
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 October 2, 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 by check whether registrant is a shell company (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 November 1, 2005

Common Stock, \$0.01 par value

51,507,595

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 “expect”, “may”, “will”, “continue”, “anticipate”, “estimate”, “project”, “believes”, “could”, “opportunity”, “future”, “project”, and 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. We caution investors not to place undue reliance on forward-looking statements contained in this report.

For a further description of the risks and uncertainties associated with our business, we encourage you to read carefully Exhibit 99 to our Quarterly Report on Form 10-Q for the quarterly period ended July 3, 2005—“Important Factors Regarding Forward-Looking Statements”, which is incorporated into this Form 10-Q by this reference.

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>October 2, 2005</u>	<u>January 2, 2005</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 11,885	\$ 1,835
Marketable securities	8,641	20,446
Accounts receivable and unbilled contract revenue	222	725
Inventory	291	466
Other current assets	1,359	1,479
	<u>22,398</u>	<u>24,951</u>
Total current assets	22,398	24,951
Net property, plant and equipment	17,631	20,279
Net intangible assets	9,282	10,059
Other assets	1,557	1,562
Restricted cash	450	450
	<u>51,318</u>	<u>57,301</u>
Total assets	\$ 51,318	\$ 57,301
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,696	\$ 2,391
Accrued liabilities	3,177	3,517
Accrued liabilities – Genzyme	2,858	2,806
Deferred contract revenue	1,402	733
Current portion of long-term debt and capital leases	3,203	2,479
Note payable – Genzyme	2,386	2,386
	<u>15,722</u>	<u>14,312</u>
Total current liabilities	15,722	14,312
Long-term debt and capital leases, net of current portion	6,170	6,926
Note payable – Genzyme	—	2,387
Deferred lease obligation	20	23
	<u>21,912</u>	<u>23,648</u>
Total liabilities	21,912	23,648
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; 54,284,642 and 41,619,974 shares issued and 51,464,642 and 38,799,974 shares outstanding at October 2, 2005 and January 2, 2005, respectively	543	416
Capital in excess of par value – common stock	240,001	222,590
Treasury stock, at cost, 2,820,000 shares	(9,545)	(9,545)
Accumulated deficit	(201,520)	(179,672)
Accumulated other comprehensive loss	(73)	(136)
	<u>29,406</u>	<u>33,653</u>
Total shareholders' equity	29,406	33,653
	<u>51,318</u>	<u>57,301</u>
Total liabilities and shareholders' equity	\$ 51,318	\$ 57,301

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		Nine months ended	
	October 2, 2005	October 3, 2004	October 2, 2005	October 3, 2004
Revenues				
Revenue	\$ 1,184	\$ 920	\$ 3,523	\$ 3,383
Revenue from related party (Genzyme)	—	4	—	46
	<u>1,184</u>	<u>924</u>	<u>3,523</u>	<u>3,429</u>
Costs of revenue and operating expenses:				
Cost of revenue	767	1,182	3,046	3,745
Research and development	4,778	4,655	15,383	13,923
Selling, general and administrative	2,191	2,100	6,487	7,515
	<u>7,736</u>	<u>7,937</u>	<u>24,916</u>	<u>25,183</u>
Operating loss	(6,552)	(7,013)	(21,393)	(21,754)
Other income (expense):				
Interest income	129	111	381	219
Interest expense	(272)	(271)	(884)	(745)
Other income	—	23	48	295
	<u>—</u>	<u>23</u>	<u>48</u>	<u>295</u>
Net loss	\$ (6,695)	\$ (7,150)	\$ (21,848)	\$ (21,985)
Net loss per common share (basic and diluted)	\$ (0.14)	\$ (0.18)	\$ (0.46)	\$ (0.60)
Weighted average number of common shares outstanding (basic and diluted)	<u>49,355</u>	<u>38,751</u>	<u>47,009</u>	<u>36,894</u>
Comprehensive loss:				
Net loss	\$ (6,695)	\$ (7,150)	\$ (21,848)	\$ (21,985)
Other comprehensive loss:				
Unrealized change in holding gain (loss) on securities available for sale	(21)	49	(63)	(124)
Total other comprehensive gain (loss)	<u>(21)</u>	<u>49</u>	<u>(63)</u>	<u>(124)</u>
Comprehensive loss	\$ (6,716)	\$ (7,101)	\$ (21,911)	\$ (22,109)

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

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

	Nine months ended	
	October 2, 2005	October 3, 2004
Cash flows from operating activities:		
Net loss	\$(21,848)	\$(21,985)
Adjustments to reconcile net loss from continuing operations to net cash used in operating activities:		
Depreciation and amortization	2,981	3,041
Stock based compensation	—	35
Amortization of premium (discount) on marketable securities	(97)	1,220
Non-cash common stock issuance to GTC savings and retirement plan	193	313
Inventory write-down	419	181
Loss (gain) on disposal of fixed assets	(28)	—
Changes in assets and liabilities:		
Accounts receivable and unbilled contract revenue	503	1,189
Deferred contract costs	—	(992)
Inventory	(244)	—
Other assets and liabilities	122	(25)
Accounts payable	305	497
Accrued liabilities	(201)	(89)
Accrued liabilities – Genzyme	52	2,209
Deferred contract revenue	669	1,743
Net cash used in operating activities	(17,174)	(12,663)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(572)	(1,160)
Sale of property, plant, and equipment	651	226
Purchase of marketable securities	(6,532)	(15,804)
Redemption of marketable securities	18,497	17,235
Restricted cash	—	(450)
Net cash provided by investing activities	12,044	47
Cash flows from financing activities:		
Net proceeds from the issuance of common stock, net of offering costs	17,033	13,868
Net proceeds from employee stock purchase plan	162	291
Net proceeds from the exercise of stock options	11	119
Net proceeds from long-term debt	2,400	10,386
Repayment of long-term debt	(4,426)	(10,395)
Repayment of principal on capital leases	—	(164)
Net cash provided by financing activities	15,180	14,105
Net increase in cash and cash equivalents	10,050	1,489
Cash and cash equivalents at beginning of period	1,835	5,733
Cash and cash equivalents at end of period	\$ 11,885	\$ 7,222

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 (“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 nine months ended October 2, 2005 and October 3, 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 and consist only of normal nonrecurring adjustments.

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. We have incurred losses from operations and negative operating cash flow since inception and have an accumulated deficit of \$201.5 million at October 2, 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 the second half of 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 and equity or debt financing. Any future sales of equity 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.

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 and nine months ended October 2, 2005 and October 3, 2004 would have been increased to the pro forma amounts indicated below:

	Three Months Ended		Nine Months Ended	
	October 2, 2005	October 3, 2004	October 2, 2005	October 3, 2004
Net loss reported	\$ (6,695)	\$ (7,150)	\$(21,848)	\$(21,985)
Add: *	—	—	—	35
Deduct: **	(301)	(417)	(1,212)	(1,805)
Pro Forma net loss	\$ (6,996)	\$ (7,567)	\$(23,060)	\$(23,755)
Earnings per share:				
Basic – as reported (basic and diluted)	\$ (0.14)	\$ (0.18)	\$ (0.46)	\$ (0.60)
Basic – Pro Forma (basic and diluted)	\$ (0.14)	\$ (0.20)	\$ (0.49)	\$ (0.64)

* 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 0.93% for the third quarter of 2005 and 0.90% for the nine months ended October 2, 2005, and 100% for the third quarter of 2004 and the nine months ended October 3, 2004, a dividend yield of 0% and a risk-free interest rate of 3.7% for the third quarter of 2005 and the nine months ended October 2, 2005, and 3.11% for the third quarter of 2004 and the nine months ended October 2, 2004. The average fair value per share of those options granted during the third quarters of 2005 and 2004 was \$1.25 and \$1.34, respectively. The average fair value per share of those options granted during the first nine months of 2005 and 2004 was \$1.20 and \$2.66, 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, an expected volatility of 0.93% for the third quarter of 2005 and for the nine months ended October 2, 2005, and 100% for the third quarter of 2004 and the nine months ended October 3, 2004, a dividend yield of 0%, and a risk-free interest rate of 3.70% for the third quarter of 2005 and 2.59% for the nine months ended October 2, 2005 and 1.39% for the third quarter of 2004 and the nine months ended October 3, 2004. The average fair value of those purchase rights granted during the third quarters of 2005 and 2004 was \$0.30 and \$0.58, respectively. The average fair value of those purchase rights granted during the first nine months of 2005 and 2004 was \$0.30 and \$0.81, 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 5.9 million and 5.4 million at October 2, 2005 and October 3, 2004, respectively. The increase in potential common shares is a result of stock option grants. Since the Company was in a net loss position at October 2, 2005 and October 3, 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 October 2, 2005 we had approximately \$291,000 of work in process inventory for the manufacture of ATryn[®] which management believes will be available for commercial sale prior to expiration. At January 2, 2005, we also had approximately \$466,000 of finished goods inventory related to ATryn[®]. During the first quarter of 2005 we wrote the finished goods inventory down to zero value as we could no longer conclude with certainty that it was probable that the inventory would be sold prior to product expiration. This resulted in a \$419,000 charge to research and development expense as product has not yet been approved for commercial sale. During the first nine months 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 October 2, 2005	At January 2, 2005
Accrued payroll and benefits	\$ 1,378	\$ 1,696
Accrued bonus	699	579
Other	1,100	1,242
Total accrued expenses	\$ 3,177	\$ 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 were completed in the third quarter of 2005.

Following is a summary of accrued severance:

	(dollars in thousands)
Balance at January 2, 2005	\$ 184
2004 restructuring payments made in the first quarter of 2005	(103)
Balance at April 3, 2005	81
2004 restructuring payments made in the second quarter of 2005	(66)
Balance at July 3, 2005	\$ 15
2004 restructuring payments made in the third quarter of 2005	(15)
Balance at October 2, 2005	—

5. Intangible Assets:

Our intangible assets consist of:

	Amortization Life	(dollars in thousands)	
		October 2, 2005	January 2, 2005
Marketing rights	15 years	\$ 11,210	\$ 11,210
Accumulated amortization – marketing rights		(3,799)	(3,238)
Net		7,411	7,972
Technology licenses	10 years to 15 years	3,379	3,379
Accumulated amortization – technology licenses		(1,508)	(1,292)
Net		1,871	2,087
Total intangible assets, net		\$ 9,282	\$ 10,059

Amortization expense was \$260,000 for the three months ended October 2, 2005 and October 3, 2004, and \$777,000 for the nine months ended October 2, 2005 and October 3, 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 \$4,992,000 for 2010 and thereafter.

6. Long-Term Debt:

In February 2005, we expanded our term loan with General Electric Capital Corporation (“GE Capital”) to allow us to draw down an additional \$2.4 million, which was used to refinance the note payment made to Genzyme on April 4, 2005. The additional loan 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 \$10 million loan with GE Capital.

7. Financing:

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.

In August 2005, we sold 4,571,429 shares of our Common Stock at \$1.75 per share in a private placement to institutional investors. We also issued 5 year warrants to the investors to purchase an aggregate of 1,828,573 shares of our Common Stock at an exercise price of \$2.68 per share and we paid a fee to our placement agent in the transaction. Our proceeds from this sale, net of offering costs of approximately \$600,000, were approximately \$7.4 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 contend 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. The Court has certified the case as a class action, with the class including employees of Primedica who, at the time GTC sold it, had GTC options that had not been exercised. We have filed an answer denying all material allegations in the complaint, and are vigorously defending the case. 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. To date, no such outside financing has been obtained.

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 \$29,000.

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 cannot yet estimate the impact of Statement 123(R).

In June 2005, the FASB issued statement of Financial Accounting Standards No. 154, Accounting Changes and Error Corrections, which superseded APB Opinion No. 20, Accounting Changes and FAS No. 3, Reporting Accounting

Changes in Interim Financial Statements. APB No. 20 previously required that most voluntary changes in accounting principle be recognized by including in the current period's net income the cumulative effect of changing to the new accounting principle. In contrast, FAS 154 requires that a voluntary change in accounting principle be applied retrospectively to prior periods' financial statements, unless this would be impracticable. In addition, FAS 154 makes a distinction between retrospective application of an accounting principle and the restatement of financial statements to reflect the correction of an error. FAS 154 is effective for accounting changes and correction of errors made in fiscal years beginning after December 15, 2005. We do not expect the adoption of FAS 154 to have a material impact on our consolidated results of operations.

11. Subsequent Event:

In October 2005, we entered into a Lease Amendment ("the Amendment") with NDNE 9/90 Corporate Center LLC to extend the term of our original lease for our corporate headquarters from June 2006 until September 2010. As part of the Amendment, our annual fixed rent has been slightly reduced.

In October 2005, we entered into a collaboration agreement with LEO Pharma A/S of Ballerup Denmark ("LEO") for the commercialization of ATryn[®] in Europe, the Middle East and Canada. The agreement includes an up front payment of \$2 million which was paid on signing, with an additional \$3 million due through approval of the product for the hereditary deficiency indication in the European Community. Further milestones totaling \$68 million would be payable to GTC in future years based upon the achievement of successful clinical development in an acquired deficiency indication as well as for achievement of specified sales milestones and certain regulatory approvals in LEO's territory. Under the agreement, GTC will receive a royalty on LEO's net sales of ATryn[®] plus a transfer price for product sold to LEO. LEO will fund the phase II and phase III clinical program for the selected acquired deficiency indication. We will have unrestricted access to all phase II data for use outside LEO's territory. Should we choose to exercise our option to support half of the clinical cost of a phase III acquired deficiency study for LEO's territories, we will also have unrestricted access to that data for any filings in our own territories.

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, which are 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 as 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, including antibodies. 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 \$201.5 million at October 2, 2005. Based on the current rate of cash utilization, management believes that existing cash resources and potential future cash payments from partnering and licensing programs will be sufficient to fund operations into the second half of 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 and equity or debt financing. Any future sales of equity 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.

In October 2005, we entered into a collaboration agreement with LEO Pharma A/S of Ballerup Denmark (“LEO”) for the commercialization of ATryn[®] in Europe, the Middle East and Canada. The agreement includes an up front payment of \$2 million which was paid on signing, with an additional \$3 million due through approval of the product for the hereditary deficiency indication in the European Community. Further milestones totaling \$68 million would be payable to GTC in future years based upon the achievement of successful clinical development in an acquired deficiency indication as well as for achievement of specified sales milestones and certain regulatory approvals in LEO’s territory. Under the agreement, GTC will receive a royalty on LEO’s net sales of ATryn[®] plus a transfer price for product sold to LEO. LEO will fund the phase II and phase III clinical program for the selected acquired deficiency indication. We will have unrestricted access to all phase II data for use outside LEO’s territory. Should we choose to exercise our option to support half of the clinical cost of a phase III acquired deficiency study for LEO’s territories, we will also have unrestricted access to that data for any filings in our own territories.

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. 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. Our actual results may differ from these estimates under different assumptions or conditions.

Results of Operations

The key components to our losses are costs of revenue, research and development expenses, and selling, general and administrative expenses.

Three months ended October 2, 2005 and October 3, 2004

	(dollars in thousands)			
	October 2, 2005	October 3, 2004	\$ Change	% Change
Revenue	\$ 1,184	\$ 924	\$ 260	28%
Cost of revenue	\$ 767	\$ 1,182	\$ (415)	(35)%
Research and development	\$ 4,778	\$ 4,655	\$ 123	3%

Revenue. During the third quarter of 2005, \$1.1 million of our revenues were derived from external development programs, primarily with Merrimack Pharmaceuticals and Elan Pharmaceuticals, in addition to \$27,000 derived from the CD-137 program, which is funded by a Flexible System to Advance Innovative Research (“FLAIR”) grant awarded by the National Cancer Institute, and \$45,000 derived from the malaria program, which was funded by the National Institute of Allergy and Infectious Disease (“NIAID”). During the third quarter of 2004, \$807,000 of our revenues were derived from external development programs, primarily with Merrimack Pharmaceuticals and a license to Nexia Biotechnologies, which has subsequently transferred to PharmAthene, Inc., in addition to \$41,000 derived from the CD-137 program and \$76,000 derived from the malaria program. The Elan maintenance program was amended by Elan in the third quarter of 2005 resulting in recognition of approximately \$700,000 of the deferred revenue on this program in the third quarter of 2005. The decrease in both the Merrimack and Nexia/PharmAthene program revenues is a result of timing of milestones met on the programs in 2005. Due to current budgetary constraints at NIAID, no funding has been committed for the malaria program beyond mid-August 2005. We expect to see variation in reported revenues on a year-to-year basis due to the nature and timing of our milestone-based research and development activities. For example, Merrimack has recently signed a new agreement for further clinical production of MM-093, which will begin to be reflected in results for the fourth quarter of 2005.

Cost of revenue. The decrease in cost of revenue is primarily the result of the development stage of the various external programs in third quarter of 2005 as compared to the third quarter of 2004. The level of expenses on our external programs will fluctuate from period to period depending upon the stage of development of individual programs and their progress.

Research and development expense. The third quarter 2005 research and development expense included \$2.4 million related to the ATryn[®] program, a decrease of \$600,000 as compared to \$3 million in 2004. Included in the 2005 expenses were approximately \$1.2 million related to support of the EMEA filing for ATryn[®] as well \$ 800,000 of ATryn[®] operating costs and \$400,000 of expenses incurred in preparation for the U.S. clinical trial. The 2004 expenses included \$2.3 million in support of the EMEA filing and \$700,000 of ATryn[®] operating costs.

Additionally, in 2005, we incurred expenses of \$320,000 in the CD-137 development program representing almost entirely an allocation of internal resources as compared with \$189,000 in the third quarter of 2004, an increase of \$131,000. In 2005, we also incurred expenses of \$409,000 in support of the recombinant human alpha-1 antitrypsin (rhAAT) program as compared to \$129,000 in 2004, an increase of \$280,000. The net of the decrease in the ATryn[®] combined with the increases in the CD-137 and rhAAT programs in the year to year comparison was partially offset by a net increase in several other research and development programs. 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.

Nine months ended October 2, 2005 and October 3, 2004

	(dollars in thousands)			
	October 2, 2005	October 3, 2004	\$ Change	% Change
Revenue	\$ 3,523	\$ 3,429	\$ 94	3 %
Cost of revenue	\$ 3,046	\$ 3,745	\$ (699)	(19)%
Research and development	\$ 15,383	\$ 13,923	\$ 1,460	10 %
Selling, general and administrative	\$ 6,487	\$ 7,515	\$(1,028)	(14)%
Other income	\$ 48	\$ 295	\$ (247)	(84)%

Revenue. During the first nine months of 2005, \$3 million of our revenues were derived from external development programs, primarily with Merrimack Pharmaceuticals and Elan Pharmaceuticals, in addition to \$237,000 derived from the CD-137 program and \$253,000 derived from the malaria program. During the first nine months of 2004, \$2.5 million were derived from external development programs, primarily with Merrimack and Centocor, in addition to \$89,000 derived from the CD-137 program and \$868,000 derived from the malaria program. The Elan maintenance program was amended by Elan in the third quarter of 2005 resulting in recognition of approximately \$700,000 of the deferred revenue on this program in the third quarter of 2005. Due to current budgetary constraints, NIAID has committed no funding for the malaria program beyond mid-August 2005. 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. In 2004, the malaria program revenue was a result of breeding activities to create a new founder line. The increase in the CD-137 program revenues is the result of work performed on the second phase of the FLAIR grant during 2005.

Cost of revenue. The decrease in cost of revenue is primarily the result of a shift in internal resources to our internal ATryn[®] program in the first nine months of 2005 as compared to the first nine months of 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. The first nine months of 2005 research and development expense included \$8.4 million related to the ATryn[®] program, and increase of \$1 million as compared to \$7.4 million in the first nine months of 2004. Included in the 2005 expenses was approximately \$4.7 million related to the support of the EMEA filing of ATryn[®] compared to \$6 million in 2004, as well as \$2 million of ATryn[®] operating costs and \$1.7 million of U.S. clinical trial preparation expenses in 2005, as compared to \$1.4 million of ATryn[®] operating costs in 2004. In the first quarter of 2005, based upon our review of the proposed shelf life of ATryn[®], we wrote down the ATryn[®] inventory to zero value as we could no longer conclude with certainty that it was probable that the inventory would be sold prior to product expiration, resulting in a \$419,000 charge to research and development expense. During the first nine months of 2005, we also recorded approximately \$47,000 of research and development for ATryn[®] inventory used for development purposes.

Additionally, in 2005, we incurred expenses of approximately \$2.3 million in support of the CD-137 program representing almost entirely an allocation of internal resources, compared to \$400,000 in the first nine months of 2004, an increase of \$1.9 million. Increases in the ATryn[®] and CD-137 programs were offset by decreases in spending of approximately \$1.4 million on several other research and development programs. 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. Selling, general and administrative expenses in the first nine months of 2004 included approximately \$743,000 of restructuring charges. The remainder of the decrease year to year was a result of lower spending throughout the selling, general and administrative departments

Other Income. The decrease in other income is primarily the result of a \$200,000 refund we received in the first nine months of 2004 in connection with the termination of our option for additional sublease space at our Framingham, Massachusetts headquarters.

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, milestone payments, 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 expect our net use of cash and marketable securities for 2005 to be approximately \$23 million, exclusive of the impact of any equity financing. The net cash use projection includes approximately \$9 million of cash collections from partnering for the year, of which approximately \$8.8 million has been collected or is anticipated under existing contracts including the partnering arrangement with LEO. We expect a net use of cash in 2006 of between \$21 million and \$25 million.

In January 2005, we raised \$9.7 million in cash, net of offering costs, in a registered direct placement of our Common Stock. Also, in August 2005, we raised an additional \$7.4 million in cash, net of offering costs, in a private placement of our Common Stock and warrants to purchase Common Stock, both of which are more fully described under "Financing Activities". We had cash, cash equivalents and marketable securities of \$20.5 million at October 2, 2005.

We had working capital of \$6.7 million at October 2, 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 and we paid a fee to our placement agent in the transaction. Our proceeds from this sale, net of offering costs of approximately \$700,000, were approximately \$9.7 million.

In August 2005, we issued and sold 4,571,429 shares of our Common Stock at \$1.75 per share in a private placement to institutional investors. We also issued 5 year warrants to the investors to purchase an aggregate of 1,828,573 shares of our Common Stock at an exercise price of \$2.68 per share and we paid a placement agent fee to our placement agent in the transaction. Our proceeds from this sale, net of offering costs of approximately \$600,000, were approximately \$7.4 million.

In October, we filed a universal shelf registration statement on Form S-3 with the U.S. Securities and Exchange Commission (SEC) pursuant to which, when declared effective, we may issue up to an aggregate of \$50 million of securities, including common stock, debt securities, and other types of securities. The terms and pricing of any future offerings would be established at the time of any offering of securities covered by the registration statement through one or more methods of distribution, subject to market conditions and our capital needs.

Credit Facility

Of our \$11.8 million of outstanding long-term debt at October 2, 2005, approximately \$5.6 million is classified as current. In April 2005, we paid approximately \$2.4 million to Genzyme Corporation related to a \$4.8 million term note. The remaining \$2.4 million is payable on April 4, 2006 and is classified on the balance sheet as current.

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 loan 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 used in operating activities were \$17.2 million and \$12.7 million for the first nine months of 2005 and 2004, respectively, an increase of approximately \$4.5 million, primarily the result of the timing of cash payments in connection with the ATryn[®] program. Cash used in operating activities for the first nine months of 2005 included a net loss of \$21.8 million, which was partially offset by certain non-cash charges of approximately \$3.4 million. Use of cash also included an increase in inventory of approximately \$244,000. Sources of funds included an increase in accounts payable, accrued liabilities, and other assets and liabilities of \$278,000, a reduction of accounts receivable of approximately \$503,000, an increase of approximately \$669,000 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.

Cash Flows from Investing Activities

Cash flows from investing activities include \$12 million in net redemptions of marketable securities in our portfolio and \$651,000 realized from the sale of farm land and other assets, which were partially offset by \$572,000 used for

purchases of capital equipment. We anticipate a reduced 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 October 2, 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

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our 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, our principal executive officer and our 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 our 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, our 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	First Amendment to Lease Agreement, dated October 1, 2005, by and between NDNE 9/90 Corporate Center LLC and the Company.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a).
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a).
32	Certifications pursuant to 18 U.S.C. Section 1350.

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: November 4, 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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FIRST AMENDMENT OF LEASE

THIS FIRST AMENDMENT OF LEASE (this "Amendment") is dated as of the 1st day of October, 2005 (the "Effective Date") by and between NDNE 9/90 Corporate Center LLC (the "Landlord"), and GTC Biotherapeutics, Inc. (the "Tenant").

BACKGROUND

- A. Reference is hereby made to that certain Lease, dated March 26, 1999, by and between Landlord and Tenant (then known as Genzyme Transgenics Corporation), as affected by that certain letter agreement dated June 11, 1999 regarding term and rent commencement dates (hereinafter referred to as the "Lease").
- B. Under the Lease, the Tenant currently leases from the Landlord 12,468 rentable square feet (the "Premises") on the fourth floor of the building (the "Building") known as and numbered 175 Crossing Boulevard, Framingham, Massachusetts, more particularly described therein.
- C. Capitalized terms not defined herein shall have the same meaning ascribed to them in the Lease.
- D. The term of the Lease is currently scheduled to expire on June 30, 2006. The Landlord and the Tenant desire to amend the Lease as of the date hereof to, among other revisions, (i) extend the term of the Lease, and (ii) provide for the amount of Annual Fixed Rent commencing October 1, 2005 and through the extended term, all on the terms and conditions set forth below.

AGREEMENT

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and for the mutual promises contained herein, Landlord and Tenant hereby agree as follows:

1. Extension of Term. The Term of the Lease (sometimes referred to in the Lease as the "Original Term") is hereby extended to and including September 30, 2010, and all references to the "Term" or "Original Term" in the Lease shall be deemed a reference to the current Term as hereby extended.

2. Annual Fixed Rent During the Extended Term. From and after October 1, 2005, Annual Fixed Rent due and payable from the Tenant to the Landlord under the Lease shall be as follows:

<u>Period</u>	<u>Per Sq. Ft.</u>	<u>Monthly Amount</u>	<u>Annual Amount</u>
10/1/2005-9/30/2006	\$23.25	\$24,156.75	\$289,881.00
10/1/2006-9/30/2008	\$24.25	\$25,195.75	\$302,349.00
10/1/2008-9/30/2030	\$25.25	\$26,234.75	\$314,817.00

3. Annual Base Operating Costs During the Extended Term. From and after October 1, 2005, the term “Annual Base Operating Costs” under the Lease shall mean an amount equal to the Landlord’s Operating Costs for the Property during the calendar year January 1, 2005 through December 31, 2005.

4. Annual Base Real Estate Taxes During the Extended Term. From and after October 1, 2005, the term “Annual Base Real Estate Taxes” under the Lease shall mean an amount equal to the Real Estate Taxes for the Property applicable to the fiscal tax year July 1, 2005 through June 30, 2006,

5. Option to Extend. Exhibit G of the Lease is hereby amended to provide that (i) the Term of the Lease may be extended for only one (1) additional period of five (5) years (instead of the two (2) additional periods of five (5) years each set forth therein), and all references to a “Second Extension Period” are hereby deleted from said Exhibit G, and (ii) the reference to “97.5%” in the third paragraph of Exhibit G is hereby deleted and “100%” substituted therefor. Accordingly, if the Term of the Lease is properly extended as set forth in Exhibit G, as hereby amended, the Lease shall expire for all purposes on September 30, 2015, and Tenant shall have no further right to extend the Lease whatsoever.

6. Landlord’s Allowance. Upon Tenant’s written request given prior to August 31, 2006 and in the manner set forth in the Lease, Landlord agrees to fund the costs incurred by Tenant in connection with modifications to the Premises to be made by Tenant (“Tenant Improvements”), not to exceed a maximum amount of Fifty Thousand and No/100 Dollars (\$50,000) subject to the provisions hereof and the Lease (“Landlord’s Allowance”). The Landlord’s Allowance shall be paid to Tenant, or directly to Tenant’s general contractor, within thirty (30) days after presentation by Tenant to Landlord of evidence reasonably satisfactory to Landlord of Tenant’s payment for such work (or evidence of completion of such work in the event of any such direct payment), when finished, including, without limitation, invoices (receipted if applicable) and the like. To the extent that the cost of such work exceeds Landlord’s Allowance, Tenant shall be entirely responsible for such excess. Tenant agrees to use the Landlord’s contractor, Cranshaw Construction of New England Limited Partnership (“Cranshaw”), as the general contractor in connection with such work. Cranshaw shall competitively bid such work, including subcontractors recommended by Tenant, and the same shall be done on an open book basis with Tenant with a minimum of two (2) competitive bids for each trade/division of such work, to the extent feasible. Cranshaw shall earn a fee of five percent (5%) of the total cost of the work, such cost of the work to include, without limitation, general conditions and special conditions. All such work shall be undertaken in accordance with the applicable terms and conditions of the Lease, including, without limitation, Section 9.4 thereof. Landlord shall not charge Tenant for any supervisory or administrative fee in connection with such work. The final, actual amount of the Landlord’s Allowance paid hereunder by Landlord, if any, shall be amortized over the remainder of the Original Term (through September 30, 2010)

on a straight line basis, plus interest at the rate of eight percent (8%) per annum, commencing from and after the date of disbursement of such amount. If the Tenant shall fail to deliver such written request to Landlord by August 31, 2006, then the Landlord's agreement to provide the Landlord's Allowance set forth herein shall be void, time remaining of the essence of the Lease. Such work shall begin within thirty (30) days after August 31, 2006, and shall be completed within sixty (60) days.

7. Security Deposit/Letter of Credit. Within forty-five (45) days after the Effective Date, Tenant shall obtain a replacement Letter of Credit in the amount of \$249,360 reasonably satisfactory to Landlord, and in compliance with Section 13.8 of the Lease, which Letter of Credit shall apply to the entire Original Term as herein extended, and as provided in Section 13.8 of the Lease. The parties expressly confirm and agree that if the Term of the Lease is extended in conformity with the requirements of Exhibit G of the Lease, as herein amended, a further condition of such extension shall be the provision to Landlord of a Letter of Credit with respect to such extended period, and in conformity with the requirements of said Section 13.8.

8. Satellite Dish. The Lease is hereby amended by adding the following as Section 13.11 thereof:

Section 13.11. Satellite Dish. Notwithstanding anything to the contrary contained in this Lease, the Landlord hereby agrees that at any time during the Term, the Tenant shall have the Non-Exclusive right to install, on the roof of the Building, a satellite dish (the "Dish"). The Tenant agrees and acknowledges, however, that the location of any Dish, the method of any such installation, and the type of Dish proposed to be installed shall be subject to: (i) compliance by the Tenant with all applicable laws, rules, regulations and the like pertaining thereto; (ii) the consent by the Landlord, which consent shall not be unreasonably withheld provided that the Landlord and the Landlord's engineers are satisfied therewith; and (iii) a determination to be made that such Dish will not interfere with any other equipment or use thereof located in, on or in the vicinity of the Building, and that such Dish will not be visible from the exterior of the Building. If Tenant shall install such Dish, (a) the Tenant shall do so at its own cost and expense and in accordance with all applicable laws, rules and regulations, including, without limitation, reimbursement to Landlord for its third party engineers, if applicable; (b) the Tenant shall maintain such Dish in accordance with the Landlord's reasonable rules and regulations; and (c) the Tenant shall install such Dish in a manner so as to maintain in full force and effect any applicable roof and/or construction related warranties, failing which the Tenant shall promptly reimburse the Landlord for any costs and expenses incurred by the Landlord as a result of such failure. Additionally, the Tenant shall defend, indemnify and hold the Landlord harmless from and against any claims, costs and expenses incurred by the Landlord as a result of such installation by the Tenant or in any other manner in connection with such Dish, including, without limitation, all costs and expenses relating to roof and/or wall penetrations. If the Tenant shall install such Dish, the Tenant shall be responsible for the maintenance and repair thereof, at the Tenant's sole cost and expense, and such Dish shall be at the sole risk of the Tenant, the Landlord having no obligation with respect to any insurance relating thereto. Also, the Tenant hereby agrees, upon the Landlord's notice requesting same, to remove or relocate such Dish and to repair any and all damage caused by such removal or relocation. At the expiration or other termination

of this lease, such Dish shall remain the property of the Tenant, and shall be removed by the Tenant at its own cost and expense, and the Tenant shall repair any and all damage caused by such removal, at its own cost and expense, in accordance with all applicable laws, rules and regulations, and in such a manner so as to maintain in full force and effect any applicable roof and/or construction related warranties, failing which the Tenant shall reimburse the Landlord for any costs and expenses incurred by the Landlord as a result of such failure.

9. Miscellaneous. Tenant hereby acknowledges that, as of the date hereof: (i) Landlord has no undischarged obligations under the Lease to perform any work or improvements to the Premises or to provide any tenant improvement allowance under the Lease except as expressly set forth herein, Tenant hereby confirming that it is now occupying the Premises, and Tenant accepts the Premises as of the date hereof, and will accept the Premises as of the commencement of the extended term herein provided in "AS IS" condition; (ii) there are no offsets or defenses that Tenant has against the full enforcement of the Lease by Landlord; (iii) neither Tenant, nor to Tenant's knowledge, Landlord, is in any respect in default under the Lease; and (iv) Tenant has not assigned, transferred or hypothecated the Lease or any interest therein or subleased all or any portion of the Premises.

10. Brokers. Landlord and Tenant each represent that there are no brokers involved with respect to this Amendment other than The Staubach Company and Trammell Crow Company, whose fees shall be paid by Landlord, and each party agrees to indemnify, defend and hold harmless the other with respect to any breach of such representation.

11. Effective Date. The parties agree that this Amendment shall be effective from and after the Effective Date and not to any period of time prior thereto. To the extent this Amendment contains language which purports to amend the Lease with respect to periods of time prior to the Effective Date, such language is for clarification purposes only and shall not be deemed to change the obligations of the parties with respect thereto. In no event shall this Amendment be construed to impose any liability on Landlord for any period of time preceding its ownership of the Property.

12. Ratification of Lease Provisions. Except as otherwise expressly amended, modified and provided for in this Amendment, Tenant hereby ratifies all of the provisions, covenants and conditions of the Lease, and such provisions, covenants and conditions shall be deemed to be incorporated herein and made a part hereof and shall continue in full force and effect.

13. Entire Amendment. This Amendment contains all the agreements of the parties with respect to the subject matter hereof and supersede all prior dealings between the parties with respect to such subject matter.

14. Authority. Landlord and Tenant each warrant to the other that the person or persons executing this Amendment on its behalf has or have authority to do so and that such execution has fully obligated and bound such party to all terms and provisions of this Amendment.

15. Binding Amendment. This Amendment shall be binding upon, and shall inure to the benefit of the parties hereto, and their respective successors and assigns.

16. Governing Law. This Amendment shall be governed by the laws of The Commonwealth of Massachusetts.

17. Severability. If any clause or provision of this Amendment is or should ever be held to be illegal, invalid or unenforceable under any present or future law applicable to the terms hereof, then and in that event, it is the intention of the parties hereto that the remainder of this Amendment shall not be affected thereby, and that in lieu of each such clause or provision of this Amendment that is illegal, invalid or unenforceable, such clause or provision shall be judicially construed and interpreted to be as similar in substance and content to such illegal, invalid or unenforceable clause or provision, as the context thereof would reasonably suggest, so as to thereafter be legal, valid and enforceable.

18. No Reservation. Submission of this Amendment for examination or signature is without prejudice and does not constitute a reservation, option or offer, and this Amendment shall not be effective until execution and delivery by all parties.

19. Counterparts. This Amendment may be executed simultaneously in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

WITNESS the execution hereof under seal as of the day and year first above written.

Landlord:

NDNE 9/90 Corporate Center LLC

By: NDNE 9/90, Inc., its Manager

By: /s/ John J. O'Neil, III

Name: John J. O'Neil, III
Title: Executive Vice President

Tenant:

GTC Biotherapeutics, Inc.

By: /s/ John B. Green

Name: John B. Green
Title: Senior Vice President

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: November 4, 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: November 4, 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 October 2, 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: November 4, 2005

/s/ Geoffrey F. Cox

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

Date: November 4, 2005

/s/ John B. Green

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