
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended July 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 August 8, 2005
46,891,397

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 this Form 10-Q—“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.

GTC BIOTHERAPEUTICS, INC.
TABLE OF CONTENTS

PAGE #

PART I. FINANCIAL INFORMATION

ITEM 1 - Financial Statements

Consolidated Balance Sheets as of July 3, 2005 and January 2, 2005 (Unaudited) 2

Consolidated Statements of Operations and Comprehensive Loss for the Three Months and Six Months Ended July 3, 2005 and July 4, 2004 (Unaudited) 3

Consolidated Statements of Cash Flows for the Six Months Ended July 3, 2005 and July 4, 2004 (Unaudited) 4

Notes to Unaudited Consolidated Financial Statements 5

ITEM 2 - Management's Discussion and Analysis of Financial Condition and Results of Operations 10

ITEM 3 - Quantitative and Qualitative Disclosures About Market Risk 14

ITEM 4 - Controls and Procedures 14

PART II. OTHER INFORMATION

ITEM 4 - Submission of Matters to a Vote of Security Holders 15

ITEM 6 - Exhibits 15

SIGNATURES 16

PART I - FINANCIAL INFORMATION

ITEM 1 –FINANCIAL STATEMENTS

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

	<u>July 3, 2005</u>	<u>January 2, 2005</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 6,713	\$ 1,835
Marketable securities	12,849	20,446
Accounts receivable and unbilled contract revenue	173	725
Inventory	278	466
Other current assets	1,468	1,479
	<u>21,481</u>	<u>24,951</u>
Total current assets	21,481	24,951
Net property, plant and equipment	17,982	20,279
Net intangible assets	9,542	10,059
Other assets	1,563	1,562
Restricted cash	450	450
	<u>51,018</u>	<u>57,301</u>
Total assets	\$ 51,018	\$ 57,301
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,825	\$ 2,391
Accrued liabilities	2,968	3,517
Accrued liabilities - Genzyme	2,555	2,806
Deferred contract revenue	1,443	733
Current portion of long-term debt and capital leases	3,402	2,479
Note payable - Genzyme	2,387	2,386
	<u>15,580</u>	<u>14,312</u>
Total current liabilities	15,580	14,312
Long-term debt and capital leases, net of current portion	6,726	6,926
Note payable – Genzyme	—	2,387
Deferred lease obligation	21	23
	<u>22,327</u>	<u>23,648</u>
Total liabilities	22,327	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; 49,713,213 and 41,619,974 shares issued and 46,893,213 and 38,799,974 shares outstanding at July 3, 2005 and January 2, 2005, respectively	497	416
Capital in excess of par value – common stock	232,658	222,590
Treasury stock, at cost, 2,820,000 shares	(9,545)	(9,545)
Accumulated deficit	(194,825)	(179,672)
Accumulated other comprehensive loss	(94)	(136)
	<u>28,691</u>	<u>33,653</u>
Total shareholders' equity	28,691	33,653
Total liabilities and shareholders' equity	\$ 51,018	\$ 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		Six months ended	
	July 3, 2005	July 4, 2004	July 3, 2005	July 4, 2004
Revenues				
Revenue	\$ 1,017	\$ 1,416	\$ 2,339	\$ 2,463
Revenue from related party (Genzyme)	—	23	—	42
	<u>1,017</u>	<u>1,439</u>	<u>2,339</u>	<u>2,505</u>
Costs of revenue and operating expenses:				
Cost of revenue	906	1,491	2,279	2,563
Research and development	5,188	3,729	10,605	9,268
Selling, general and administrative	1,901	2,317	4,296	5,415
	<u>7,995</u>	<u>7,537</u>	<u>17,180</u>	<u>17,246</u>
Operating loss	(6,978)	(6,098)	(14,841)	(14,741)
Other income (expense):				
Interest income	131	125	252	108
Interest expense	(273)	(332)	(612)	(474)
Other income	—	46	48	272
	<u>—</u>	<u>46</u>	<u>48</u>	<u>272</u>
Net loss	\$ (7,120)	\$ (6,259)	\$ (15,153)	\$ (14,835)
Net loss per common share (basic and diluted)	\$ (0.15)	\$ (0.16)	\$ (0.33)	\$ (0.41)
Weighted average number of common shares outstanding (basic and diluted)	46,835	38,692	45,836	35,998
Comprehensive loss:				
Net loss	\$ (7,120)	\$ (6,259)	\$ (15,153)	\$ (14,835)
Other comprehensive loss:				
Unrealized change in holding loss on securities available for sale	(34)	(157)	(42)	(173)
Total other comprehensive loss	(34)	(157)	(42)	(173)
Comprehensive loss	\$ (7,154)	\$ (6,416)	\$ (15,195)	\$ (15,008)

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

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

	Six months ended	
	July 3, 2005	July 4, 2004
Cash flows from operating activities:		
Net loss	\$(15,153)	\$(14,835)
Adjustments to reconcile net loss from continuing operations to net cash used in operating activities:		
Depreciation and amortization	2,063	1,977
Stock based compensation	—	35
Amortization of premium (discount) on marketable securities	(174)	1,098
Non-cash common stock issuance to GTC savings and retirement plan	193	309
Inventory write-off	419	8
Loss (gain) on disposal of fixed assets	(28)	—
Changes in assets and liabilities:		
Accounts receivable and unbilled contract revenue	552	580
Deferred contract costs	—	(533)
Inventory	(231)	—
Other assets and liabilities	8	154
Accounts payable	434	(76)
Accrued liabilities	(410)	325
Accrued liabilities – Genzyme	(251)	1,378
Deferred contract revenue	710	736
Net cash used in operating activities	<u>(11,868)</u>	<u>(8,844)</u>
Cash flows from investing activities:		
Purchase of property, plant and equipment	(265)	(762)
Sale of property, plant, and equipment	651	—
Purchase of marketable securities	(6,532)	(15,804)
Redemption of marketable securities	14,345	17,235
Restricted cash	—	(450)
Net cash provided by investing activities	<u>8,199</u>	<u>219</u>
Cash flows from financing activities:		
Net proceeds from the issuance of common stock, net of offering costs	9,655	13,868
Net proceeds from employee stock purchase plan	162	210
Net proceeds from the exercise of stock options	—	111
Net proceeds from long-term debt	2,400	10,386
Repayment of long-term debt	(3,670)	(9,868)
Repayment of principal on capital leases	—	(114)
Net cash provided by financing activities	<u>8,547</u>	<u>14,593</u>
Net increase (decrease) in cash and cash equivalents	4,878	5,968
Cash and cash equivalents at beginning of period	1,835	5,733
Cash and cash equivalents at end of period	<u>\$ 6,713</u>	<u>\$ 11,701</u>

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

GTC BIOTHERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Basis of Presentation:

These unaudited 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 six months ended July 3, 2005 and July 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 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 \$194.8 million at July 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 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 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.

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 six months ended July 3, 2005 and July 4, 2004 would have been increased to the pro forma amounts indicated below:

	Three Months Ended		Six Months Ended	
	July 3, 2005	July 4, 2004	July 3, 2005	July 4, 2004
Net loss reported	\$(7,120)	\$(6,259)	\$(15,153)	\$(14,835)
Add: *	—	—	—	35
Deduct: **	(384)	(518)	(955)	(1,388)
Pro Forma net loss	\$(7,504)	\$(6,777)	\$(16,108)	\$(16,188)
Earnings per share:				
Basic – as reported (basic and diluted)	\$ (0.15)	\$ (0.16)	\$ (0.33)	\$ (0.41)

Basic – Pro Forma (basic and diluted)

\$ (0.16)

\$ (0.18)

\$ (0.35)

\$ (0.45)

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

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

The fair value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumption: an expected life of five years, expected volatility of 0.90% for the second quarter of 2005 and 0.95% for the six months ended July 3, 2005, and 100% for the second quarter of 2004 and the six months ended July 4, 2004, a dividend yield of 0% and a risk-free interest rate of 3.70% for the second quarter of 2005 and the six months ended July 3, 2005, and 3.11% for the second quarter of 2004 and the six months ended July 4, 2004. The average fair value per share of those options granted during the second quarters of 2005 and 2004 was \$0.71 and \$1.38, respectively. The average fair value per share of those options granted during the first six months of 2005 and 2004 was \$1.20 and \$2.70, 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 0.90% for the second quarter of 2005 and 0.95% for the six months ended July 3, 2005, and 100% for the second quarter of 2004 and the six months ended July 4, 2004, a dividend yield of 0%, and a risk-free interest rate of 2.54% for the second quarter of 2005 and 2.03% for the six months ended July 3, 2005 and 0.98% for the second quarter of 2004 and the six months ended July 4, 2004. The average fair value of those purchase rights granted during the second quarters of 2005 and 2004 was \$0.64 and \$0.86, respectively. The average fair value of those purchase rights granted during the first six months of 2005 and 2004 was \$0.60 and \$0.96, 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 5.4 million at July 3, 2005 and July 4, 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 July 3, 2005 and July 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 July 3, 2005 we had approximately \$278,000 of work in process inventory for the manufacture of ATryn[®] which management believes will be available for commercial sale before 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 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 forecasted timelines. In connection with our response to the List of Outstanding Issues, we reviewed the proposed shelf life of ATryn[®] in the first quarter of 2005 and, we wrote the inventory down 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 \$419,000 charge to research and development. During the first six 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 July 3, 2005	At January 2, 2005
Accrued payroll and benefits	\$ 1,558	\$ 1,696
Accrued bonus	468	579
Other	942	1,242
Total accrued expenses	\$ 2,968	\$ 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 made in the first quarter of 2005	(103,000)
Balance at April 3, 2005	81,000
2004 restructuring payments made in the second quarter of 2005	(66,000)
Balance at July 3, 2005	\$ 15,000

5. Intangible Assets:

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

	Amortization Life	(dollars in thousands)	
		July 3, 2005	January 2, 2005
Marketing rights	15 years	\$ 11,210	\$ 11,210
Accumulated amortization—marketing rights		(3,612)	(3,238)
Net		7,598	7,972
Technology licenses	10 years to 15 years	3,379	3,379
Accumulated amortization — technology licenses		(1,435)	(1,292)
Net		1,944	2,087
Total intangible assets, net		\$ 9,542	\$ 10,059

Amortization expense was \$259,000 for the three months ended July 3, 2005 and July 4, 2004, and \$517,000 for the six months ended July 3, 2005 and July 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 \$4,992,000 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.

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. 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.

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 superceded 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 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 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.

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 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 \$194.8 million at July 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 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 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. 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 July 3, 2005 and July 4, 2004

	(dollars in thousands)			
	July 3, 2005	July 4, 2004	\$ Change	% Change
Revenue	\$ 1,017	\$ 1,439	\$ (422)	(29)%
Cost of revenue	\$ 906	\$ 1,491	\$ (585)	(39)%
Research and development	\$ 5,188	\$ 3,729	\$ 1,459	39 %
Selling, general and administrative	\$ 1,901	\$ 2,317	\$ (416)	(18)%

Revenue. During the second quarter of 2005, \$773,000 of our revenues were derived from external development programs, primarily Merrimack Pharmaceuticals and Elan Pharmaceuticals, in addition to \$210,000 derived from the CD-137 program, which is funded by a FLAIR grant awarded by the National Cancer Institute, and \$34,000 derived from the malaria program, which is funded by the National Institute of Allergy and Infectious Disease (“NIAID”). During the second quarter of 2004, \$1.2 million of our revenues were derived from external development programs, primarily Merrimack Pharmaceuticals and Centocor, in addition to \$234,000 derived from the malaria program. The programs with Elan have been successfully completed in December 2004 and animals are now being maintained at reduced levels with funding from Elan. The increase in the CD-137 program revenues is the result of work performed on the second phase of the grant during 2005. The current contract of the MM-093 program with Merrimack was successfully completed in the second quarter of 2005. Negotiations for further supply of MM-093 to Merrimack are in process. Due to current budgetary constraints at NIAID, no funding has been committed for the malaria program beyond mid-August 2005. The decrease 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 limited to breeding activities to create a new founder line.

Cost of revenue. The decrease in cost of revenue is primarily the result of a shift in resources to our internal program for ATryn[®] in the second quarter of 2005 as compared to the second quarter 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 major component of the increase in research and development expense year to year was a \$1.4 million increase in spending on the ATryn[®] program, which totaled \$3.5 million in 2005 as compared to \$2.1 million in 2004. Included in these expenses is approximately \$2.6 million related to support of the EMEA filing for ATryn[®], as compared to \$1.4 million in 2004, as well as \$500,000 of expenses incurred in preparation for the U.S. clinical trial.

Additionally, we incurred expenses of \$748,000 in the CD-137 development program representing almost entirely an allocation of internal resources as compared with \$83,000 in the second quarter of 2004. Increases in the ATryn[®] and CD-137 programs were partially offset by decreases in spending of approximately \$600,000 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. The decrease in selling, general and administrative expense year to year was primarily a result of lower public company related costs. Selling, general and administrative expenses are expected to decrease slightly in the remainder of 2005 primarily as a result of a decrease in directors and officer’s insurance premiums as well as lower costs related to ongoing compliance with the Sarbanes-Oxley Act of 2002.

Six months ended July 3, 2005 and July 4, 2004

	(dollars in thousands)			
	July 3, 2005	July 4, 2004	\$ Change	% Change
Revenue	\$ 2,339	\$ 2,505	\$ (166)	(7)%
Cost of revenue	\$ 2,279	\$ 2,563	\$ (284)	(11)%
Research and development	\$ 10,605	\$ 9,268	\$ 1,337	14 %
Selling, general and administrative	\$ 4,296	\$ 5,415	\$(1,119)	(21)%
Other income	\$ 48	\$ 272	\$ (224)	(82)%

Revenue. During the first six months of 2005, \$1.9 million of our revenues were derived from external development programs, primarily Merrimack Pharmaceuticals and Elan Pharmaceuticals, in addition to \$210,000 derived from the CD-137 program and \$208,000 derived from the malaria program. During the first six months of 2004, \$1.7 million were derived from external

development programs, primarily Merrimack and Centocor, in addition to \$792,000 derived from the malaria program. The decrease 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 grant during 2005.

Cost of revenue. The decrease in cost of revenue is primarily the result of a shift in resources to our internal program, ATryn[®], in the first six months of 2005 as compared to the first six 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 major component of the increase in research and development expense year to year was a \$1.7 million increase in spending on the ATryn[®] program, which totaled \$6 million in 2005 as compared to \$4.3 million in 2004. Included in these expenses is approximately \$3.6 million related to the support of the EMEA filing of ATryn[®] in both 2005 and 2004, as well as \$1.9 million of ATryn[®] operating costs and U.S. clinical trial preparation expenses in 2005, as compared to \$700,000 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 can no longer conclude with certainty that it is probable that the inventory will be sold prior to expiration, resulting in a \$419,000 charge to research and development. During the first quarter of 2005, we also recorded approximately \$47,000 of research and development for ATryn[®] inventory used for development purposes.

Additionally, the first six months of 2005 included approximately \$1.9 million in support of the CD-137 program representing almost entirely an allocation of internal resources, compared to \$70,000 in the first six months of 2004. Increases in the ATryn[®] and CD-137 programs were offset by decreases in spending of approximately \$2.3 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. The first six months of 2004 included approximately \$743,000 of restructuring charges. The remainder of the decrease year to year was primarily a result of lower public company related costs. 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 and lower costs related to ongoing compliance with the Sarbanes-Oxley Act of 2002, as well as the impact of the 2004 restructuring.

Other Income. The decrease in other income is primarily the result of a \$200,000 refund we received in the first six 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 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 \$20 million, exclusive of any equity financing. The net cash use projection includes approximately \$12 million of cash collections from partnering for the year, of which approximately \$5 million has been collected or is anticipated under existing contracts.

In August 2005, we raised approximately \$7.4 million in cash, net of offering costs, in a private placement of our Common Stock and warrants to purchase Common Stock. Also, 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, both of which are more fully described under "Financing Activities". We had cash, cash equivalents and marketable securities of \$19.6 million at July 3, 2005.

We had working capital of \$5.9 million at July 3, 2005 compared to \$10.6 million at January 2, 2005.

Financing Activities

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 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 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.

Credit Facility

Of our \$12.5 million of outstanding long-term debt at July 3, 2005, approximately \$5.8 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 flows used in operating activities were \$11.9 million and \$8.8 million for the first six months of 2005 and 2004, respectively, an increase of approximately \$3 million, primarily the result of the timing of cash payments in connection with the ATryn[®] program. Cash used in operating activities for the first six months of 2005 included a net loss of \$15.2 million offset by certain non-cash charges of approximately \$2.5 million. Use of cash also included an increase in inventory of approximately \$231,000 and decreased accounts payable and accrued liabilities of approximately \$219,000. Sources of funds included a reduction of accounts receivable of approximately \$552,000, 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 \$710,000.

Cash Flows from Investing Activities

Cash flows from investing activities include \$7.8 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 \$265,000 used 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 July 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

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 4 – SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

We held our Annual Meeting of Stockholders on May 25, 2005. The following represents the results of voting on the proposals submitted to the Company's stockholders to elect each of the following nominees to the Board of Directors for a three-year term:

<u>Nominee</u>	<u>Total Vote "FOR"</u>	<u>Total Vote Withheld</u>
Francis J. Bullock	41,450,592	574,291
Geoffrey F. Cox	40,194,151	1,830,732
Alan W. Tuck	41,480,328	544,555

Each nominee received a plurality of the votes cast, and, therefore, has been duly elected a director of GTC. The directors whose term of office as a director continued after the meeting are Robert W. Baldrige, Kenneth A. Bauer, James A. Geraghty, Michael J. Landine, Pamela W. McNamara, and Marvin L. Miller.

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. |
| 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. |
| 99 | Risk Factors. |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 11, 2005

GTC BIOTHERAPEUTICS, INC.

By: /s/ John B. Green

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

EXHIBIT INDEX

<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 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.
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.
99	Risk Factors.

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: August 11, 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: August 11, 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 July 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: August 11, 2005

/s/ Geoffrey F. Cox

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

Date: August 11, 2005

/s/ John B. Green

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

GTC BIOTHERAPUEITICS, INC.

Important Factors Regarding Forward-Looking Statements

August 11, 2005

In this Exhibit 99, “we,” “us,” “our” and “GTC” refer only to GTC Biotherapeutics, Inc. and its subsidiaries.

From time to time, we may make forward-looking public statements, such as statements concerning our then expected future revenues or earnings, prospects for clinical trials or regulatory approvals, or our projected plans for research and development programs and collaborations, as well as other estimates relating to future operations. Forward-looking statements may be in reports filed under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), in press releases or informal statements made with the approval of an authorized executive officer. In some cases, words or phrases of expectation or uncertainty like “expect,” “believe,” “continue,” “anticipate,” “estimate,” “may,” “will,” “could,” “opportunity,” “future,” “project,” “intend”, “plan”, or similar expressions are intended to identify “forward-looking statements” within the meaning of Section 21E of the Exchange Act and Section 27A of the Securities Act of 1933, as amended, as enacted by the Private Securities Litigation Reform Act of 1995.

We caution you not to place undue reliance on these forward-looking statements, which speak only as of the date on which they are made. In addition, we advise you that the factors listed below, as well as other factors we have not currently identified, could affect our financial or other performance and could cause our actual results for future periods to differ materially from any opinions or statements expressed with respect to future periods or events in any forward-looking statement.

We will not undertake and specifically decline any obligation to publicly release revisions to these forward-looking statements to reflect either the circumstances after the date of the statements or the occurrence of events which may cause us to re-evaluate our forward-looking statements.

In connection with the “safe harbor” provisions of the Private Securities Litigation Reform Act, we are hereby filing the following cautionary statements identifying important factors that could cause our actual results to differ materially from those projected in forward-looking statements made by us or on our behalf:

Risks Related to Our Business***We expect to incur future operating losses and may never become profitable.***

We have had operating losses since our inception, and we expect losses to continue for the next several years. From our inception in 1993 to July 3, 2005, we have incurred cumulative losses of approximately \$194.8 million. These losses have resulted principally from the costs of our research and development activities and losses from our discontinued operations. Our net losses for fiscal years ended 2002, 2003, and 2004 and for the six months ended July 3, 2005, have been \$24.3 million, \$29.5 million, \$29.5 million, and \$15.2 million, respectively. We expect to continue incurring significant operating losses for at least the next several years. We may never receive material revenues from product sales or become profitable.

We depend on collaboration agreements for our current revenue.

Our revenues and business strategy depend largely on our entering into additional development and marketing agreements with third parties, including development programs for our own therapeutic compounds. We may not be able to establish these agreements on commercially acceptable terms, if at all,

depending on the market position of our technology and our compounds. The willingness of potential collaborators to enter into agreements with us depends on factors such as the perceived technological or economic advantages of transgenic production and our ability to structure a mutually acceptable collaboration arrangement. In the case of our own programs for development of proteins proprietary to us, known as internal programs, the attractiveness of the program's commercial potential or other advantages the program offers the partner will also affect our ability to obtain collaborators. Even if we enter into development agreements, the collaborations may ultimately be unsuccessful, our partners could terminate the agreements or the agreements could expire before meaningful developmental milestones are reached. The failure of any significant number of these collaborations could have a material adverse effect on our business.

The majority of our collaborations have been external programs that involve proteins proprietary to our partners. Much of the continuing revenue, if any, that we may receive under these collaborations will depend upon our partners' willingness and ability to successfully develop and commercially introduce, market and sell the version of the collaborator's product derived from our transgenic production systems. Our partners may choose competitive production technologies or competitive products outside of their collaborations with us, which could have a material adverse effect on our business.

To date, the scope of our external collaboration programs have generally been limited to transgenically producing quantities of targeted proteins. These initial development projects may not successfully produce the desired protein quantities or lead to collaboration agreements to commercially produce any proteins. The success of any collaboration ultimately will be dependent upon our collaborator deciding to seek regulatory approval and to market our transgenically produced version of their product or to invest in a transgenically produced product that we have developed. Depending upon the terms of any future collaborations, our role in the collaboration will often be limited to the production aspects of the proteins. As a result, we may also be dependent on collaborators for other aspects of the development of any transgenically produced product, including preclinical and clinical testing and regulatory approval, and marketing and distribution.

We face uncertainty in raising additional funds for our operations.

In order to develop and bring our transgenically produced products to market, we and our collaboration partners must commit substantial resources to costly and time-consuming research, preclinical testing and clinical trials. As of July 3, 2005, we had \$6.7 million in cash and cash equivalents and \$12.8 million in marketable securities, which were offset in part by our \$15.6 million in current liabilities. Subsequently, we have sold 4.57 million shares of common stock to obtain approximately \$7.4 million of net proceeds in a private placement that also included warrants to purchase approximately 1.8 million additional shares of common stock at an exercise price of \$2.68 per share. These warrants may not be exercised for the first six months following the closing of the private placement. We expect our current cash resources and partnering revenue opportunities to be sufficient to fund operations into the second half of 2006. Our projected revenue and cash use depends upon attracting additional partnering revenues from existing and additional collaborations for both internal and external programs. If we do not substantially achieve our revenue projections, we could be forced to delay, scale back or eliminate one or more of our research and development programs.

Our cash requirements may vary materially from those now planned, depending upon the results of research and development, competitive and technological advances, the terms of future collaborations, regulatory requirements and other factors. If our business does not become profitable before we exhaust existing resources, we will need to obtain additional financing, through public or private sources, including debt or equity financing, or through collaborative or other arrangements with corporate partners. Depending on the state of the capital markets, interest rates, our financial profile and other factors at that time, we may not be able to obtain adequate funds on acceptable terms when needed. If we raise capital through the sale of equity, or securities convertible into equity, existing shareholders' proportionate ownership in us will be reduced. If we cannot obtain financing, we could be forced to delay, scale back or eliminate some of our research and development programs.

Transgenic technology is in a relatively early stage.

Developing products based on transgenic technology is subject to significant technological risks. Most of our transgenically produced products are in the early development stage. Each DNA construct is unique and it is possible that it might not be expressed in the transgenic animal's milk at a level that is commercially viable. Purifying the recombinant protein out of the milk to use as a biotherapeutic may be too difficult to be commercially feasible. In addition, production of the recombinant protein may have negative effects on the health of either the mammary gland or more systematically on the animal as a whole. This would compromise the ability of the animal to produce the recombinant protein. Directing the mammary gland to produce additional proteins in the milk could negatively affect lactation, thereby shutting down milk production. The mammary gland may also modify a protein in such a manner that it is non-functional or harmful to human subjects. It is also possible that there may be disease agents present in goats or cows that would prevent the use of products derived from these animals. If an as yet unknown disease was identified that could not be effectively mitigated, government agencies may confiscate or destroy the animals, or prevent the utilization of their milk. Any of these governmental actions would prevent the use of the recombinant proteins.

To our knowledge, no other entity has completed human clinical trials necessary to receive marketing authorization in the United States or Europe for any protein produced in the milk of transgenic animals. Until European regulatory authorities approve our application for marketing authorization of ATryn[®] in Europe, we will not have confirmation that our ATryn[®] trials are sufficient for approval in Europe. If we are unable to complete all clinical trials that may be required, or if a transgenically produced protein is not proved to be safe or effective to the satisfaction of regulatory authorities, it would have a material adverse effect on our business and operations. In addition, it is possible that research and discoveries by others could render our transgenic technology obsolete or noncompetitive as a method of production for protein-based therapeutic products.

If clinical trials of any of our transgenically produced products are unsuccessful or delayed, we would be unable to meet our anticipated development timeline, which could cause our stock price to decline.

We and our collaborators must demonstrate through preclinical and clinical trials that our transgenically produced products are safe and effective for use in humans. Clinical trials are expensive and may take several years. Several factors could prevent or delay completion of these trials, including an inability to enroll the required number of patients or demonstrate adequately the safety or efficacy of the product for humans. If safety concerns develop, regulatory authorities could stop or delay our trials. Furthermore, the results from early clinical trials are often not predictive of results in later clinical trials.

We cannot market and sell our transgenically produced products in the United States or in other countries if we fail to obtain the necessary regulatory approvals.

Before we can sell any transgenically produced drug or biological products that we or our collaborators develop, we must receive regulatory approvals from federal, state and local governmental authorities, including the United States Food and Drug Administration, or FDA, and similar agencies in other countries, such as the European Medicines Agency, or EMEA, in Europe. To date, none of our transgenically produced products have been approved for sale in the United States or any foreign country. Moreover, to our knowledge, no therapeutic protein produced in the milk of a transgenic animal has been submitted to the FDA or, except for our submission of ATryn[®] to the EMEA in January 2004, to any other regulatory agency for final regulatory approval. Obtaining required regulatory approvals for our transgenically produced products may take several years to complete and is expensive and uncertain. It is possible that the FDA or any other regulatory authority may not act quickly or favorably on our requests for approval or will require us to provide additional data that we do not currently anticipate. For example, the FDA may impose restrictions and demands on our clinical trials that require additional resources and result in longer delays than we anticipate. In addition, the FDA may require us to conduct further clinical trials and post-marketing testing and surveillance to monitor the effects of approved products. The FDA or other regulatory authorities may also place conditions on approval that could restrict the commercial applications of such products.

Failure to comply with extensive FDA or similar regulations may result in delay, suspension or cancellation of a trial or a regulatory authority's refusal to accept test results. Regulatory authorities may have varying interpretations of our pre-clinical and clinical trial data, which could delay, limit or prevent regulatory approval or clearance. Because transgenically produced products represent novel therapeutic products, the process for regulatory approval is unproven. There may be additional delays in regulatory approval due to issues arising from the breeding of transgenic animals and the use of proteins derived from them. Any delays or difficulties in obtaining regulatory approval or clearance for transgenically produced products may:

- adversely affect the marketing of any transgenically produced products we or our collaborators develop;
- impose significant additional costs on us or our collaborators;
- diminish any competitive advantages that we or our collaborators may attain; and
- limit our ability to receive royalties and generate revenue and profits.

If we do not receive regulatory approvals for our transgenically produced products in a timely manner, we will not be able to commercialize our products, or their commercialization may be limited or delayed and, therefore, our business and stock price will suffer.

Even if we receive regulatory approval for our transgenically produced products, the FDA or similar agencies in other countries may impose limitations on the indicated uses for which our products may be marketed. These limitations could reduce the size of the potential market for a product. Failure to comply with applicable FDA and other regulatory requirements can result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to renew our marketing applications and criminal prosecution.

We filed an investigational new drug application, or IND, with the FDA in 2003 for clinical development of ATryn[®] in the hereditary deficiency indication. In April 2005, we received authorization from the FDA to begin a further clinical trial of ATryn[®] under an amended version of our IND. If we are able to conduct this study successfully and on schedule, we currently anticipate filing a Biologics License Application for ATryn[®] for the HD indication in the United States no earlier than 2006. Delays in completing our current ATryn[®] trial or in obtaining FDA approval of ATryn[®] could cause substantial delays in the commercialization of ATryn[®] in the United States and adversely affect our business and stock price.

Any transgenically produced products for which we obtain regulatory approval will be subject to continuing review and extensive regulatory requirements, which could affect their manufacture and marketing.

If and when the FDA or other foreign agencies approve any of our transgenically produced products under development, the manufacture and marketing of these products will be subject to continuing regulation and product approvals may be withdrawn if problems occur after initial approval. Post-approval regulation includes compliance with current Quality Systems Regulations and Good Manufacturing Practices, known as QSR/GMP, adverse event reporting requirements and prohibitions on promoting a product for unapproved uses. We will also be required to obtain additional approvals for any significant alterations in the product's labeling or manufacturing process. Enforcement actions resulting from failure to comply with QSR/GMP requirements could result in fines, suspensions of approvals, recalls of products, operating restrictions and criminal prosecutions, and affect the manufacture and marketing of our transgenically produced products. The FDA or other regulatory agencies could withdraw a previously approved product from the market upon receipt of newly discovered information, including a failure to comply with regulatory requirements and the occurrence of unanticipated problems with products following approval. Any of these withdrawals could adversely affect our operating results.

We have limited manufacturing capability and may rely on third party contract manufacturers to purify and formulate our transgenically produced products.

We have the capability to purify pre-clinical and clinical trial quantities of our transgenically produced products. Our current capacity allows us to purify products for clinical trials, up to and including Phase II. We also rely upon third party manufacturers to purify and formulate significant pre-clinical, clinical and commercial quantities of our transgenically produced products. We will depend on these third party manufacturers to perform their obligations in a timely manner and in accordance with applicable government regulations in order to conduct our clinical trials or commercialize any of our products. In addition, there are very few third party manufacturers that have sufficient production capacity to manufacture all of our products either for our clinical trials or on a commercial scale. Our third party manufacturers may encounter difficulties, including problems involving:

- inconsistent production yields;
- poor quality control and assurance or inadequate process controls;
- lack of compliance with FDA, EMEA and other regulations; and
- high production costs.

These contract manufacturers may not be able to manufacture our products at a cost or in quantities necessary to make them commercially viable. If we are unable to enter into agreements with additional manufacturers on commercially reasonable terms, or if there is poor performance on the part of our third party manufacturers, we may not be able to complete development of, or market, our transgenically produced products.

We have entered into contracts with Cambrex Bio Science MA, Inc. for large scale purification and with Medimmune (Holland) for fill/finish services of our lead product, ATryn[®]. Both contracts have a five-year, renewable term, which will expire in 2007 if not renewed. Although we have identified possible alternative suppliers with respect to these services for this product, interruptions in these services and the process of changing to an alternative manufacturer could have a material adverse effect on our timely ability to manufacture bulk delivery of ATryn[®] for delivery to our collaborators or to market distribution after regulatory approval.

Transgenically produced products may never become commercially successful.

Even if our transgenically produced products are successfully developed and approved by the FDA and foreign regulatory agencies, they may not enjoy commercial acceptance or success, which would adversely affect our business and results of operations. Several factors could limit our success, including:

- limited market acceptance among patients, physicians, medical centers and third party payors;
- our inability to access a sales force capable of marketing the product, either through a third party contract sales force or by establishing our own internal sales force;
- our inability to supply a sufficient amount of product to meet market demand;
- the number and relative efficacy of competitive products that may subsequently enter the market; and
- for a transgenically produced product designed to replace or supplement currently marketed non-transgenically produced products, the relative risk-benefit profile and cost-effectiveness of the transgenically produced product.

In addition, it is possible that we or our collaborative partners will be unsuccessful in developing, marketing or implementing a commercialization strategy for any transgenically produced products.

Our business may fail due to intense competition in our industry.

The industry in which we operate is highly competitive and may become even more so. Some of our competitors have greater financial and human resources and more experience in research and development than we have. We will need to continue to devote substantial efforts and expense in research and development to maintain a competitive position for our transgenic production technology and potential product offerings. It is also possible that others will develop alternative technologies or products that will render our proposed products or technologies obsolete. We may encounter significant competition for our protein development and production contracts from other companies. In addition, our potential transgenic production capabilities may face significant competition from biological products manufactured in cell culture or by other traditional protein production methods. Our business will also compete against other companies whose business is dedicated to offering transgenic production and with prospective customers or collaborators who decide to pursue such transgenic production internally. Competitors that complete clinical trials, obtain regulatory approvals and begin commercial sales of their products before us will enjoy a significant competitive advantage. We anticipate that we will face increased competition in the future as new companies enter the market and alternative technologies become available.

Pharming Group N.V. and BioProtein Technologies are other companies known to us that are extensively engaged in the application of transgenic technology in mammals for the production of proteins for therapeutic use in humans. Pharming, based in the Netherlands, is primarily engaged in the development of recombinant proteins in the milk of transgenic cows and rabbits. Pharming reports that it has one product in clinical development that is in Phase III studies in the United States. BioProtein Technologies is a contract manufacturing organization specializing in the production of human therapeutic proteins and vaccines in the milk of transgenic rabbits also under a technology license agreement. There are also other companies seeking to develop transgenic technology in animals and in plants, which may be competitive with our technology with respect to our patents and proprietary rights as discussed further below.

For ATryn[®], a number of companies internationally produce and market antithrombin from the fractionation of human plasma. CSL has approximately a 40% share of this market worldwide, but is not approved in the U.S. Talecris Biotherapeutics, which purchased Bayer's plasma business, is the only company that has commercially available fractionated antithrombin material that is approved for sale in the U.S., which sales represent only about 1% of the worldwide market.

There are a number of companies worldwide that produce and market human serum albumin from the fractionation of human plasma, including Talecris, CSL and Baxter. We are aware of two companies internationally that are developing recombinant forms of human serum albumin derived from yeast cultures. One company, Aventis, is developing its recombinant albumin product for the excipient market. The other lead company is Yoshitomi (formerly Green Cross Corporation) which has been active in developing human albumin through genetic manipulation of *Pichia pastoris* (better known as yeast) on a commercial scale for use in Japan and other parts of Asia.

We may face public concerns about genetic engineering in animals.

Our activities involve genetic engineering in animals. The success of our potential commercial products will depend in part on public acceptance of the use of genetic engineering. Public attitudes may be influenced by claims that these types of activities are unsafe and our products may not gain the acceptance of the public or the medical community. Negative public reaction to genetic engineering activities in general could result in greater restrictive legislation and regulations involving nuclear transfer and other methodologies which could impede our ability to conduct our business efficiently, delay preclinical studies or future clinical trials, or prevent us or our partners from obtaining regulatory approvals or commercializing transgenically produced products.

We depend on patents and proprietary rights that may fail to protect our business.

Our success will partly depend on our ability to obtain and maintain patent or other proprietary protection for our technologies, products and processes such as:

- compositions of matter or processes;
- processes developed by our employees; or
- uses of compositions of matter discovered through our technology.

We may not be able to obtain the necessary proprietary protection. Our success will also depend on our ability to operate without infringing the proprietary rights of other parties. Legal standards relating to the validity of patents covering pharmaceutical and biotechnological inventions and the scope of claims made under these patents are still developing. There is no consistent policy regarding the breadth of claims allowed in biotechnology patents. The patent position of a biotechnology company is highly uncertain and involves complex legal and factual questions.

We hold 18 issued or allowed U.S. patents and 111 corresponding foreign patents. Our patents generally expire between 2013 and 2019, with the most significant patent expiring in 2015. Of our patents expiring in 2015, two relate to ATryn[®], our lead program. One in-licensed European patent, pertaining to transgenic animals secreting proteins in milk, expires in 2006. In accordance with ongoing research and development efforts, we have 51 pending U.S. patent applications and 159 corresponding foreign applications covering relevant and newly developed portions of its transgenic technology. Several of these pending applications are included in various cross-licensing or out-licensing arrangements with other companies that in turn provide access to their proprietary technologies. Specifically we have cross-licensed our proprietary technology for the production of proteins in milk to Pharming B.V. Recently issued U.S. patents provide claim coverage for protein purification from the milk of transgenic animals, the production of monoclonal and assembled antibodies at commercial levels in the milk of transgenic mammals, the production of recombinant antithrombin in the milk of transgenic goats and the production of Prolactin in the milk of transgenic animals. We cannot be certain that we will receive issued patents based on pending or future applications. Our issued patents may not contain claims sufficiently broad to protect us against competitors with similar technology. Additionally, our patents, our partners' patents and patents for which we have license rights may be challenged, narrowed, invalidated or circumvented. Furthermore, rights granted under patents may not provide us with any competitive advantage.

We may have to initiate arbitration or litigation to enforce our patent and license rights. If our competitors file patent applications that claim technology also claimed by us, we may have to participate in interference or opposition proceedings to determine the priority of invention. An adverse outcome could subject us to significant liabilities to third parties and require us to cease using the technology or to license the disputed rights from third parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all.

The cost to us of any litigation or proceeding relating to patent rights, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of any pending patent or related litigation could have a material adverse effect on our ability to compete in the marketplace. Advanced Cell Technologies, Inc., or ACT, has announced that the Board of Patent Appeals and Interferences of the U.S. Patent Office has entered a judgment in an interference proceeding in favor of Geron Corporation against ACT on all counts as to the priority of ACT's U.S. Patent No. 5,945,577, which we license from ACT. ACT has appealed that decision in a proceeding in U.S. District Court, during which proceeding we believe that we may continue

to rely on the validity of the disputed patent. While we have also licensed nuclear transfer technology from Pharming, we do not know at this time what impact, if any, this proceeding involving ACT may ultimately have on our ability to practice nuclear transfer for the production of animals expressing therapeutic proteins in their milk. Our principle product, ATryn[®], does not utilize this technology.

We rely on certain proprietary trade secrets and know-how that are not patentable. We have taken measures to protect our unpatented trade secrets and know-how, including having our employees, consultants and some contractors execute confidentiality agreements. These agreements could be breached. If so, it is possible that our remedies for a given breach might be inadequate. It is also possible that competitors emerge who could independently develop or discover our trade secrets or that the trade secrets could otherwise become known.

Recovery from any catastrophic event may not be adequate.

While we have measures in place to minimize and recover from catastrophic events that may substantially destroy our animal herd(s), these measures may not be adequate to recover our production processes quickly enough to support critical timelines, collaborator needs or market demands. These catastrophic events may include animal diseases that breach our biosecurity measures or weather events such as tornadoes, earthquakes or fires. In addition, these catastrophic events may render some or all of the products at the affected facilities unusable.

Successful commercialization of our products will depend on obtaining coverage and reimbursement for use of the products from third-party payors.

Sales of pharmaceutical products depend largely on the reimbursement of patients' medical expenses by government health care programs and private health insurers. It is possible that third party payors will not reimburse sales of our transgenically produced products. Reimbursement by third party payors depends on a number of factors, including the payor's determination that use of the product is safe and effective, not experimental or investigational, medically necessary, appropriate for the specific patient and cost-effective. Reimbursement in the United States or foreign countries may not be available or maintained for any of our products. If we do not obtain approvals for adequate third party reimbursements, we may not be able to establish or maintain price levels sufficient to realize an appropriate return on our or our partners' investment in product development. Any limits on reimbursement available from third party payors may reduce the demand for, or negatively affect the price of, our or our partners' products. Without the financial support of the government or third party insurers, the market for transgenically produced products will be limited.

The U.S. federal government and private insurers are continually working on ways to contain health care costs, particularly by limiting both coverage and the level of reimbursement for new therapeutic products. The government or private insurers may institute future price controls and other cost-containment measures on Medicare, Medicaid and other health care insurance spending. These controls and limits could affect the payments we collect from sales of our products. Internationally, medical reimbursement systems vary significantly, with some medical centers having fixed budgets, regardless of levels of patient treatment, and other countries requiring application for, and approval of, government or third party reimbursement. Even if we or our partners succeed in bringing transgenically produced products to market, uncertainties regarding future health care policy, legislation and regulation, as well as private market practices, could affect our ability to sell our products in commercially acceptable quantities at profitable prices.

Our ability to negotiate with potential marketing partners may be limited.

If we choose to commercialize ATryn[®] with a marketing partner outside of Asia, Genzyme Corporation has an exclusive first right of negotiation for exclusive commercialization rights. This right is triggered on an indication-by-indication basis at such time as we apply for marketing approval with a regulatory authority. This right does not apply if we have already entered into a collaboration or other agreement with a prospective research, development and marketing partner prior to such regulatory submission. The right also does not apply to the hereditary deficiency indication which has been filed with the EMEA.

The manufacture and sale of our products may expose us to product liability claims for which we could have substantial liability.

We face an inherent risk of product liability exposure related to testing of our transgenically produced products in human clinical trials and will face even greater risks when we commercialize our products. An individual may bring a product liability claim against us if one of our products causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use, even if the product involved is granted regulatory authorization for commercial sale. We do not maintain product liability insurance, although we do have product liability insurance in place for the clinical trials conducted to support our MAA filing with the EMEA for our ATryn[®] program under an insurance policy arrangement with Genzyme Corporation and we have obtained product liability coverage for the clinical trials to be conducted to support a filing for marketing approval of ATryn[®] with the FDA through our own policies. It is possible that our insurance coverage will not be sufficient to cover any claim. Any product liability claim brought against us, with or without merit, could result in:

- liabilities that substantially exceed our product liability insurance, which we would then be required to pay from other sources, if available;
- an increase of our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms or at all;
- damage to our reputation and the reputation of our products, resulting in lower sales;
- regulatory investigations that could require costly recalls or product modifications; and
- the diversion of management's attention from managing our business.

Qualified managerial and scientific personnel are scarce in our industry.

We are highly dependent on the principal members of our scientific and management staff. Our success will depend in part on our ability to identify, attract and retain qualified managerial and scientific personnel. There is intense competition for qualified personnel in our industry. We may not be able to continue to attract and retain personnel with the advanced technical qualifications or managerial expertise necessary for the development of our business. If we fail to attract and retain key personnel, it could have a material adverse effect on our business, financial condition and results of operations. We have employment agreements with our executive officers, but these agreements do not guarantee that they will remain employed with us in the future. If we lose an executive officer, or a significant number of any of our staff, or are unable to hire and retain qualified personnel, then our ability to develop and commercialize our products and processes may be delayed or impaired. We do not carry key man insurance.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud. As a result, investors may lose confidence in our financial reporting.

The Sarbanes-Oxley Act of 2002 requires that we report annually on the effectiveness of our internal controls over financial reporting. Among other things, we must perform systems and process evaluation and testing. We must also conduct an assessment of our internal controls to allow management to report on, and our independent registered public accounting firm to audit, our assessment of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. These requirements were effective for the first time for our fiscal year ended January 2, 2005. In connection with our Section 404 compliance efforts, we have incurred or expended, and expect to continue to incur or expend, substantial accounting and other expenses and significant management time and resources. Any

subsequent assessment by us or our independent registered public accounting firm may reveal significant deficiencies or material weaknesses in our internal controls, which may need to be disclosed in subsequent periodic reports filed with the SEC. Disclosures of this type could cause investors to lose confidence in our financial reporting and may negatively affect the price of our common stock. Moreover, effective internal controls are necessary to produce reliable financial reports and to prevent fraud. If we have deficiencies in our internal controls over financial reporting, these deficiencies may negatively impact our business and operations.

Risks Related to Our Common Stock

Genzyme's significant ownership interest in us could give it significant influence over matters requiring shareholder approval.

Genzyme is our largest single shareholder, beneficially owning 5,298,243 shares or 11% of our outstanding common stock at August 8, 2005, assuming the exercise of all of its 373,324 currently exercisable common stock purchase warrants with exercise prices ranging from \$6.30 to \$4.88. As an 11% shareholder, Genzyme's ownership interest could give it significant influence if it were to oppose matters requiring our shareholders' approval, including electing directors, adopting or amending provisions of our charter or by-laws and approving or preventing some mergers or similar transactions, such as a sale of substantially all of our assets, or transactions that could give our shareholders the opportunity to realize a premium over the market price of their shares. Subsequent to our August 2005 private placement, Genzyme owns approximately 9.6% of our outstanding common stock and approximately 10% on a fully diluted basis.

We have obligations to issue shares of common stock in the future that will dilute your ownership interest and may adversely affect our stock price.

Sales of substantial amounts of our common stock in the public market, or the perception that such sales may occur, could adversely affect our common stock's market price. As of August 8, 2005, there were 46,891,397 shares of our common stock outstanding which does not include the 4,571,429 shares of common stock we sold in our private placement that closed after August 8, 2005. As of August 8, 2005, options to purchase an aggregate of 4,432,193 shares of common stock at varying exercise prices were outstanding; of this total, options to purchase 2,966,078 shares were immediately exercisable and these shares could be immediately resold into the public market. As of August 8, 2005, Genzyme held 4,924,919 shares of our common stock which could be sold into the public markets under Rule 144 of the Securities Act. Genzyme is also entitled to registration rights with respect to some of these shares. An additional 373,324 shares of our common stock, issuable to Genzyme upon exercise of outstanding warrants, are also entitled to registration rights, which could expedite the resale of such shares into the public market.

In our August 2003, private placement we issued warrants to purchase an aggregate 961,009 shares of our common stock at an exercise price of \$3.30 per share. We have registered for resale the shares of common stock issuable under the warrants that were issued in the private placement transaction. To date, none of these warrants have been exercised.

In our August 2005 private placement we issued warrants to purchase an aggregate 1,828,573 shares of our common stock at an exercise price of \$2.68 per share. These warrants may not be exercised for the first six months following the closing of the private placement.

Our capital raising efforts may dilute shareholder interests.

If we raise additional capital by issuing equity securities, the issuance will result in a reduction of the percentage of ownership for our existing shareholders, a result commonly referred to as dilution. The extent of such dilution will vary based upon the amount of capital raised.

Our common stock may have a volatile public trading price and low trading volume.

Historically, the market price of our common stock has been highly volatile and the market for our common stock has experienced significant price and volume fluctuations, some of which are unrelated to our company's operating performance. Since January 1, 2001, the trading price of our stock has fluctuated from a high of \$15.50 to a low of \$0.61. It is likely that the market price of our common stock will continue to fluctuate in the future. Factors which may have a significant adverse effect on our common stock's market price, include:

- announcements by us or our competitors of technological innovations or new commercial products;
- developments concerning our proprietary rights, including patent and litigation matters;
- publicity regarding actual or potential results relating to our or our partners' products or compounds under development;
- an unexpected termination of one of our partnerships;
- regulatory developments in the United States and other countries;
- general market conditions; and
- quarterly fluctuations in our revenues and other financial results.

The average daily trading volume of our common stock for the six-month period ending July 3, 2005 was 267,000 shares.

Anti-takeover provisions in our charter and by-laws and Massachusetts law may result in management entrenchment and adversely affect our stock price.

Anti-takeover provisions in our charter, our by-laws and Massachusetts statutes could delay or make more difficult a merger, tender offer or proxy contest involving us. These provisions may delay or prevent a change of control without action by the shareholders, and may resist important changes shareholders seek to make if they are dissatisfied with the conduct of our management. Therefore, these provisions could result in the entrenchment of our management and adversely affect the price of our common stock.

Our charter grants authority to the board of directors to issue series of preferred stock with certain rights and privileges, including voting rights, as it deems appropriate. This authority may enable our board of directors to deter or delay a change in control despite a shift in stock ownership, as a result of an increase in the number of shares needed to gain voting control. This may have the effect of discouraging tender offers and proxy contests, and give management the power to reject certain transactions which might be desired by shareholders. This provision could also be deemed to benefit incumbent management to the extent it deters offers by persons who would wish to make changes in management or exercise control over management.

In addition, our by-laws may have the effect of preventing changes in our management because shareholders are required to give us written notice of any proposal or director nomination within a specified period of time before the annual meeting of shareholders, certain qualifications for a person to be elected to the board of directors must be established, and shareholders are prohibited from calling a special meeting of shareholders, unless the shareholder owns 90% of our outstanding voting stock.

Our shareholder rights plan is another anti-takeover device. It involves a distribution to our shareholders of certain rights to acquire shares of our capital stock in the event of an acquisition of a predetermined number of shares by an investor. The shareholder rights plan is designed to deter coercive takeover tactics and to encourage a party interested in acquiring the corporation to negotiate with the board of directors.

Certain Massachusetts corporate statutes provide anti-takeover protections. Our charter gives effect to a provision of Massachusetts law that places directors of publicly-held Massachusetts corporations into three classes of nearly equal sizes with staggered terms, thereby permitting only one-third of the board of directors to be elected at once. In addition, with certain exceptions, Massachusetts law prohibits a publicly-held Massachusetts corporation from engaging in a business combination transaction with an "interested stockholder" for a period of three years. An "interested stockholder" is a person who owns 5% or more of the outstanding voting stock of the corporation. Finally, our by-laws include a provision excluding us from the applicability of a Massachusetts statute that denies voting rights to any person acquiring 20% or more of the outstanding voting stock of a corporation, unless such voting rights are approved by a majority of the corporation's disinterested shareholders. Our by-laws may be amended at any time to subject us to this statute prospectively.