided by investing activities	4,142	(2,488)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of offering costs	9,710	13,868
Proceeds from long-term debt	2,400	386
Repayment of long-term debt	(549)	(695)
Repayment of principal on capital leases	—	(66)
Net proceeds from employee stock purchase plan	61	116
Net proceeds from the exercise of stock options	—	88
Net cash provided by financing activities	11,622	13,697
Net increase in cash and cash equivalents	9,131	4,850
Cash and cash equivalents at beginning of period	1,835	5,733
Cash and cash equivalents at end of period	\$10,966	\$ 10,583

* Three months ended April 3, 2005 includes 13 weeks and the three months ended April 4, 2004 includes 14 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. (“GTC”) for the fiscal year ended January 2, 2005 (the “2004 Form 10-K”) 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 3, 2005 and April 4, 2004, are unaudited but include, in our opinion, all adjustments necessary for a fair presentation of the results for the periods presented. Certain reclassifications have been made to prior years’ financial statements to conform to the 2005 presentation.

We are subject to risks common to companies in the biotechnology industry, including, but not limited to, the uncertainties of clinical trials and the regulatory requirements for approval of therapeutic compounds, the need for additional capital, competitive new technologies, dependence on key personnel, protection of proprietary technology, and compliance with the United States Food and Drug Administration (“FDA”) and other government regulations.

Our consolidated financial statements have been presented on the basis that we are a going concern, which contemplates the continuity of business, realization of assets and the satisfaction of liabilities in the ordinary course of business.

2. Accounting Policies:

The accounting policies underlying the quarterly financial statements are those set forth in Note 2 of the financial statements included in our 2004 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 our 2004 Form 10-K.

Accounting for Employee Equity Plans

In December 2002, the Financial Accounting Standards Board (“FASB”) issued Statement of Financial Accounting Standards 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, amended Statement of Financial Accounting Standards No. 123 (“SFAS 123”), Accounting for Stock Based Compensation and provided 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. We continue to apply Accounting Practices Board (“APB”) Opinion 25, Accounting for Stock Issued to Employees (“APB Opinion No. 25”), and related interpretations in accounting for our 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. We apply the disclosure only provisions of SFAS 148. If the compensation cost for our 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, our net loss and loss per share for the three months ended April 3, 2005 and April 4, 2004 would have been increased to the pro forma amounts indicated below:

	April 3, 2005		April 4, 2004	
	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	\$ (8,033)	\$ (0.18)	\$ (8,576)	\$ (0.26)
Add: *	—	—	35	—
Deduct: **	(556)	(0.01)	(870)	(0.02)
Pro forma net loss	\$ (8,589)	\$ (0.19)	\$ (9,411)	\$ (0.28)

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

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

The fair value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions: an expected life of five years, expected volatility of 95% for the first quarter of 2005 and 100% for the first quarter of 2004, a dividend yield of 0% and a risk-free interest rate of 3.70% for the first quarter of 2005 and 3.11% for the first quarter of 2004. The average fair value of those options granted during the first quarter of 2005 and the first quarter of 2004 was \$1.26 and \$2.88, respectively.

The fair value of the employees' purchase rights was estimated using the Black-Scholes model with the following weighted-average assumptions: an expected life of six months, expected volatility of 95% for the first quarter of 2005 and 100% for the first quarter of 2004, a dividend yield of 0%, and a risk-free interest rate of 1.60% for the first quarter of 2005 and 0.98% for the first quarter of 2004. The average fair value of those purchase rights granted during the first quarter of 2005 and the first quarter of 2004 was \$0.57 and \$1.05, 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 6 million and 5.6 million at April 3, 2005 and April 4, 2004, respectively. The increase in potential common shares is a result of stock option grants. Since we were in a net loss position at April 3, 2005 and April 4, 2004, these potential common shares were not used to compute diluted loss per share, as the effect would have been antidilutive.

3. Inventory:

We carry inventory at the lower of cost or market using the first-in, first-out method. We capitalize inventory produced for commercial sale. At April 3, 2005, we had approximately \$251,000 of work in process inventory for the manufacture of ATryn[®] which management believes will be available for commercial sale. At April 3, 2005 and January 2, 2005, we also had approximately \$419,000 and \$466,000, respectively, of finished goods inventory related to ATryn[®]. During the first quarter of 2005, we received a List of Outstanding Issues from the European Medicines Agency (“EMA”) as part of its review of our Market Authorization Application for ATryn[®], which has delayed the approval and launch of the product from our previously forecast timelines. As part of the List of Outstanding Issues, the proposed shelf life of ATryn[®] is being reviewed. As a result, we have written down the inventory to zero value as we can no longer conclude with certainty that it is probable that the inventory will be sold prior to expiration, resulting in a charge to research and development of \$419,000. If our proposed shelf life is accepted, and there are no further delays in the approval process, then we expect that this inventory could be saleable prior to expiration. During the first quarter of 2005, we also recorded approximately \$47,000 of research and development expense related to the usage of ATryn[®] inventory for development purposes.

We analyze our inventory levels quarterly and will write down inventory as it becomes obsolete, as the inventory cost basis exceeds its expected net realizable value and as the inventory exceeds expected requirements. Inventory that expires will be disposed of and the related costs will be written off. In addition, if actual market or regulatory conditions are less favorable than those projected by management, additional inventory write downs may be required.

4. Accrued Liabilities:

Accrued liabilities include the following:

	(dollars in thousands)	
	At April 3, 2005	At January 2, 2005
Accrued payroll and benefits	\$ 1,665	\$ 1,696
Accrued bonus	237	579
Other	915	1,242
Total accrued expenses	\$ 2,817	\$ 3,517

In February 2004, we announced a restructuring of our organization to control costs and to support our focus on clinical development and commercialization of our internal pipeline of proprietary products and our 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 were included in selling, general and administrative expense and research and development expenses, respectively, in the first quarter of 2004. Payments related to the restructuring will be completed in the third quarter of 2005.

Following is a summary of accrued severance:

Balance at January 2, 2005	\$ 184,000
2004 restructuring payments	(103,000)
Balance at April 3, 2005	<u>\$ 81,000</u>

5. Intangible Assets:

Our intangible assets as of April 3, 2005 and January 2, 2005 consist of:

		(dollars in thousands)	
	<u>Amortization Life</u>	<u>April 3, 2005</u>	<u>January 2, 2005</u>
Marketing rights	15 years	\$ 11,210	\$ 11,210
Accumulated amortization—marketing rights		(3,425)	(3,238)
Net		<u>7,785</u>	<u>7,972</u>
Technology licenses	10 years to 15 years	3,379	3,379
Accumulated amortization — technology licenses		(1,364)	(1,292)
Net		<u>2,015</u>	<u>2,087</u>
Total intangible assets, net		<u>\$ 9,800</u>	<u>\$ 10,059</u>

Amortization expense was \$259,000 for the three months ended April 3, 2005 and April 4, 2004.

The estimated aggregate amortization expense for the next five fiscal years is \$1,035,000 per year from 2005 through 2008, \$927,000 for 2009 and \$4,994,000 for 2010 and thereafter.

6. Long-Term Debt:

In May 2004, we entered into a four year loan agreement with General Electric Capital Corporation (“GE Capital”) in the amount of \$10 million with a 9.94% interest rate and monthly payments of principal and interest of approximately \$253,000, which was used to refinance our outstanding loan with Silicon Valley Bank. Collateral for the loan includes all of our existing and future acquired assets, excluding intellectual property. As a result of this refinancing, we were no longer required to maintain \$18.2 million as unrestricted cash and marketable securities before we would be required to provide cash collateral for the loan. In connection with the refinancing, we were required to provide \$450,000 of cash collateral for our two outstanding stand-by letters of credit, which appears as restricted cash on the balance sheet.

In February 2005, we expanded the term loan with GE Capital to allow us to draw down an additional \$2.4 million, which was used to refinance the note payment due and paid to Genzyme on April 4, 2005. The additional amount will be re-paid over three years through March 2008 with monthly payments of principal and interest of approximately \$77,000. The expanded loan carries a 10.01% interest rate and is secured by the same collateral as the existing loan with GE Capital.

7. Financing:

In March 2004, we sold 6,395,298 shares of our Common Stock at \$2.35 per share in a registered direct offering to institutional investors. These shares were issued under a shelf registration statement. SG Cowen Securities, as the lead agent, and Rodman & Renshaw, LLC acted as placement agents for the offering and we paid a placement agent fee for their services. Our proceeds, net of offering costs of approximately \$1.2 million, were approximately \$13.9 million.

In January 2005, we sold 7,740,739 shares of our Common Stock at \$1.35 per share in a registered direct offering to institutional investors. These shares were issued under a shelf registration statement. SG Cowen Securities acted as the placement agent for the offering and we paid a placement agent fee for its services. Our proceeds from the sale, net of offering costs of approximately \$700,000, were approximately \$9.7 million.

8. Commitments and Contingencies:

On November 13, 2001, two employees of one of our former subsidiaries filed an action against us in the Court of Common Pleas for Philadelphia County in Pennsylvania seeking damages, declaratory relief and certification of a class action relating primarily to their GTC stock options. The claims arose as a result of our sale of Primedica Corporation to Charles River Laboratories International, Inc. in February 2001, which we believe resulted in the termination of Primedica employees' status as employees of GTC or its affiliates and the termination of their stock options. The plaintiffs contend that the sale of Primedica to Charles River did not constitute a termination of their employment with GTC or its affiliates for purposes of our equity incentive plan and, therefore, that we breached our 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. We have filed an answer denying all material allegations in the complaint, and are vigorously defending the case and objecting to certification of the claims as a class action. We believe that we have 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 our financial position, results of operations or cash flows.

We maintain our herd of cattle for the Taurus hSA LLC ("Taurus"), a joint venture, at TransOva Genetics ("TOG") in Iowa under an agreement signed in December 2002. As part of the agreement, TOG agreed to be compensated partially in equity of Taurus only when, and if, Taurus receives outside third party financing. The amount of equity would be valued under the same terms as such outside financing. The issuance of Taurus equity to TOG under the agreement is not expected to result in any material expense to us.

9. Property, Plant and Equipment

In March 2005, we completed the sale of 135 acres of farm land located in eastern New York State. As a result of the sale, we received net proceeds of approximately \$534,000 and recorded a gain of approximately \$37,000.

10. New Accounting Pronouncements

In December 2004, the FASB issued Statement of Financial Accounting Standards No. 123(R) (revised 2004), Share-Based Payment. Statement 123(R) addresses the accounting for share-based payment transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments. Statement 123(R) requires an entity to recognize the grant-date fair-value of stock options and other equity-based compensation issued to employees in the income statement. Statement 123(R) generally requires that an entity account for those transactions using the fair-value-based method, and eliminates the intrinsic value method of accounting in APB Opinion No. 25 which was permitted under Statement 123, as originally issued. Statement 123(R) requires entities to disclose information about the nature of the share-based payment transactions and the effects of those transactions on the financial statements.

Statement 123(R) is effective for public companies that do not file as small business issuers for annual periods that begin after June 15, 2005 (i.e., our first quarter of fiscal year 2006). All public companies must use either the modified prospective or the modified retrospective transition method. We expect to use the modified prospective application. We estimate the impact of this statement to be less than the amounts previously disclosed under SFAS 123.

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

Business Overview

We are a leader in the development and production of human therapeutic proteins through transgenic technology. We are focusing our pipeline of internal product programs on recombinant forms of human plasma proteins, or proteins currently derived from the human blood supply, for therapeutic purposes. Our lead product, a recombinant form of human antithrombin known as ATryn®, is undergoing review for market authorization in Europe by the European Medicines Agency ("EMA").

We are dependent upon funding from equity financings, partnering programs and proceeds from short and long-term debt to finance operations until such time product sales and royalties occur and we achieve positive cash flow from operations. Our partnering initiatives include licensing and development agreements with collaborative partners for the development, production and purification of transgenically produced forms of therapeutic recombinant proteins. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon the achievement of certain milestones, revenue from sales of product to partners, and royalties on future product sales, if any.

We have incurred losses from operations and negative operating cash flow since inception and have an accumulated deficit of \$187.7 million at April 3, 2005. Based on the current rate of cash utilization, management believes that existing cash resources and potential future cash payments from new partnering and licensing programs will be sufficient to fund operations into 2006. The primary sources of additional capital raised have been equity and debt financing, and management expects that future sources of funds may include new or expanded partnering arrangements, or the sale of equity or debt-related instruments. Any future sales of Common Stock will proportionately reduce the ownership interest of our current shareholders and may have an adverse impact on the price of our Common Stock. However, there can be no assurance that we will be able to raise needed capital on terms that are acceptable to us, or at all.

This discussion and analysis of our financial condition should be read in connection with our consolidated financial statements and accompanying notes thereto, our 2004 Form 10-K and the information set forth under the heading "Critical Accounting Policies and Estimates" in our 2004 Form 10-K. Our key value drivers remain substantially the same as those described in Management's Discussion and Analysis of Financial Condition and Results of Operations set forth in Item 7 of our 2004 Form 10-K.

Critical Accounting Policies and Estimates

The preparation of consolidated financial statements requires that we make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. Our critical accounting policies are summarized in Note 2 in the Notes to Consolidated Financial Statements included in Item 8 of our 2004 Form 10-K. On an on-going basis, we evaluate our estimates, including those related to revenue recognition, investments, intangible and long-lived assets,

inventory, income taxes, accrued expenses, financing operations, and contingencies and litigation. We base our estimates on historical experience and on various other assumptions that we believe 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. Our actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to the critical accounting policies that are set forth in Management's Discussion and Analysis of Financial Condition and Results of Operations included in Item 7 of our 2004 Form 10-K.

Results of Operations

The key components to our losses are costs of revenue, research and development expenses, and selling, general and administrative expenses. In addition, an additional week of operating expenses is included in the first quarter of 2004 due to the fact that it was a fourteen week fiscal quarter. The impact of the additional week of operating expense in 2004 was approximately \$600,000.

Three months ended April 3, 2005 and April 4, 2004

	(dollars in thousands)			
	April 3, 2005	April 4, 2004	\$ Change	% Change
Revenue	\$1,322	\$1,066	\$ 256	24%
Cost of revenue	\$1,373	\$1,072	\$ 301	28%
Research and development	\$5,417	\$5,538	\$ (121)	(2)%
Selling, general and administrative	\$2,395	\$3,099	\$ (704)	(23)%
Interest income	\$ 121	\$ (17)	\$ 138	812%

Revenue. During the first quarter of 2005, \$1.1 million of our revenue was derived from external development programs, primarily the programs with Merrimack Pharmaceuticals and Elan Pharmaceuticals, and \$173,000 of our revenue was derived from the malaria program, which is funded by the National Institute of Allergy and Infectious Disease ("NIAID"). The programs with Elan Pharmaceuticals have been successfully completed and are now being maintained with funding from Elan. During the first quarter of 2004, \$508,000 of our revenue was derived from external programs, primarily the programs with Merrimack and Centocor, and \$558,000 was derived from the malaria program. The increase in revenues from external programs reflects the nature and timing of our milestone-based research and development activities for these programs. We expect to continue to see variation in reported revenues on a year-to-year basis.

Cost of revenue. The increase in cost of revenue is primarily the result of a corresponding increase in revenue in 2005 compared to 2004. The level of expenses on our external programs will continue to fluctuate from period to period depending upon the stage of development of individual programs and their progress.

Research and development expense. Research and development expenses included ATryn® related expenses of \$2.7 million in the first quarter of 2005 as compared to \$2.2 million in the first quarter of 2004. Included in the first quarter 2005 research and development expenses is approximately \$419,000 related to non-cash charges to write down the ATryn® inventory pending acceptance by the EMEA of our proposed shelf life for ATryn®, as well as approximately \$47,000 for inventory used for development purposes.

Additionally, we incurred expenses of \$1.2 million in the CD-137 development program as compared with \$100,000 in the first quarter of 2004. Increases in the ATryn® and CD-137 programs were offset by decreases in spending of approximately \$2 million on several other research and development programs. The first quarter of 2004 research and development expenses included approximately \$200,000 of expense related to the February 2004 restructuring. Research and development expenses going forward are expected to fluctuate based on a number of factors including the timing and status of research and development activities for ATryn® and other programs.

Selling, General and Administrative Expense. In the first quarter of 2005 we incurred costs of approximately \$70,000 related to compliance with the Sarbanes-Oxley Act of 2002. The first quarter of 2004 expenses include approximately \$744,000 of charges associated with the February 2004 restructuring. Ongoing selling, general and administrative expenses are expected to decrease slightly in 2005 primarily as a result of a decrease in directors and officer's insurance premiums as well as lower costs related to ongoing Sarbanes-Oxley compliance.

Interest income. The increase in interest income is primarily the result of a \$155,000 adjustment to reduce interest income on our investments during the first quarter of 2004 which related to activity during 2003.

Liquidity and Capital Resources

Our objective is to finance our business appropriately through a mix of equity financings, collaboration and grant revenue, debt financings and interest income earned on our cash and cash equivalents, until such time as product sales and royalties occur and we achieve positive cash flow from operations. Our ability to raise future funds will be affected by the progress of clinical trials and the regulatory review of ATryn®, our ability to enter into new or expanded transgenic research and development collaborations, the terms of such collaborations, the results of research and development and preclinical testing of our other internal product candidates, and competitive and technological advances, as well as general market conditions.

We use our 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. We anticipate utilizing approximately \$20 million of cash in 2005, which includes supporting the regulatory review of ATryn® in Europe and the initiation of a clinical trial in the U.S. in the hereditary deficiency indication, as well as anticipated partnering revenues. Since we plan to defer manufacturing additional ATryn® until late 2005 to match our expected approval timing, we expect much of the cash impact to occur in early 2006.

In January 2005 we raised an additional \$9.7 million in cash, net of offering costs, in a registered direct placement of our Common Stock, which is more fully described under "Financing Activities". We had cash, cash equivalents and marketable securities of \$27.8 million at April 3, 2005.

We had working capital of \$15.2 million at April 3, 2005 compared to \$10.6 million at January 2, 2005.

Financing Activities

In January 2005, we sold 7,740,739 shares of our Common Stock at \$1.35 per share in a registered direct offering to institutional investors. SG Cowen Securities acted as placement agent for the offering and we paid a placement agent fee for its services. Our proceeds from this sale, net of offering costs of approximately \$700,000, were approximately \$9.7 million.

Credit Facility

Of our \$15.6 million of outstanding long-term debt at April 3, 2005, approximately \$5.4 million is classified as current.

Approximately \$4.8 million of our long term debt is related to a promissory note payable to Genzyme Corporation. The principal is payable in two installments: \$2.4 million which was due and paid on April 4, 2005 and \$2.4 million which is due on April 4, 2006.

In February 2005, we expanded our term loan with GE Capital to allow us to draw down an additional \$2.4 million which was used to refinance the note payment due to Genzyme in April 2005. The additional amount will be re-paid over three years through March 2008 with monthly payments of principal and interest of approximately \$77,000. The loan carries a 10.01% interest rate and is secured by the same collateral as the existing loan with GE Capital.

Cash Flows used in Operating Activities

Cash flows used in operating activities were \$6.6 million and \$6.4 million for the first quarter of 2005 and 2004, respectively. Our net loss for the first quarter 2005 was \$8 million compared to \$8.6 million in the first quarter of 2004, while net cash used for operating activities increased \$274,000. Cash used in operating activities for the first quarter of 2005 included a net loss of \$8 million offset by certain non-cash charges of approximately \$1.4 million. Use of cash also included an increase in inventory of approximately \$204,000 and decreased accounts payable and accrued liabilities of approximately \$1.2 million. Sources of funds included a reduction of accounts receivable of approximately \$408,000, an increase in advance payments from customers as a result of the timing of invoices as well as the deferral of revenue on contracts that contain multiple elements of approximately \$994,000.

Cash Flows from Investing Activities

Cash flows from investing activities include \$3.8 million in net redemptions of marketable securities in our portfolio, \$570,000 cash inflow for the sale of farm land and other assets, and \$240,000 for purchases of capital equipment. We anticipate a similar level of capital expenditures company-wide in 2005 as compared to 2004.

We have entered into transactions with related parties in the normal course of business. The terms of these transactions are considered to be at arm's length.

COMMITMENTS AND CONTINGENCIES

Our commitments and contingencies are disclosed in Note 8 of this Form 10-Q as well as in Note 6 in the Notes to Consolidated Financial Statements included in Item 8 of our 2004 Form 10-K. We have reviewed the commitments and contingencies at April 3, 2005 and noted that there were no material changes or additions.

We are 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 our 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 our market risk since January 2, 2005. Our market risk disclosures are discussed in our 2004 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

GTC'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 (the "Exchange Act"), as amended) 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 our disclosure controls and procedures were effective and designed to ensure that the information required to be disclosed in the reports filed or submitted by us 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 GTC'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 our internal control that occurred during our 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

<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 Securities and Exchange 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 the Company and designating the Series C Junior Participating Cumulative Preferred Stock. Filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 1, 2001 (File No. 0-21794) 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.
10.3*	Executive Compensation Disclosure Schedule. Filed as Exhibit 10.33 to the Company's Annual Report on Form 10-K for the year ended January 2, 2005 (File No. 000-21794) 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.

* Indicates a management contract or compensatory plan.

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 12, 2005

GTC BIOTHERAPEUTICS, INC.

By: /s/ John B. Green

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

EXHIBIT INDEX

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32	Certifications pursuant to 18 U.S.C. Section 1350. Filed herewith.

* Indicates a management contract or compensatory plan.

LOAN MODIFICATION AGREEMENT

This Loan Modification Agreement (this "Loan Modification Agreement") is entered into as of January 25, 2004, by and between SILICON VALLEY BANK, a California-chartered bank, with its principal place of business at 3003 Tasman Drive, Santa Clara, California 95054 and with a loan production office located at One Newton Executive Park, Suite 200, 2221 Washington Street, Newton, Massachusetts 02462, doing business under the name "Silicon Valley East" ("Bank") and GTC BIOTHERAPEUTICS, INC., a Massachusetts corporation with its chief executive office located at 175 Crossing Boulevard, Suite 410, Framingham, Massachusetts 01702 ("Borrower").

1. DESCRIPTION OF EXISTING INDEBTEDNESS AND OBLIGATIONS. Among other indebtedness and obligations which may be owing by Borrower to Bank, Borrower is indebted to Bank pursuant to a loan arrangement dated as of March 27, 2002, evidenced by, among other documents, a certain Loan and Security Agreement dated as of March 27, 2002, between Borrower and Bank, as amended by a Loan Modification Agreement dated June 11, 2003, and by a Loan Modification Agreement dated August 13, 2003 (as amended, the "Loan Agreement"). Capitalized terms used but not otherwise defined herein shall have the same meaning as in the Loan Agreement.

2. DESCRIPTION OF COLLATERAL. Repayment of the Obligations is secured by the Collateral as described in the Loan Agreement (together with any other collateral security granted to Bank, the "Security Documents").

Hereinafter, the Security Documents, together with all other documents evidencing or securing the Obligations shall be referred to as the "Existing Loan Documents".

3. DESCRIPTION OF CHANGE IN TERMS.

A. Modifications to Loan Agreement.

1. The Loan Agreement shall be amended by deleting the following provision appearing in the first sentence of Section 2.1.6(a) thereof:

“2.1.6. 2003 Equipment Advances.

(a) Availability. Through December 31, 2003 (the "2003 Equipment Availability End Date"), Bank shall make Equipment Advances under the 2003 Committed Equipment not exceeding the 2003 Committed Equipment Line.”

and inserting in lieu thereof the following:

“2.1.6. 2003 Equipment Advances.

(a) Availability. Through June 30, 2004 (the "2003 Equipment Availability End Date"), Bank shall make Equipment Advances under the 2003 Committed Equipment not exceeding the 2003 Committed Equipment Line.”

2. The Loan Agreement shall be amended by deleting the following, appearing as Section 6.7(a) thereof, in its entirety:

“(a) **Liquidity.** Borrower and its Subsidiaries shall maintain unrestricted cash and marketable securities less outstanding Obligations under the Committed Revolving Line, of not less than Twenty-Five Million Dollars (\$25,000,000.00). If, at any time, the Borrower shall fail to satisfy the terms of this Section 6.7(a), then the Borrower shall immediately deposit with the Bank an amount of unrestricted cash equal to the outstanding Obligations hereunder, and shall thereafter maintain unrestricted cash with the Bank equal to the outstanding Obligations, as such amount may increase or decrease.”

and inserting in lieu thereof the following:

“(a) **Liquidity.** Borrower and its Subsidiaries shall maintain unrestricted cash and marketable securities less outstanding Obligations under the Committed Revolving Line, of not less than Eighteen Million Dollars (\$18,000,000.00). If, at any time, the Borrower shall fail to satisfy the terms of this Section 6.7(a), then the Borrower shall immediately deposit with the Bank an amount of unrestricted cash equal to the outstanding Obligations hereunder, and shall thereafter maintain unrestricted cash with the Bank equal to the outstanding Obligations, as such amount may increase or decrease.”

3. The Loan Agreement shall be amended by inserting the following provision to appear as Section 6.9 thereof:
“**6.9 Market Approval.** On or before February 28, 2004, the Borrower shall provide the Bank with a evidence, acceptable to the Bank, in it reasonable discretion, that the Borrower has submitted to the European Medicines Evaluation Agency a market approval application for its drug, rhATIII”.
4. The Compliance Certificate appearing as **Exhibit D** to the Loan Agreement is hereby replaced with the Compliance Certificate attached as **Exhibit A** hereto.

4. **FEES.** The Borrower shall pay to Bank a modification fee equal to Twenty Thousand Dollars (\$20,000.00), which modification fee shall be due and payable on the date hereof and shall be deemed fully earned as of the date hereof The Borrower shall also reimburse Bank for all legal fees and expenses incurred in connection with this amendment to the Existing Loan Documents.

5. **RATIFICATION OF PLEDGE AGREEMENT.** Borrower hereby ratifies, confirms and reaffirms, all and singular, the terms and conditions of a certain Pledge Agreement dated as of March 27, 2002, between Borrower and Bank, and acknowledges, confirms and agrees that said Pledge Agreement shall remain in full force and effect and the Collateral defined therein shall continue to secure the Obligations under the Loan Agreement, as amended hereby.

6. **RATIFICATION OF NEGATIVE PLEDGE** Borrower hereby ratifies, confirms and reaffirms, all and singular, the terms and conditions of a certain Negative Pledge Agreement dated as of March 27, 2002, between Borrower and Bank, and acknowledges, confirms and agrees that said Negative Pledge Agreement shall remain in full force and effect

7. **RATIFICATION OF PERFECTION CERTIFICATE.** Borrower hereby ratifies, confirms and reaffirms, all and singular, the terms and disclosures contained in a certain Perfection Certificate dated as of March 27, 2002, between Borrower and Bank, and acknowledges, confirms and agrees the disclosures and information above Borrower provided to Bank in the Perfection Certificate has not changed, as of the date hereof.

8. **CONSISTENT CHANGES.** The Existing Loan Documents are hereby amended wherever necessary to reflect the changes described above.

9. **RATIFICATION OF LOAN DOCUMENTS.** Borrower hereby ratifies, confirms, and reaffirms all terms and conditions of all security or other collateral granted to the Bank, and confirms that the indebtedness secured thereby includes, without limitation, the Obligations.

10. **NO DEFENSES OF BORROWER.** Borrower hereby acknowledges and agrees that Borrower has no offsets, defenses, claims, or counterclaims against Bank with respect to the Obligations, or otherwise, and that if Borrower now has, or ever did have, any offsets, defenses, claims, or counterclaims against Bank, whether known or unknown, at law or in equity, all of them are hereby expressly WAIVED and Borrower hereby RELEASES Bank from any liability thereunder.

11. CONTINUING VALIDITY. Borrower understands and agrees that in modifying the existing Obligations, Bank is relying upon Borrower's representations, warranties, and agreements, as set forth in the Existing Loan Documents. Except as expressly modified pursuant to this Loan Modification Agreement, the terms of the Existing Loan Documents remain unchanged and in full force and effect. Bank's agreement to modifications to the existing Obligations pursuant to this Loan Modification Agreement in no way shall obligate Bank to make any future modifications to the Obligations. Nothing in this Loan Modification Agreement shall constitute a satisfaction of the Obligations. It is the intention of Bank and Borrower to retain as liable parties all makers of Existing Loan Documents, unless the party is expressly released by Bank in writing. No maker will be released by virtue of this Loan Modification Agreement.

12. COUNTERSIGNATURE. This Loan Modification Agreement shall become effective only when it shall have been executed by Borrower and Bank (provided, however, in no event shall this Loan Modification Agreement become effective until signed by an officer of Bank in California).

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**EXHIBIT A
COMPLIANCE CERTIFICATE**

TO: SILICON VALLEY BANK

FROM: GTC BIOTHERAPEUTICS, INC.

The undersigned authorized officer of GTC Biotherapeutics, Inc. certifies that under the terms and conditions of the Loan and Security Agreement between Borrower and Bank (the "Agreement"), (i) Borrower is in complete compliance for the period ending _____ with all required covenants except as noted below and (ii) all representations and warranties in the Agreement are true and correct in all material respects on this date. Attached are the required documents supporting the certification. The Officer certifies that these are prepared in accordance with Generally Accepted Accounting Principles (GAAP) consistently applied from one period to the next except as explained in an accompanying letter or footnotes. The Officer acknowledges that no borrowings may be requested at any time or date of determination that Borrower is not in compliance with any of the terms of the Agreement, and that compliance is determined not just at the date this certificate is delivered.

Please indicate compliance status by circling Yes/No under "Complies" column.

<u>Reporting Covenant</u>	<u>Required</u>			<u>Complies</u>
Quarterly financial statements with CC	Within 5 days after filing with SEC			Yes No
Annual (CPA Audited)	With 5 days after filing with SEC			Yes No
Projects approved by Board of Directors	Annually, and as updated			Yes No
<u>Financial Covenant</u>		<u>Required</u>	<u>Actual</u>	<u>Complies</u>
Maintain on a Quarterly Basis:				
Minimum Liquidity		\$18,000,000.00	\$ _____	Yes No

Comments Regarding Exceptions: See Attached.

BANK USE ONLY

Sincerely,

_____	Received by:	_____
SIGNATURE		AUTHORIZED SIGNER
	Date:	_____
_____	Verified:	_____
TITLE		AUTHORIZED SIGNER
_____	Date:	_____
DATE		

LOAN MODIFICATION AGREEMENT

This Loan Modification Agreement (this "Loan Modification Agreement") dated as of April 7, 2004, by and between **SILICON VALLEY BANK**, a California-chartered bank, with its principal place of business at 3003 Tasman Drive, Santa Clara, California 95054 and with a loan production office located at One Newton Executive Park, Suite 200, 2221 Washington Street, Newton, Massachusetts 02462, doing business under the name "Silicon Valley East" ("Bank") and **GTC BIOTHERAPEUTICS, INC.**, a Massachusetts corporation with its chief executive office located at 175 Crossing Boulevard, Suite 410, Framingham, Massachusetts 01702 ("Borrower").

1. **DESCRIPTION OF EXISTING INDEBTEDNESS AND OBLIGATIONS.** Among other indebtedness and obligations which may be owing by Borrower to Bank, Borrower is indebted to Bank pursuant to a loan arrangement dated as of March 27, 2002, evidenced by, among other documents, a certain Loan and Security Agreement dated as of March 27, 2002, between Borrower and Bank, as amended by a Loan Modification Agreement dated June 11, 2003, as amended by a Loan Modification Agreement dated August 13, 2003, and a further amended by a Loan Modification Agreement dated January 25, 2004 (as amended, the "Loan Agreement"). Capitalized terms used but not otherwise defined herein shall have the same meaning as in the Loan Agreement.

2. **DESCRIPTION OF COLLATERAL.** Repayment of the Obligations is secured by the Collateral as described in the Loan Agreement (together with any other collateral security granted to Bank, the "Security Documents").

Hereinafter, the Security Documents, together with all other documents evidencing or securing the Obligations shall be referred to as the "Existing Loan Documents".

3. **DESCRIPTION OF CHANGE IN TERMS.**

A. Modifications to Loan Agreement.

1 The Loan Agreement shall be amended by deleting the following definition appearing in Section 13.1 thereof:

“**Revolving Maturity Date**” means March 25, 2004.”

and inserting in lieu thereof the following:

“**Revolving Maturity Date**” means March 24, 2005.”

4. **FEES.** Borrower shall pay to Bank a modification fee equal to Two Thousand Five Hundred Dollars (\$2,500.00), which fee shall be due on the date hereof and shall be deemed fully earned as of the date hereof. The Borrower shall also reimburse Bank for all legal fees and expenses incurred in connection with this amendment to the Existing Loan Documents.

5. **RATIFICATION OF PLEDGE AGREEMENT.** Borrower hereby ratifies, confirms and reaffirms, all and singular, the terms and conditions of a certain Pledge Agreement dated as of March 27, 2002, between Borrower and Bank, and acknowledges, confirms and agrees that said Pledge Agreement shall remain in full force and effect.

6. **RATIFICATION OF NEGATIVE PLEDGE AGREEMENT.** Borrower hereby ratifies, confirms and reaffirms, all and singular, the terms and conditions of a certain Negative Pledge Agreement dated as of March 27, 2002, between Borrower and Bank, and acknowledges, confirms and agrees that said Negative Pledge Agreement shall remain in full force and effect.

7. **CONSISTENT CHANGES.** The Existing Loan Documents are hereby amended wherever necessary to reflect the changes described above.

8. RATIFICATION OF LOAN DOCUMENTS. Borrower hereby ratifies, confirms, and reaffirms all terms and conditions of all security or other collateral granted to the Bank, and confirms that the indebtedness secured thereby includes, without limitation, the Obligations.

9. NO DEFENSES OF BORROWER. Borrower hereby acknowledges and agrees that Borrower has no offsets, defenses, claims, or counterclaims against Bank with respect to the Obligations, or otherwise, and that if Borrower now has, or ever did have, any offsets, defenses, claims, or counterclaims against Bank, whether known or unknown, at law or in equity, all of them are hereby expressly WAIVED and Borrower hereby RELEASES Bank from any liability thereunder.

10. CONTINUING VALIDITY. Borrower understands and agrees that in modifying the existing Obligations, Bank is relying upon Borrower's representations, warranties, and agreements, as set forth in the Existing Loan Documents. Except as expressly modified pursuant to this Loan Modification Agreement, the terms of the Existing Loan Documents remain unchanged and in full force and effect. Bank's agreement to modifications to the existing Obligations pursuant to this Loan Modification Agreement in no way shall obligate Bank to make any future modifications to the Obligations. Nothing in this Loan Modification Agreement shall constitute a satisfaction of the Obligations. It is the intention of Bank and Borrower to retain as liable parties all makers of Existing Loan Documents, unless the party is expressly released by Bank in writing. No maker will be released by virtue of this Loan Modification Agreement.

11. COUNTERSIGNATURE. This Loan Modification Agreement shall become effective only when it shall have been executed by Borrower and Bank (provided, however, in no event shall this Loan Modification Agreement become effective until signed by an officer of Bank in California).

[The remainder of this page is intentionally left blank]

This Loan Modification Agreement is executed as a sealed instrument under the laws of the Commonwealth of Massachusetts as of the date first written above.

BORROWER:

GTC BIOTHERAPEUTICS, INC.

By: _____ /s/ JOHN B. GREEN
Name: John B. Green
Title: SVP and CFO

BANK:

SILICON VALLEY BANK, doing business as
SILICON VALLEY EAST

By: _____ /s/ DOUGLAS MARSHALL
Name: Douglas Marshall
Title: Vice President

SILICON VALLEY BANK

By: _____
Name: _____
Title: _____
(signed in Santa Clara County, California)

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) 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
 - d) 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: May 12, 2005

/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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) 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
 - d) 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: May 12, 2005

/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 the GTC Biotherapeutics, Inc. (the "Company") for the quarterly period ended April 3, 2005, 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: May 12, 2005

/s/ Geoffrey F. Cox

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

Date: May 12, 2005

/s/ John B. Green

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