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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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## FORM 10-Q

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

For the quarterly period ended April 2, 2006

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

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# GTC BIOTHERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

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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

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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 a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "Accelerated Filer" and "Large Accelerated Filer" in Rule 12b-2 of the Exchange Act.  
Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check whether registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

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

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Class	Outstanding at May 4, 2006
Common Stock, \$0.01 par value	61,398,095

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## **NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This Quarterly Report on Form 10-Q contains forward-looking statements, including statements regarding future revenues, research and development programs, clinical trials and collaborations and our future cash requirements. The words or phrases “will”, “will likely result”, “are expected to”, “will continue”, “estimate”, “project”, “potential”, “believe”, “plan”, “anticipate”, “expect”, “intend”, or similar expressions and variations of such words are intended to identify forward-looking statements. Statements that are not historical facts are based on our current expectations, beliefs, assumptions, estimates, forecasts and projections for our business and the industry and markets related to our business. The statements contained in this report are not guarantees of future performance and involve certain risks, uncertainties and assumptions which are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed in such forward-looking statements. Important factors which may affect future revenues, research and development programs, clinical trials and collaborations and our future cash requirements include, without limitation, regulatory review of our ATryn® product, our ability to enter into transgenic research and development collaborations in the future and the terms of such collaborations, the results of research and development and preclinical and clinical testing of our internal products, competitive and technological advances and regulatory requirements, and those factors set forth in “Risk Factors” in Item 1A of our Annual Report on Form 10-K for the fiscal year ended January 1, 2006 as filed with the Securities and Exchange Commission.

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.**  
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**PART I—FINANCIAL INFORMATION**

**ITEM 1—FINANCIAL STATEMENTS**

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

	April 2, 2006	January 1, 2006
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$ 15,617	\$ 26,351
Marketable securities .....	10,500	9,818
Accounts receivable and unbilled contract revenue.....	279	204
Inventory.....	876	1,343
Other current assets .....	1,221	1,207
Total current assets.....	28,493	38,923
Net property, plant and equipment .....	16,191	16,735
Net intangible assets.....	8,766	9,024
Other assets .....	1,576	1,587
Restricted cash .....	450	450
Total assets.....	<u>\$ 55,476</u>	<u>\$ 66,719</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable.....	\$ 6,431	\$ 4,327
Accrued liabilities.....	2,740	3,627
Accrued liabilities – Genzyme.....	1,782	3,108
Deferred contract revenue.....	2,822	2,877
Current portion of long-term debt and capital leases .....	4,090	3,997
Note payable – Genzyme.....	-	2,386
Total current liabilities .....	17,865	20,322
Long-term deferred contract revenue .....	2,451	2,663
Long-term debt and capital leases, net of current portion .....	6,007	7,005
Deferred lease obligation .....	20	20
Total liabilities .....	26,343	30,010
Shareholders' equity:		
Preferred stock, \$.01 par value; 5,000,000 shares authorized; no shares were issued and outstanding.....	—	—
Common stock, \$.01 par value; 102,820,000 shares authorized; 64,176,075 and 63,467,874 shares issued and 61,356,075 and 60,647,874 shares outstanding at April 2, 2006 and January 1, 2006, respectively.....	613	606
Capital in excess of par value – common stock.....	246,836	245,930
Accumulated deficit.....	(218,287)	(209,784)
Accumulated other comprehensive loss .....	(29)	(43)
Total shareholders' equity .....	29,133	36,709
Total liabilities and shareholders' equity .....	<u>\$ 55,476</u>	<u>\$ 66,719</u>

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

**GTC BIOTHERAPEUTICS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
(Unaudited, dollars in thousands except per share amounts)

	<b>Fiscal three months ended</b>	
	<b>April 2, 2006</b>	<b>April 3, 2005</b>
Revenues		
Revenue	\$ 2,201	\$ 1,322
Costs of revenue and operating expenses:		
Cost of revenue	1,223	1,373
Research and development	7,478	5,417
Selling, general and administrative	2,037	2,395
	10,738	9,185
Operating loss	(8,537)	(7,863)
Other income (expense):		
Interest income	279	121
Interest expense	(255)	(340)
Other income	10	49
	\$ (8,503)	\$ (8,033)
Net loss		
Net loss per common share (basic and diluted)	\$ (0.14)	\$ (0.18)
Weighted average number of common shares outstanding (basic and diluted)	60,773	44,837
Comprehensive loss:		
Net loss	\$ (8,503)	\$ (8,033)
Other comprehensive gain:		
Unrealized change in holding gain on securities available for sale	14	8
	14	8
Total other comprehensive gain		
Comprehensive loss	\$ (8,489)	\$ (8,025)

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

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

	<b>Fiscal three months ended</b>	
	April 2, 2006	April 3, 2005
Cash flows from operating activities:		
Net loss .....	\$ (8,503)	\$ (8,033)
Adjustments to reconcile net loss from continuing operations to net cash used in operating activities:		
Depreciation and amortization.....	855	1,150
Stock based compensation.....	204	-
Amortization discount on marketable securities.....	(281)	(193)
Non-cash common stock issuance to GTC savings and retirement plan .....	184	-
Inventory write-down .....	1,231	419
Loss on disposal of fixed assets.....	-	(37)
Changes in assets and liabilities:		
Accounts receivable and unbilled contract revenue .....	(75)	408
Inventory .....	(764)	(204)
Other assets and liabilities .....	(3)	22
Accounts payable .....	2,104	94
Accrued liabilities.....	(328)	(561)
Accrued liabilities – Genzyme .....	(1,326)	(692)
Deferred contract revenue .....	(267)	994
Net cash used in operating activities .....	(6,969)	(6,633)
Cash flows from investing activities:		
Purchase of property, plant and equipment.....	(53)	(240)
Sale of property, plant, and equipment .....	-	570
Purchase of marketable securities .....	(5,510)	(5,938)
Redemption of marketable securities .....	5,123	9,750
Net cash (used in) provided by investing activities .....	(440)	4,142
Cash flows from financing activities:		
Net proceeds from the issuance of common stock, net of offering costs .....	(34)	9,710
Net proceeds from employee stock purchase plan .....	-	61
Net proceeds from long-term debt .....	-	2,400
Repayment of long-term debt .....	(3,291)	(549)
Net cash (used in) provided by financing activities.....	(3,325)	11,622
Net (decrease) increase in cash and cash equivalents.....	(10,734)	9,131
Cash and cash equivalents at beginning of period.....	26,351	1,835
Cash and cash equivalents at end of period.....	\$ 15,617	\$ 10,966

*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., or GTC, for the fiscal year ended January 1, 2006, or the 2005 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 rules and regulations.

The financial statements for the fiscal three months ended April 2, 2006 and April 3, 2005, are unaudited but include, in our opinion, all adjustments necessary for a fair presentation of the results for the periods presented.

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 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 \$218.3 million at April 2, 2006. The primary sources of additional capital raised in 2005, 2004 and 2003 have been equity financings and debt financings under our credit facility. Management expects that future sources of funding may include new or expanded partnering arrangements and sales of equity or debt securities. Management believes that existing cash resources and potential future cash payments from new or existing partnering and licensing programs will be sufficient to fund operations to mid-2007. 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. If we are unable to achieve additional revenues from new or expanded partnering arrangements, or successfully raise additional capital, management has the ability to implement cost reductions necessary to continue our operations into the second quarter of 2007.

2. Accounting Policies:

Our significant accounting policies are the same as described in Note 2 to our Notes to Consolidated Financial Statements included in our 2005 Form 10-K other than the adoption of Statement of Financial Accounting Standards No. 123(R) "Share-Based Payments", SFAS 123(R), as described below. The following is a summary of the significant accounting policies used in the preparation of these financial statements.

**Accounting for Employee Equity Plans**

We have various types of share-based compensation plans. These plans are administered by the Compensation Committee of the Board of Directors, which selects persons to receive awards and determines the number of shares subject to each award and the terms, conditions, performance measures and other provisions of the award. In 1993, our Board of Directors adopted and our shareholders approved the 1993 Equity Incentive Plan, or the 1993 Plan and the 1993 Director Stock Option Plan, or the Director Plan. In 2002, our Board of Directors adopted and our shareholders approved the 2002 Equity Incentive Plan, or the 2002 Plan, and subsequently approved the inclusion of shares that became available after options granted under the 1993 Plan and the Director Plan are forfeited or expire by their terms.

As of April 2, 2006, 2,015,000 shares of Common Stock were issued or reserved for issuance under the 2002 Plan pursuant to incentive stock options, non-statutory stock options, restricted stock awards, stock appreciation rights or stock units in accordance with specific provisions to be established by a committee of the Board of Directors at the time of grant. To date, all options have been issued at 100% or greater of the fair value at the grant date. The 2002 Plan also permits us to assume outstanding options in an acquisition without using shares reserved under the 2002 Plan.

In 2003, our Board of Directors and our shareholders approved the 2003 Employee Stock Purchase Plan, or the Purchase Plan. Under the Purchase Plan, the Compensation Committee has established offerings for participants to purchase shares of Common Stock at not less than 85% of the lower of the market value at the beginning or the end of each offering. As of 2006, offering dates occur every three months. Purchase dates occur at the end of each offering. Participants may not carry over balances from one offering to the next.

Effective January 2, 2006, we adopted SFAS 123(R) which requires companies to measure and recognize compensation expense for all share-based payments at fair value. SFAS 123(R) is being applied on the modified prospective basis. Prior to the adoption of SFAS 123(R), we accounted for our share-based compensation plans under the recognition and measurement principles of Accounting Principles Board, or APB, Opinion 25, Accounting for Stock Issued to Employees, and related interpretations. We did not recognize compensation expense related to the share-based plans because the options were granted with an exercise price equal to the fair market value on the date of the grant.

Under the modified prospective approach, SFAS 123(R) applies to new awards and to awards that were outstanding on January 2, 2006 that are subsequently modified, repurchased or cancelled. Under the modified prospective approach, compensation cost recognized for the first quarter of fiscal 2006 includes compensation cost for all share-based payments granted prior to, but not yet vested on, January 2, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R), and compensation cost for all share-based payments granted subsequent to January 2, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R). Prior periods were not restated to reflect the impact of adopting the new standard.

As a result of adopting SFAS 123(R) on January 2, 2006, the net loss for the fiscal three months ended April 2, 2006, was approximately \$205,000 higher than if we had continued to account for share-based compensation under APB Opinion 25. There was no material impact on the net loss per share for the fiscal three months ended April 2, 2006.

The following table illustrates the effect on net loss and net loss per share had we accounted for share-based compensation in accordance with SFAS 123(R) for the fiscal three months ended April 3, 2005:

	<u>Unaudited</u>
Net loss, as reported (in thousands)	\$ (8,033)
Deduct: Total stock-based employee and director compensation expense determined under fair-value-based method for all awards	<u>(556)</u>
Pro forma net loss	<u>\$ (8,589)</u>
Net loss available per common share (basic and diluted):	
As reported	\$ (0.18)
Pro forma	\$ (0.19)

We use the Black-Scholes option-pricing model to estimate fair value of share-based awards with the following weighted average assumptions:

	<u>Fiscal three months ended</u>	
	<u>April 2, 2006</u>	<u>April 3, 2005</u>
<i>Stock Options and Awards:</i>		
Expected life	6 years	5 years
Expected volatility	90%	95%
Dividend yield	0%	0%
Risk-free interest rate	4.77%	3.70%
<i>Employee Stock Purchase Plan:</i>		
Expected life	3 months	6 months
Expected volatility	90%	95%
Dividend yield	0%	0%
Risk-free interest rate	4.37%	1.60%

The weighted average estimated fair value at the date of grant for options granted in the first quarter of 2006 was \$0.80 per share and \$1.26 for the first quarter of 2005.

We calculate expected volatility for stock options and other equity awards using historical volatility.

We calculate expected volatility for employee stock purchase plan shares using historical volatility over a three month period. A three month period is used to coincide with the maximum three month offering period under the employee stock purchase plan.

We have an Equity Incentive Plan which provides for the granting of stock options and other equity awards to employees, directors and consultants. Incentive stock options may be granted only to our employees. Options which do not qualify as incentive stock options may be granted to both employees and to non-employee directors and consultants. Under the Equity Incentive Plan, stock options must be granted at an exercise price not less than the fair market value of our common stock on the grant date. The options expire on the date determined by the Board of Directors but may not extend more than ten years from the grant date. Both the incentive stock options and the non-qualified stock options generally become exercisable over a four-year period. Unexercised options are canceled 90 days after termination of employment and become available under the Equity Incentive Plan for future grants.

Stock option activity is summarized as follows:

	Options Outstanding	Exercise Price	Weighted Average Exercise Price	Weighted Average Remaining Term in Years	Aggregate Intrinsic Value
Outstanding at January 1, 2006	4,417,441	\$ 0.81 - \$ 37.75	\$ 4.85		
Granted	581,100	1.03 - 1.79	1.04		
Exercised	-	-	-		
Canceled	<u>(43,350)</u>	1.45 - 17.31	5.78		
Outstanding at April 2, 2006	4,955,191	\$ 0.81 - \$ 37.75	\$ 4.39	6.55	\$ 5,875
Exercisable at April 2, 2006	3,824,311		\$5.25	5.83	\$ 4,625

As of April 2, 2006, there was \$1,073,918 of total unrecognized compensation costs related to unvested stock options. This cost is expected to be recognized over a weighted average period of 1.9 years.

At April 2, 2006, a total of 855,267 shares were available for grant under the Equity Incentive Plan.

#### **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, stock options and stock to be issued under the defined contribution retirement plan totaled 13.3 million and 6 million at April 2, 2006 and April 3, 2005, respectively. Since we were in a net loss position at April 2, 2006 and April 3, 2005, these potential common shares were not used to compute diluted loss per share, as the effect would have been antidilutive.

3. Inventory:

Inventory consists of:

	At April 2, 2006	At January 1, 2006
Raw materials	\$ 192	\$ 112
Work in process	684	1,231
Total inventory	<u>\$ 876</u>	<u>\$ 1,343</u>

We value inventory at the lower of cost or market using the first-in, first-out method. Inventories on hand at April 2, 2006, and January 1, 2006 are related to ATryn<sup>®</sup>, which we expect will be sold to LEO for clinical trials. If at any time we believe that the sale of inventory to LEO is no longer probable, we will charge the inventory to expense.

We analyze our inventory levels quarterly and will write down inventory that is expected to expire prior to sale, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements. Expired inventory will be disposed of and the related costs will be written off. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required. Also, if we should need to use a portion of the capitalized inventory for clinical trials, for which we will not be paid by LEO, we would expense the inventory when it was designated for use in such clinical trials.

During the first quarter of 2005, we wrote off approximately \$419,000 of the inventory that was designated for our own clinical trials as well as inventory that was used for development purposes and expected to expire prior to sale. During the first quarter of 2006, we recorded a net realizable value write-down of approximately \$1.2 million resulting from lower than anticipated yields in completion of additional inventory that was in process at the end of 2005.

4. Accrued Liabilities:

Accrued liabilities included the following:

	At April 2, 2006	At January 1, 2006
Accrued payroll and benefits	\$ 1,346	\$ 1,523
Accrued bonuses	278	868
Other	1,116	1,236
Total accrued expenses	<u>\$ 2,740</u>	<u>\$ 3,627</u>

5. Intangible Assets:

Our intangible assets consist of:

		(dollars in thousands)	
	Amortization Life	January 1, 2006	January 1, 2006
Marketing rights	15 years	\$ 11,210	\$ 11,210
Accumulated amortization—marketing rights		(4,172)	(3,986)
Net		<u>7,038</u>	<u>7,224</u>
Technology licenses	10 years to 15 years	3,379	3,379
Accumulated amortization — technology licenses		(1,651)	(1,579)
Net		<u>1,728</u>	<u>1,800</u>
Total intangible assets, net		<u>\$ 8,766</u>	<u>\$ 9,024</u>

Amortization expense was \$258,000 and \$259,000, respectively for the fiscal three months ended April 2, 2006 and April 3, 2005.

The estimated aggregate amortization expense for the next five years is as follows:

Nine months remaining in 2006	\$ 777,000
2007	\$ 1,035,000
2008	\$ 1,035,000
2009	\$ 926,000
2010	\$ 849,000
2011 and thereafter	\$ 4,145,000

6. Long-Term Debt:

In February 2005, we increased the term loan with GE Capital to allow us to draw down an additional \$2.4 million which was used to pay down the note due to Genzyme in April 2005. The additional amount will be repaid to GE Capital over three years through March 2008. The increased loan carries a fixed 10.01% annual interest rate and is secured by the same collateral as the existing loan with GE Capital.

In December 2005, we further increased the term loan with GE Capital to allow us to refinance the final \$2.4 million payment on the note payable to Genzyme due in 2006. The \$2.4 million in proceeds from GE Capital was received in December 2005 and the Genzyme note was repaid in full in January 2006. The additional amount on the GE term loan will be repaid over three years through January 2009. The loan carries a fixed 10.79% annual interest rate and is secured by the same collateral as the existing loan with GE Capital.

7. 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 arise 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 termination of their options. The plaintiffs contend that the sale of Primedica to Charles River did not constitute a termination of their employment with GTC or its affiliates for purposes of our equity incentive plan and, therefore, that we breached our contractual obligations to them and other Primedica employees who had not exercised their stock options. The complaint demands damages in excess of \$5 million, plus interest. We have filed an answer denying all material allegations in the complaint, and are vigorously defending the case and objecting to certification of the claims as a class action. We believe that we have meritorious defenses and that, although the ultimate outcome of the matter 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 at TransOva Genetics in Iowa under an agreement signed in December 2002. As part of the agreement, TransOva agreed to be compensated partially in equity of Taurus only when, and if, Taurus receives outside third party financing. The amount of equity would be valued under the same terms as such outside financing. The issuance of Taurus equity to TransOva under the agreement is not expected to result in any material expense to us.

8. 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.

9. New Accounting Pronouncements:

In November 2004, the Financial Accounting Standards Board, or FASB, issued SFAS No. 151, "Inventory Costs, an amendment of ARB No. 43, Chapter 4," which clarifies the types of costs that should be expensed rather than capitalized as inventory. This statement also clarifies the circumstances under which fixed overhead costs associated with operating facilities involved in inventory processing should be capitalized. The provisions of SFAS No. 151 are effective for fiscal years beginning after June 15, 2005. The adoption of this standard did not have a material effect on our financial position, results of operations or cash flows.

In December 2004, the FASB issued SFAS 123(R), which requires us to expense share-based payments, including employee stock options, based on their fair value. We adopted SFAS 123(R) on January 2, 2006. We discuss our adoption of SFAS 123(R) and the adoption's effects above and in Note 2 to our consolidated financial statements in this quarterly report.

## **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 focused primarily on using our transgenic technology in our internal programs to develop and produce products for use in critical care. Our lead product candidate is a recombinant form of human antithrombin known as ATryn<sup>®</sup>, which is being developed for patients with hereditary or acquired antithrombin deficiency. The Committee for Medical Products for Human Use, or CHMP, of the European Medicines Agency, or EMEA, issued a negative opinion on ATryn<sup>®</sup> on February 23, 2006. We exercised our right to request re-examination of our Market Authorization Application for sale and use of ATryn<sup>®</sup> in patients with hereditary deficiency undergoing high risk procedures. We have submitted our grounds for re-examination to the CHMP and we expect the CHMP to complete their review process by early June 2006.

We also use our transgenic technology in our external programs to produce therapeutic products for our partners. For our external programs, we enter licensing and development agreements with partners to use our transgenic technology to develop, produce and purify recombinant forms of therapeutic proteins. Historically, we have operated on a service contract basis, essentially receiving fees for the development of the production platform and production and purification of the proteins. We have begun structuring our agreements with our partners in our external programs so that we also receive payments based on future developments related to the proteins, such as downstream partnering with third parties and collection of royalties. Substantially all of our first quarter 2006 and first quarter 2005 revenues came from our external programs.

We have operated at a net loss since our inception in 1993. We are dependent upon funding from equity financings, partnering agreements in our external programs and short and long-term debt to finance our operations until we achieve commercial success in selling and licensing our products and positive cash flow from operations.

In November 2005, we entered into a collaboration agreement with LEO Pharma A/S of Denmark to develop and market ATryn<sup>®</sup>, if and when approved, for markets in LEO's territories of Europe, the Middle East, and Canada. The agreement includes up to \$73 million (USD) in potential milestone payments to GTC for meeting regulatory, clinical and sales goals. These payments include a total of \$5 million for achieving approval of ATryn<sup>®</sup> for the hereditary antithrombin deficiency indication in Europe, \$2 million of which was paid upon signing of the agreement and is non-refundable. This milestone revenue will be recognized over the life of the agreement on a straight-line basis beginning with the first delivery of material to LEO. We also received a payment of \$1.4 million as an advance for the sale of clinical material which LEO has committed to purchase. The revenue related to the \$1.4 million payment will be recognized upon delivery of the material. As of April 2, 2006 and January 1, 2006, the \$3.4 million is accounted for as deferred revenue. We will be responsible for production of ATryn<sup>®</sup> and will receive a transfer price for all product used by LEO. We will also receive a royalty on net sales. LEO will be responsible for sales and marketing of ATryn<sup>®</sup> in all indications for the agreed territories as well as the clinical and regulatory development for acquired antithrombin deficiency indications. We retain all rights to ATryn<sup>®</sup> in all other territories.

This discussion and analysis of our financial condition should be read in connection with our consolidated financial statements and accompanying notes thereto, our 2005 Form 10-K and the information set forth under the heading “Critical Accounting Policies and Estimates” in our 2005 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 2005 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 2005 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 2005 Form 10-K other than the adoption of SFAS 123(R) as described below. Our actual results may differ from these estimates under different assumptions or conditions.

**Share-Based Compensation**

Share-based compensation expense, which is a non-cash charge, results in part from using the Black-Scholes option pricing model for estimating the fair value of employee stock options and other equity awards. The exercise price for equity awards is based on the market value of our common shares.

Prior to January 2, 2006, we accounted for employee equity awards using the fair value method in accordance with Statement of Financial Accounting Standards No. 123, or SFAS123, Accounting for Stock-Based Compensation. As of January 2, 2006 we adopted Statement of Financial Accounting Standards No. 123(R) “Share-Based Payment”, SFAS 123(R), Share-Based Payments, to account for employee equity awards. The Black-Scholes option pricing model requires the input of the fair value of our stock at the date of grant of an equity award as well as the input of several subjective assumptions including: the expected life of the award, the expected volatility at the time the award is granted, and the expected forfeiture rate at the time the award is granted. We calculate expected volatility for stock options and other equity awards using historical volatility. Our current estimate of expected stock price volatility is 90%, expected award life is six years. The estimated fair value of our equity awards as calculated by the Black-Scholes option pricing model is amortized, over the vesting period, which is four years.

Changes in the inputs and assumptions can materially affect the measure of the estimated fair value of our employee equity awards. Also, the accounting estimate of share-based compensation expense is reasonably likely to change from period to period as further equity awards are granted and adjustments are made for equity award forfeitures and cancellations.

Included within the statements of operations for the fiscal three months ended April 2, 2006 are the following charges for share-based compensation:

	<b><u>April 2, 2006</u></b>
Research and development expense	\$ 91
Selling, general and administrative expense	114
Total share-based compensation	<u>\$ 205</u>

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

*Fiscal three months ended April 2, 2006, and April 3, 2005*

	(dollars in thousands)			
	April 2, 2006	April 3, 2005	\$ Change	% Change
Revenue .....	\$ 2,201	\$ 1,322	\$ 879	66%
Cost of revenue .....	\$ 1,223	\$ 1,373	\$ (150)	(11)%
Research and development .....	\$ 7,478	\$ 5,417	\$ 2,061	38%
Selling, general and administrative .....	\$ 2,037	\$ 2,395	\$ (358)	(15)%
Other income .....	\$ 34	\$ (170)	\$ 204	120%

*Revenue.* During the first quarter of 2006, all of our revenues were derived from external development programs, primarily with Merrimack Pharmaceuticals. During the first quarter of 2005, \$1.1 million of our revenues were derived from external development programs, primarily with Merrimack Pharmaceuticals and Elan Pharmaceuticals, in addition to \$173,000 derived from the malaria program, which was funded by the National Institute of Allergy and Infectious Disease, or NIAID. The Tysabri program with Elan was completed in early 2005 and the NIAID ended its funding of the malaria program in August 2005 due to budgetary constraints. The increase in revenues from external programs reflects the nature and timing of our milestone-based research and development activities for these programs

*Cost of revenue.* The decrease in cost of revenue is primarily the result of the completion of the Tysabri program with Elan in early 2005. The level of expenses on our external programs will fluctuate from period to period depending upon the stage of development of individual programs and their progress.

*Research and development expense.* The first quarter 2006 research and development expense included \$6.1 million related to the ATryn<sup>®</sup> program, an increase of \$3.4 million as compared to \$2.7 million in 2005. The increase was due in part to the reallocation of resources to the ATryn<sup>®</sup> program as we focused on the CHMP re-examination, manufacturing of clinical material and recruitment in the U. S. clinical trial. Included in the 2006 expenses were approximately \$900,000 related to support of the EMEA filing for ATryn<sup>®</sup> as well as \$3.3 million of ATryn<sup>®</sup> costs related to the manufacturing of clinical material and \$700,000 of expenses incurred in connection with the U.S. clinical trial. Also included in the first quarter 2006 ATryn<sup>®</sup> related expenses was an approximately \$1.2 million charge related to a net realizable value write down of the ATryn<sup>®</sup> inventory resulting from lower than anticipated yields in completion of the inventory that was in process at the end of 2005. The first quarter 2005 expenses included \$1.4 million in support of the EMEA filing, \$600,000 of ATryn<sup>®</sup> operating costs and \$300,000 of expenses incurred in preparation for the U.S. clinical trials. Also included in the first quarter 2005 ATryn<sup>®</sup> expenses was approximately \$400,000 related to a net realizable value write down of the ATryn<sup>®</sup> inventory

The increase in ATryn<sup>®</sup> expenses during the first quarter of 2006 was partially offset by a decrease in spending of approximately \$1 million on the CD-137 development program during the first quarter of 2006 as well as a net decrease in a number of other research and development programs as a result of the reallocation of resources to the ATryn<sup>®</sup> program.

*Selling, general and administrative expense.* The decrease in selling, general and administrative expenses in the first quarter of 2006 was primarily the result of a reduction in the commercial development costs.

*Other income.* The increase in other income is primarily the result of an increase to interest income from our investment account due to a higher balance in that account in the first quarter of 2006 as compared to the first quarter of 2005.

## **Liquidity and Capital Resources**

Our objective is to finance our business appropriately through a mix of equity financings, collaboration and grant revenue, debt financings and interest income earned on our cash and cash equivalents, until such time as product sales, milestone payments, and royalties occur and we achieve positive cash flow from operations. Our ability to raise future funds will be affected by the progress of clinical trials and the regulatory review of ATryn<sup>®</sup>, 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 primarily to pay salaries and wages, facility and facility-related costs of office and laboratory space and other outside direct costs such as manufacturing and clinical trial expenses. During the first quarter of 2006, we had a net cash use of \$10.1 million. This includes a \$2.4 million final repayment on a promissory note to Genzyme, which was financed by the expanded loan from GE Capital at the end of 2005. We expect the net use of cash, exclusive of the promissory note payment, to be between \$21 million and \$25 million for the full year 2006. This includes additional manufacturing of ATryn<sup>®</sup> to support clinical requirements in 2006.

We had working capital of \$10.6 million at April 2, 2006 compared to \$18.6 million at January 1, 2006.

### ***Credit Facility***

Of our \$10.1 million of outstanding long-term debt at April 2, 2006, approximately \$4.1 million is classified as current, which reflects the amount due through March 2007 on our GE Capital term loan. In January 2006, we paid approximately \$2.4 million to Genzyme which represented the final payment related to a \$4.8 million term note.

During the first quarter of 2006, our long-term debt with GE Capital was reduced by approximately \$1 million.

### ***Cash Flows Used in Operating Activities***

Cash used in operating activities totaled \$7 million and \$6.6 million for the first fiscal three months of 2006 and 2005, respectively, an increase of approximately \$400,000. Cash used in operating activities for the first fiscal three months of 2006 included a net loss of \$8.5 million, which was partially offset by certain non-cash charges of approximately \$2.2 million, including an inventory write-down of approximately \$1.2 million. Use of cash also included a decrease in accrued liabilities of approximately \$1.6 million, including a payment of approximately \$1.5 million for expenses that were accrued at the end of 2005, an increase of approximately \$800,000 in inventory, a decrease of approximately \$300,000 in advance payments from partners that were recorded as deferred revenue and an increase of approximately \$75,000 in accounts receivable. Sources of funds included an increase of approximately \$2.1 million in accounts payable, primarily the result of the timing of cash payments in connection with the ATryn<sup>®</sup> program.

### ***Cash Flows from Investing Activities***

Cash flows from investing activities include \$387,000 in net purchases of marketable securities in our portfolio and \$53,000 used for purchases of capital equipment. We anticipate a reduced level of capital expenditures company-wide in 2006 as compared to 2005.

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 2005 Form 10-K. We have reviewed the commitments and contingencies at April 2, 2006 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 1, 2006. Our market risk disclosures are discussed in our 2005 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**

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this quarterly report.

#### **(b) Changes in Internal Control over Financial Reporting**

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) identified in connection with the evaluation of our internal control that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### ITEM 6—EXHIBITS

Exhibit	Description
3.1.1	Restated Articles of Organization of the Company, filed with the Secretary of the Commonwealth of Massachusetts on December 27, 1993. Filed as Exhibit 3.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 1993 (File No. 0-21794) and incorporated herein by reference.
3.1.2	Articles of Amendment to the Restated Articles of Organization filed with the Secretary of the Commonwealth of Massachusetts on October 3, 1994. Filed as Exhibit 3.1.2 to the Company's Annual Report on Form 10-K for the year ended December 28, 1997 (File No. 0-21794) and incorporated herein by reference.
3.1.3	Articles of Amendment to the Restated Articles of Organization filed with the Secretary of Commonwealth of Massachusetts on June 26, 1997. Filed as Exhibit 3 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 29, 1997 (File No. 0-21794) and incorporated herein by reference.
3.1.4	Articles of Amendment to the Restated Articles of Organization of the Company filed with the Secretary of the Commonwealth of Massachusetts on June 1, 2000. Filed as Exhibit 4.1.5 to the Company's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 2, 2000 (File No. 333-38490) and incorporated herein by reference.
3.1.5	Certificate of Vote of Directors Establishing a Series of a Class of Stock of the Company and designating the Series C Junior Participating Cumulative Preferred Stock. Filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 1, 2001 (File No. 0-21794) and incorporated herein by reference.
3.1.6	Articles of Amendment to the Restated Articles of Organization of the Company filed with the Secretary of the Commonwealth of Massachusetts on May 31, 2002. Filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 3, 2002 (File No. 0-21794) and incorporated herein by reference.
3.2	By-Laws of the Company, as amended. Filed as Exhibit 3.1 to the Company's Form 10-Q for the quarter ended July 4, 1999 (File No. 000-21794) and incorporated herein by reference.
10.1	First Amendment to Lease Agreement, dated October 1, 2005, by and between NDNE 9/90 Corporate Center LLC and the Company.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a).
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a).
32	Certifications pursuant to 18 U.S.C. Section 1350.

## SIGNATURES

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

Date: May 10, 2006

GTC BIOTHERAPEUTICS, INC.

By: /s/ John B. Green

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