UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2004

OR

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 005-79588

GTx, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**62-1715807**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

3 N. Dunlap Street, 3rd Floor
Van Vleet Building
Memphis, Tennessee 38163
(Address of principal executive offices)

(901) 523-9700
(Registrant's telephone number, including area code)

Not Applicable
(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report

Indicate by check mark 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 [X] No [ ]

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes [ ] No [X]

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

As of July 30, 2004, 24,656,923 shares of the Registrant's Common Stock were outstanding.

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PART I
FINANCIAL INFORMATION

GTx, Inc.

CONDENSED BALANCE SHEETS
(in thousands, except share data)

	June 30, 2004	December 31, 2003
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 81,444	$ 14,769
Inventories	106	194
Other receivables	825	—
Prepaid expenses	997	61
Total current assets	83,372	15,024
Property and equipment, net	1,439	815
Other assets	231	—
Deferred initial public offering costs	—	1,471
Total assets	$ 85,042	$ 17,310
LIABILITIES, CUMULATIVE REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,178	$ 461
Accrued expenses	2,043	1,788
Deferred revenue	1,338	—
Total current liabilities	4,559	2,249
Deferred revenue	4,963	—
Cumulative redeemable convertible preferred stock	—	165,292
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value 5,000,000 shares authorized, none issued or outstanding	—	—
Common stock, $0.001 par value: 60,000,000 shares authorized; 24,656,923 shares issued and outstanding at June 30, 2004 and 7,735,848 shares issued and outstanding at December 31, 2003	25	8
Deferred stock compensation	(3,071)	(3,505)
Additional paid-in capital	223,988	5,018
Accumulated deficit	(145,422)	(151,752)
Total stockholders' equity (deficit)	75,520	(150,231)
Total liabilities and stockholders' equity (deficit)	$ 85,042	$ 17,310

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

GTx, Inc.

CONDENSED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Collaboration revenue:				
License fees	$ 334	$ —	$ 386	$ —
Reimbursement of development costs	760	—	760	—
Total collaboration revenue	1,094	—	1,146	—
Operating expenses:				
Research and development	4,139	2,590	8,475	4,703
General and administrative	1,585	801	3,185	1,411
Depreciation	101	88	188	175
Total operating expenses	5,825	3,479	11,848	6,289
Loss from operations	(4,731)	(3,479)	(10,702)	(6,289)
Interest income	212	14	362	43
Net loss	(4,519)	(3,465)	(10,340)	(6,246)
Accrued preferred stock dividends	—	(683)	(455)	(1,366)
Adjustments to preferred stock redemption value	—	4,809	17,125	4,736
Net income (loss) attributable to common stockholders	$ (4,519)	$ 661	$ 6,330	$ (2,876)
Net income (loss) per share attributable to common stockholders:				
Basic	$ (0.18)	$ 0.09	$ 0.30	$ (0.37)
Diluted	$ (0.18)	$ (0.22)	$ (0.44)	$ (0.39)
Weighted average shares used in computing net loss per share attributable to common stockholders:				
Basic	24,656,923	7,734,998	21,309,897	7,734,998
Diluted	24,656,923	15,982,982	23,524,621	15,886,677

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

GTx, Inc.

CONDENSED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Six Months Ended June 30,	
	2004	**2003**
Cash flows from operating activities:		
Net loss	$(10,340)	$(6,246)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	188	175
Stock-based compensation expense	434	—
Changes in assets and liabilities:		
Inventories	88	—
Prepaid expenses	(936)	17
Other receivables	(825)	—
Other assets	(231)	—
Accounts payable	717	(465)
Accrued expenses	688	745
Deferred revenue	6,301	—
Net cash used in operating activities	(3,916)	(5,774)
Cash flows from investing activities:		
Purchase of property and equipment	(812)	(39)
Net cash used in investing activities	(812)	(39)
Cash flows from financing activities:		
Proceeds from initial public offering	71,403	—
Net cash provided by financing activities	71,403	—
Net increase in cash and cash equivalents	66,675	(5,813)
Cash and cash equivalents, beginning of period	14,769	8,925
Cash and cash equivalents, end of period	$ 81,444	$ 3,112
Supplemental schedule of non-cash investing and financing activities:		
Preferred stock dividends	$ 455	$ 1,366
Preferred stock adjustment to redemption value	$ 17,125	$ 4,736
Deferred initial public offering costs reclassified to additional paid-in capital	$ 1,471	$ —

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

GTx, Inc.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS
(in thousands, except share and per share data)

NOTE 1— BUSINESS AND BASIS OF PRESENTATION

Business – GTx, Inc. (the "Company" or "GTx") is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics primarily related to the treatment of serious men's health conditions. GTx's drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens.

Basis of Presentation – The accompanying unaudited condensed financial statements reflect, in the opinion of management, all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation of GTx's financial position, results of operations and cash flows for each period presented in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted from the accompanying statements. These interim financial statements should be read in conjunction with the audited financial statements and related notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2003. Operating results for the three and six month periods ended June 30, 2004 are not necessarily indicative of future results that may be expected for the year ending December 31, 2004.

Prior to March 2004, the Company operated as a development-stage company and did not generate any revenue. Effective March 2004, the Company exited the development stage when it entered into a joint collaboration and license agreement with Ortho Biotech Products L.P., a wholly owned subsidiary of Johnson & Johnson.

NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly-liquid investments with an original maturity of three months or less to be cash equivalents.

Inventory

ACAPODENE™ inventory consists of a drug that is manufactured by Orion Corporation and delivered to the Company as a finished good. Inventories are stated at the lower of cost (first-in, first-out method) or market. The inventory is expensed by the Company at the time it is sent to clinical trial facilities.

Deferred Initial Public Offering Costs

Deferred initial public offering costs represent professional fees incurred in connection with the filing of a registration statement with the Securities and Exchange Commission for the sale of shares of the Company's common stock (see Note 4).

GTx, Inc.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS
(in thousands, except share and per share data)

Property and Equipment

Property and equipment is recorded at cost. Depreciation of equipment and furniture and fixtures is computed based on the straight-line method over estimated useful lives of three to five years. Amortization of leasehold improvements is recognized over the shorter of the lease term or the estimated useful life of the leasehold improvement.

Impairment

The Company accounts for long-lived assets in accordance with Statement of Financial Accounting Standards ("SFAS") No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets and for Long-Lived Assets to be Disposed of*, which requires that companies consider whether events or changes in facts and circumstances, both internally and externally, may indicate that an impairment of long-lived assets held for use are present. Management periodically evaluates the carrying value of long-lived assets and has determined that there was no impairment as of June 30, 2004. Should there be impairment in the future, the Company would recognize the amount of the impairment based on the expected future cash flows from the impaired assets. The cash flow estimates would be based on management's best estimates, using appropriate and customary assumptions and projections at the time.

Fair Value of Financial Instruments

Financial instruments consist of cash and cash equivalents, other receivables, accounts payable and preferred stock. The carrying values of cash and cash equivalents, other receivables, and accounts payable approximate the fair value due to the short-term nature of such instruments. Preferred stock is carried at redemption value which approximates fair value.

Income Taxes

The Company accounts for deferred taxes by recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and the tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. At June 30, 2004, net of the valuation allowance, the deferred tax assets and liabilities were reduced to zero.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. The Company has established guidelines relating to diversification and maturities that allow the Company to manage risk.

Revenue Recognition

Revenues associated with the Company's collaboration and license agreement discussed in Note 6 consist of non-refundable, up-front license fees and reimbursement of development expenses. Through June 30, 2004, the Company has not generated any product revenue.

GTx, Inc.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS
(in thousands, except share and per share data)

The Company uses revenue recognition criteria outlined in Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" and Emerging Issues Task Form ("EITF") Issue 00-21, "Revenue Arrangements with Multiple Deliverables" ("EITF 00-21"). Accordingly, revenues from licensing agreements are recognized based on the performance requirements of the agreement. Non-refundable up-front fees, where the Company has an ongoing involvement or performance obligation, are generally recorded as deferred revenue in the balance sheet and amortized into license fees in the statement of operations over the term of the performance obligation.

Revenues derived from reimbursements of costs associated with the development of andarine are recorded in compliance with EITF Issue 99-19, "Reporting Revenue Gross as a Principal Versus Net as an Agent" ("EITF 99-19"). According to the criteria established by this EITF Issue, in transactions where the Company acts as a principal, with discretion to choose suppliers, bears credit risk and performs part of the services required in the transaction, the Company has met the criteria to record revenue for the gross amount of the reimbursements.

Research and Development Costs

The Company expenses research and development costs in the period in which they are incurred. These costs consist of direct and indirect costs associated with specific projects as well as fees paid to various entities that perform research and clinical trial studies on behalf of the Company.

Patent Costs

The Company expenses patent costs, including legal expenses, in the period in which they are incurred. Patent expenses are included in general and administrative expenses in the Company's statements of operations.

Preferred Stock Redemption Value

The Company's preferred stock was recorded at its redemption value. The per share redemption price was equal to the greater of liquidation value, which included accrued dividends, or the fair value calculated on an as-if converted to common stock basis. At December 31, 2003, the per share redemption value was determined based on the estimated projected midpoint of the range of the Company's initial public offering price per common share of approximately $14.50 per share. At February 6, 2004, the date of the closing of the Company's IPO and automatic conversion of all outstanding preferred stock and accrued dividends thereon, into common stock, the market price for the Company's common stock was $12.90 per share. Prior to conversion into common stock, the carrying value of the preferred stock and accrued dividends was adjusted to reflect the per share redemption value on the date of conversion resulting in a decrease in the carrying value of preferred stock of $17,125 and an offsetting increase in stockholders' equity. The changes in redemption value affect the net income (loss) attributable to common stockholders.

Stock Compensation

Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB No. 25"), and its related interpretations are applied to measure compensation expense for stock-based compensation plans. The Company complies with the disclosure provisions of Statement of Financial Accounting Standards No. 123,

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Accounting for Stock-Based Compensation ("SFAS No. 123"), as amended by SFAS No. 148, *Accounting for Stock-Based Compensation, Transition and Disclosure*. Under APB No. 25, unearned stock compensation is based on the difference, if any, on the date of grant, between the fair value of the Company's common stock and the exercise price.

Deferred Stock Compensation

In anticipation of the Company's initial public offering (IPO) on February 6, 2004, the Company determined that, for financial reporting purposes, the estimated value of its common stock was in excess of the exercise price for stock options issued to employees from June 30, 2003 to December 31, 2003. Accordingly, the Company recorded non-cash deferred stock based compensation expense of $4,055 in 2003, and is amortizing the related expense over the service period, which is generally five years. Deferred stock compensation for options granted to employees has been determined as the difference between the deemed fair value of the Company's common stock for financial reporting purposes on the date such options were granted and the applicable exercise price. Such amount is included as a reduction of stockholders' equity and is being amortized on the straight-line basis. The Company recorded amortization of deferred stock compensation of approximately $184 and $434 for the three and six month periods ended June 30, 2004, respectively. Of these amounts, $133 and $266 for the respective periods were included in research and development expenses and $51 and $168, respectively, were included in general and administrative expenses in the statement of operations. No amortization of deferred stock compensation was recorded for the three or six month periods ended June 30, 2003. At June 30, 2004, the Company had approximately $3,071 to be amortized over the remaining vesting periods of the stock options.

NOTE 3—STOCK COMPENSATION

Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB No. 25"), and its related interpretations are applied to measure compensation expense for stock-based compensation plans. The Company complies with the disclosure provisions of Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation (*"SFAS No. 123"), as amended by SFAS No. 148, *Accounting for Stock-Based Compensation, Transition and Disclosure*. Under APB No. 25, unearned stock compensation is based on the difference, if any, on the date of grant, between the fair value of the Company's common stock and the exercise price.

SFAS 123 requires pro forma disclosure of net loss attributable to common stockholders, assuming all stock options were valued on the date of grant using the minimum value option pricing model for stock options granted prior to the Company's initial public offering in February 2004 and using the Black-Scholes option-pricing model for stock options granted after the IPO. The following weighted average assumptions were used for 2004 and 2003, respectively: risk free interest rates of 4.0% and 3.2%, expected volatility of 60.6% and 0.0%, no

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expected dividend yield, and expected option life of 6 years and 8 years. If compensation cost for stock-based compensation plans had been determined under SFAS 123, the Company's net income (loss) attributable to common stockholders would have been the pro forma amounts indicated as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Net income (loss) attributable to common stockholders, as reported	$(4,519)	$ 661	$6,330	$(2,876)
Add: Deferred compensation amortization included in reported net income (loss)	184	—	434	—
Deduct: Stock-based employee compensation determined under fair value based method for all awards	(319)	(33)	(596)	(64)
Pro forma net income (loss) attributable to common stockholders	$(4,654)	$ 628	$6,168	$(2,940)
Pro forma SFAS 123 disclosure:				
Net income (loss) per share attributable to common stockholders as reported:				
Basic	$ (0.18)	$ 0.09	$ 0.30	$ (0.37)
Diluted	$ (0.18)	$(0.22)	$ (0.44)	$ (0.39)
Net income (loss) per share attributable to common stockholders pro forma:				
Basic	$ (0.19)	$ 0.08	$ 0.29	$ (0.38)
Diluted	$ (0.19)	$(0.22)	$ (0.45)	$ (0.40)

NOTE 4—INITIAL PUBLIC OFFERING

On February 6, 2004, GTx successfully completed an IPO of 5.4 million shares of common stock at an offering price to the public of $14.50 per share, resulting in net proceeds of $70,365. Upon the closing of the IPO, all outstanding shares of preferred stock, and accrued dividends thereon, were converted into 11,521,075 shares of common stock. At June 30, 2004, GTx had outstanding 24,656,923 shares of common stock.

NOTE 5—ADJUSTMENT TO PREFERRED STOCK REDEMPTION VALUE

The Company's preferred stock was recorded at its redemption value. The per share redemption price was equal to the greater of liquidation value, which included accrued dividends, or the fair value calculated on an as-if converted to common stock basis. At December 31, 2003, the per share redemption value was determined based on the estimated projected midpoint on the range of the Company's initial public offering price per common share of approximately $14.50 per share. At February 6, 2004, the date of the closing of the Company's IPO and automatic conversion of all outstanding preferred stock, and accrued dividends thereon, into common stock, (see Note 4), the market price for the Company's common stock was $12.90 per share. Prior to conversion into common stock, the carrying value of the preferred stock and accrued dividends was adjusted to reflect the per share redemption value on the date of conversion resulting in a decrease in the carrying value of preferred stock of $17,125 and an offsetting increase in stockholders' equity. The changes in redemption value affect the income (loss) attributable to common stockholders.

GTx, Inc.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS
(in thousands, except share and per share data)

NOTE 6—COLLABORATION, LICENSE AND CO-PROMOTION AGREEMENT

In March 2004, we entered into a joint collaboration and license agreement with Ortho Biotech Products L.P., a wholly owned subsidiary of Johnson & Johnson for andarine, our most advanced selective androgen receptor modulator (SARM) compound, and specified backup SARM compounds. Under the terms of the agreement, we received in April 2004 an up-front licensing fee and reimbursement of development expenses of the completed Phase Id clinical trial for andarine totaling $6,687. Additionally, we will receive licensing fees and milestone payments of up to $82,000 based on andarine and up to $45,000 for each additional licensed compound achieving specific clinical development decisions or obtaining regulatory approvals. All milestone payments are based on achievements prior to the commercial launch of andarine. Johnson & Johnson Pharmaceutical Research & Development will be responsible for further clinical development and related expenses for andarine and other licensed SARM compounds. Ortho Biotech will be responsible for commercialization and related expenses for andarine and other licensed SARM compounds. If andarine is approved for commercial sale, Ortho Biotech will exclusively market andarine in the United States and in markets outside the United States. Under the agreement, we have the option to co-promote andarine and the other licensed SARM compounds to urologists in the United States for indications specifically related to men's health. We will receive up to double digit royalties on all United States and worldwide sales plus additional royalty payments in excess of 20% on all co-promoted sales generated from urologists in the United States.

The up-front licensing fee and reimbursement of Phase Id clinical trial expenses for andarine totaling $6,687 are expected to be amortized into revenue on a straight-line basis through March 2009. The Company recognized revenue of $334 and $386 for the three months and six months ended June 30, 2004, respectively, from the amortization of the up-front license fee and expense reimbursement. Additionally, the Company recognized revenue of $760 in the second quarter and first six months of 2004 from the reimbursement of andarine development costs in accordance with this collaboration and license agreement. The reimbursement amount approximated the Company's actual expenses which were recognized in the following periods: $298 in 2003, $354 in the first quarter of 2004, and $108 in the second quarter of 2004.

NOTE 7—BASIC AND DILUTED NET INCOME (LOSS) PER SHARE

The Company computed net income (loss) per common share according to Statement of Financial Accounting Standards No. 128, *"Earnings per Share,"* which requires disclosure of basic and diluted earnings (loss) per share.

GTx, Inc.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS
(in thousands, except share and per share data)

The following table sets forth the computation of the Company's basic and diluted net income (loss) per common share:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Basic net income (loss) per share				
Numerator:				
Net income (loss) attributable to common stockholders	$ (4,519)	$ 661	$ 6,330	$ (2,876)
Denominator:				
Common stock outstanding at beginning of period	24,656,923	7,734,998	7,735,848	7,734,998
Conversion of preferred stock to common stock	—	—	9,242,181	—
Issuance of common stock in initial public offering	—	—	4,331,868	—
Other share activity	—	—	—	—
Weighted average shares used in computing basic net income (loss) per share	24,656,923	7,734,998	21,309,897(1)	7,734,998
Basic net income (loss) per share attributable to common stockholders	$ (0.18)	$ 0.09	$ 0.30	$ (0.37)

(1) The weighted average shares used in computing basic net income per share attributable to common stockholders for the six months ended June 30, 2004 include 4,331,868 shares, which represent the weighted average effect during the period of the issuance of 5.4 million shares of common stock for the Company's IPO on February 6, 2004, and 9,242,181 shares, which represent the weighted average effect during the quarter of the issuance of 11,521,075 shares for the conversion of all preferred stock, and accrued dividends thereon, into common stock at the closing of the IPO. At June 30, 2004, the Company had outstanding 24,656,923 shares of common stock.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Diluted net loss per share				
Numerator:				
Net loss	$ (4,519)	$ (3,465)(2)	$ (10,340)(2)	$ (6,246)(2)
Denominator:				
Common stock outstanding at beginning of period	24,656,923	7,734,998	7,735,848	7,734,998
Conversion of preferred stock to common stock	—	8,247,984	11,456,905	8,151,679
Issuance of common stock in initial public offering	—	—	4,331,868	—
Other share activity	—	—	—	—
Weighted average shares used in computing diluted net loss per share	24,656,923	15,982,982(2)	23,524,621(2)	15,886,677(2)
Diluted net loss per share attributable to common stockholders	$ (0.18)	$ (0.22)	$ (0.44)	$ (0.39)

(2) Diluted net loss per share attributable to common stockholders is calculated as if the conversion of all preferred stock, and accrued dividends thereon, into shares of common stock occurred as of the beginning of the period. As a result, the diluted net loss per share attributable to common stockholders does not include accrued preferred stock dividends or the adjustments to preferred stock redemption value.

GTx, Inc.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS
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Outstanding options to purchase shares of common stock of 961,750 and 388,875 were excluded from the calculation of diluted earnings per share attributable to common stockholders for the periods ended June 30, 2004 and 2003, respectively, as inclusion of the options would have an anti-dilutive effect on the net loss for the periods. Of the 961,750 options outstanding at June 30, 2004, 828,750 had an exercise price less than the market price of the common stock at June 30, 2004.

NOTE 8—COMPREHENSIVE LOSS

The Company has adopted the provisions of SFAS No. 130, *Comprehensive Income.* SFAS 130 establishes standards for the reporting and display of comprehensive loss and its components for general purpose financial statements. For all periods presented, there were no differences between net loss and comprehensive loss.

NOTE 9—STOCK SPLIT

On January 14, 2004, the Company effected an 8.5-for-1 stock split of its common stock in the form of a stock dividend. All common stock share and per share amounts in these condensed financial statements have been adjusted retroactively to reflect the stock split.

NOTE 10—2004 OPTION PLANS

On January 14, 2004, the Company adopted its 2004 Equity Incentive Plan and 2004 Non-Employee Directors' Stock Option Plan, both of which became effective upon consummation of the Company's IPO of its common stock. The Company may issue awards for up to 1,500,000 shares of common stock under the 2004 Equity Incentive Plan, which amount may be increased annually on January 1st of each year, from 2005 until 2013, by the lesser of five percent of the number of shares of common stock outstanding on such date or an amount designated by the Company's Board of Directors. The Company may issue options for up to 200,000 shares of common stock under the 2004 Non-Employee Directors' Stock Option Plan, which amount may be increased annually on January 1st of each year, from 2005 until 2013, by the lesser of the number of shares of options granted during the prior calendar year or such amount designated by the Company's Board of Directors.

GTx, Inc.
(in thousands, except share and per share data)

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

The following discussion should be read in conjunction with the condensed financial statements and the notes thereto included in Item 1 of this Quarterly Report on Form 10-Q.

Forward-Looking Information is Subject to Risk and Uncertainty

This Quarterly Report on Form 10-Q contains forward-looking statements, including, without limitation, statements related to potential future licensing fees and milestone and royalty payments and GTx's current and anticipated clinical trials and research and development programs. These forward-looking statements are based upon GTx's current expectations. Forward-looking statements involve risks and uncertainties. GTx's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks that neither GTx nor its collaboration partners will be able to commercialize its product candidates if preclinical studies do not produce successful results or clinical trials do not demonstrate safety and efficacy in humans; if third parties do not manufacture the Company's product candidates in sufficient quantities and at an acceptable cost, clinical development and commercialization of its product candidates would be delayed; use of third-party manufacturers may increase the risk that the Company will not have adequate supplies of its product candidates; if third parties on whom the Company relies do not perform as contractually required or expected, the Company may not be able to obtain regulatory approval for or commercialize its product candidates; the Company is dependent upon collaborative arrangements to complete the development and commercialization of some of its product candidates, and these collaborative arrangements may place the development of its product candidates outside its control, may require it to relinquish important rights or may otherwise be on terms unfavorable to the Company; and if the Company is not able to obtain required regulatory approvals, the Company will not be able to commercialize its product candidates. You should not place undue reliance on these forward- looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. The annual report filed on Form 10-K with the U.S. Securities and Exchange Commission on March 26, 2004 contains under the heading "Additional Factors That Might Affect Future Results," a more comprehensive description of these and other risks to which GTx is subject. GTx expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

OVERVIEW

We are a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics primarily related to the treatment of serious men's health conditions. Our drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens. In our first clinical program, we are currently conducting clinical trials on ACAPODENE™ (toremifene citrate) tablets, our most advanced product candidate, for two separate indications: (i) a pivotal Phase III clinical trial to assess the effect of ACAPODENE™ in the treatment of serious side effects of androgen deprivation therapy for advanced prostate cancer and (ii) our now completed Phase IIb clinical trial to assess the effect of ACAPODENE™ in the reduction in the incidence of prostate cancer in high risk men with precancerous prostate lesions, known as high grade PIN. In our second clinical program, we are developing a second product candidate now in Phase I, andarine, and other specified backup compounds, with our collaboration partner, Ortho Biotech Products, L.P., a wholly owned subsidiary of Johnson & Johnson. Andarine will be entering a planned Phase II clinical trial this year. We retain all rights to the discovery, development, and commercialization of the rest of our selective androgen receptor modulator (SARM) program, including our other specific product candidates, ostarine, prostarine and our anti-cancer compound, andromustine.

GTx, Inc.
(in thousands, except share and per share data)

On February 6, 2004, we successfully completed an initial public offering (IPO) of 5.4 million shares of common stock at an offering price to the public of $14.50 per share resulting in net proceeds of $70,365. Upon the closing of the IPO, all outstanding shares of preferred stock, and accrued dividends thereon, were converted into 11,521,075 shares of common stock. At June 30, 2004, we had outstanding 24,656,923 shares of common stock.

In March 2004, we entered into a joint collaboration and license agreement with Ortho Biotech Products L.P., a wholly owned subsidiary of Johnson & Johnson for andarine, our most advanced selective androgen receptor modulator (SARM) compound, and specified backup SARM compounds. Under the terms of the agreement, we received in April 2004 an up-front licensing fee and reimbursement of development expenses of the completed Phase Id clinical trial for andarine totaling $6,687. The up-front licensing fee and reimbursement of development expenses is expected to be amortized into revenue on a straight-line basis through March 2009. Additionally, we will receive licensing fees and milestone payments of up to $82,000 based on andarine and up to $45,000 for each additional licensed compound achieving specific clinical development decisions or obtaining regulatory approvals. All milestone payments are based on achievements prior to the commercial launch of andarine. Johnson & Johnson Pharmaceutical Research & Development will be responsible for further clinical development and related expenses for andarine and other licensed SARM compounds. Ortho Biotech will be responsible for commercialization and related expenses for andarine and other licensed SARM compounds. If andarine is approved for commercial sale, Ortho Biotech will exclusively market andarine in the United States and in markets outside the United States. Under the agreement, we have the option to co-promote andarine and the other licensed SARM compounds to urologists in the United States for indications specifically related to men's health. We will receive up to double digit royalties on all United States and worldwide sales plus additional royalty payments in excess of 20% on all co-promoted sales generated from urologists in the United States.

During the second quarter of 2004, GTx entered into two separate collaboration agreements, one with Hybritech, Inc., a wholly owned subsidiary of Beckman Coulter, Inc., and the other with diaDexus, Inc., to provide clinical samples to each party from GTx's now completed Phase IIb clinical trial of ACAPODENE™. Information resulting from these collaborations will be utilized by Beckman Coulter, an innovator in prostate cancer assays, and diaDexus, one of the first companies to recognize the potential of genomics to generate diagnostic tests, to evaluate whether a commercial test from blood or urine may be effectively developed to detect high grade PIN and/or prostate cancer. GTx believes that there now exists the opportunity to develop a non-invasive test for high grade PIN and/or prostate cancer. By continuing to collaborate with leading diagnostic labs, GTx hopes to have a test developed to detect high grade PIN in the millions of American men who may today unknowingly harbor this precancerous prostate lesion.

On June 4, 2004, GTx announced positive Phase IIb clinical trial results for its lead program ACAPODENE™. The ACAPODENE™ Phase IIb study was a double-blind, placebo-controlled, one-year clinical trial in 514 men with high grade PIN who are at high risk for prostate cancer. The primary endpoint was the incidence of prostate cancer. This is the largest prospective study to determine the natural history of patients with high grade PIN and supports the premise that high grade PIN patients have a high risk for developing prostate cancer. The study also suggests that ACAPODENE™ may be an effective agent in preventing prostate cancer. The objectives of the Phase IIb clinical trial were achieved. This Phase IIb clinical trial demonstrated that ACAPODENE™ 20mg can produce a clinically significant reduction of prostate cancer cumulative risk by one year with the incidence of prostate cancer being 24.4% with ACAPODENE™ 20mg compared to 31.2% with placebo. Furthermore, the data appears to suggest that the longer men with high grade PIN are treated with ACAPODENE™, the greater the likelihood that their risk of prostate cancer is reduced. This is evidenced by the fact that patients in the study who had a negative prostate cancer biopsy after 6 months of treatment had a risk reduction of 48% after a full 12 months of treatment with ACAPODENE™. The study demonstrated that ACAPODENE™ was well tolerated by patients compared

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to placebo. GTx is planning a pivotal Phase III clinical trial to confirm the positive findings of its Phase IIb study in the fourth quarter 2004 following discussions with the Food and Drug Administration (FDA).

Our net loss for the quarter and six-month period ended June 30, 2004 was $4,519 and $10,340, respectively. Our net loss was reduced by the recognition of collaboration revenue of $1,094 and $1,146 for the three month and six month periods ended June 30, 2004, respectively. Collaboration income included $760 from the reimbursement of andarine development costs by Johnson & Johnson. The reimbursement amount approximated the Company's actual expenses which were recognized in the following periods: $298 in 2003, $354 in the first quarter of 2004 and $108 for the second quarter of 2004. Through June 30, 2004, we have not generated any product revenue. We have financed our operations and internal growth almost exclusively through private placements of preferred stock and our recently completed initial public offering. We expect to continue to incur net losses over the next several years as we continue our clinical development and research and development activities, apply for regulatory approvals, establish sales and marketing capabilities and expand our operations.

Since our inception in 1997, we have been focused on drug discovery and development programs. Research and development expenses represented 71% and 72% of our total operating expenses for the three months and six months ended June 30, 2004, respectively. Research and development expenses include our expenses for: personnel associated with our research activities, screening and identification of product candidates, formulation and synthesis activities, manufacturing, preclinical studies, toxicology studies, clinical trials, regulatory affairs, and quality assurance activities.

We expect that research and development expenditures will continue to increase during the remainder of the year and in subsequent years due to (1) the continuation of the pivotal Phase III clinical trial of ACAPODENE™ for the treatment of side effects of androgen deprivation therapy, (2) the planned commencement of a pivotal Phase III clinical trial of ACAPODENE™ for reduction of prostate cancer incidence in men with high grade PIN in the fourth quarter of 2004, (3) the continued preclinical development of other product candidates in the Company's SARM program that are not included in our collaboration with Ortho Biotech, including ostarine, prostarine and andromustine, (4) the continued preclinical development of other product candidates, (5) the increase in research and development personnel and (6) the planned expansion of office and lab space in our corporate headquarters. Under the terms of our collaboration with Ortho Biotech, Johnson & Johnson Pharmaceutical Research and Development will be responsible for future clinical development and expenses of andarine. We expect to expand the scope of our drug discovery and development programs in future periods, which may result in substantial increases in research and development expenses.

General and administrative expenses consist primarily of salaries and other related costs for personnel serving executive, finance, accounting, legal, human resources, information technology, public relations and marketing functions. Other costs include facility costs not otherwise included in research and development expense, travel expenses, insurance costs, taxes, marketing expenses, professional fees for legal (including patent costs), accounting, and public relations. We expect that our general and administrative expenses will increase as we add personnel, facilities (including our office space expansion) and infrastructures to support our planned growth of our business as well as additional expenses associated with operating as a public company. We plan to expand our sales and marketing efforts which will result in increased sales and marketing expenses during the remainder of the year and subsequent years.

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CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

Our management's discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments related to revenue recognition. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing in the Company's Annual Report on Form 10-K for the year ended December 31, 2003 filed with the Securities and Exchange Commission, we believe that the following accounting policies are most critical to aid you in fully understanding and evaluating our reported financial results.

Revenue Recognition

In connection with our collaboration with Ortho Biotech Products, L.P., a wholly owned subsidiary of Johnson & Johnson (J&J), we recognize revenue from non-refundable, up-front license fees, milestone payments, and reimbursement of development expenses not specifically tied to a separate earnings process ratably over the term of the collaboration, license and related agreements, generally the development period. When the period of deferral cannot be specifically identified from the agreement, our management estimates the development period. The estimated development period is based on the attainment of a particular goal and is determined based on the estimated time required to achieve that goal considering experience with similar projects, the level of effort and the development stage of the project. We continually review these estimates which could result in a change in the deferral period and which might impact the timing and the amount of revenue recognized. When payments are specifically tied to a separate earnings process, we will recognize revenue when the specific performance obligation associated with the payment is completed. Performance obligations typically consist of significant milestones in the development life cycle of the related technology, such as initiation of clinical trials, filing for approval with regulatory agencies and receipt of approvals by regulatory agencies. To date, we have received $6,687 as an initial license fee and reimbursement of development expenses for andarine from J&J. We will amortize this initial license fee and expense reimbursement over the estimated development period which we currently estimate to be five years. At June 30, 2004, we have recorded a receivable for costs incurred for which we will be reimbursed by J&J. During the quarter and six months ended June 30, 2004, we recognized $334 and $386, respectively, of license fee revenue. At June 30, 2004, we had $1,338 of current deferred revenue and $4,963 of long-term deferred revenue both related to unamortized license fees on our balance sheet.

We use revenue recognition criteria outlined in Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" and Emerging Issues Task Force ("EITF") Issue 00-21, "Revenue Arrangements with Multiple Deliverables" ("EITF 00-21"). Accordingly, revenues from licensing agreements are recognized based on the performance requirements of the agreement. Non-refundable up-front fees, where the Company has an ongoing involvement or performance obligation, are generally recorded as deferred revenue in the balance sheet and amortized into license fees in the statement of operations over the term of the performance obligation.

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Revenues derived from reimbursements of costs associated with the development of andarine are recorded in compliance with EITF Issue 99-19, "Reporting Revenue Gross as a Principal Versus Net as an Agent" ("EITF 99-19"). According to the criteria established by this EITF Issue, in transactions where the Company acts as a principal, with discretion to choose suppliers, bears credit risk and performs part of the services required in the transaction, the Company has met the criteria to record revenue for the gross amount of the reimbursements.

Research and Development Costs

We expense research and development costs in the period in which they are incurred. These costs consist of direct and indirect costs associated with specific projects as well as fees paid to various entities that perform research and clinical trial studies on our behalf.

Patent Costs

The Company expenses patent costs, including legal expenses, in the period in which they are incurred. Patent expenses are included in general and administrative expenses in our statements of operations.

Preferred Stock Redemption Value

Our preferred stock was recorded at its redemption value. The per share redemption price was equal to the greater of liquidation value, which included accrued dividends, or the fair value calculated on an as-if converted to common stock basis. At December 31, 2003, the per share redemption value was determined based on the estimated projected midpoint of the range of the Company's initial public offering price per common share of approximately $14.50 per share. At February 6, 2004, the date of the closing of our IPO and automatic conversion of all outstanding preferred stock, and accrued dividends thereon, into common stock, the market price for our common stock was $12.90 per share. Prior to conversion into common stock, the carrying value of the preferred stock and accrued dividends was adjusted to reflect the per share redemption value on the date of conversion resulting in a decrease in the carrying value of preferred stock of $17,125 and an offsetting increase in stockholders' equity. The changes in redemption value affect the net income (loss) attributable to common stockholders.

Stock Compensation

Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB No. 25"), and its related interpretations are applied to measure compensation expense for stock-based compensation plans. We comply with the disclosure provisions of Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation (*"SFAS No. 123"), as amended by SFAS No. 148, *Accounting for Stock-Based Compensation, Transition and Disclosure*. Under APB No. 25, unearned stock compensation is based on the difference, if any, on the date of grant, between the fair value of our common stock and the exercise price.

Deferred Stock Compensation

In anticipation of the Company's IPO on February 6, 2004, the Company determined that, for financial reporting purposes, the estimated value of its common stock was in excess of the exercise price for stock options issued to employees from June 30, 2003 to December 31, 2003. Accordingly, the Company recorded non-cash deferred stock based compensation expense of $4,055 in 2003, and is amortizing the related expense over the service period, which is generally five years. Deferred stock compensation for options granted to employees has been determined as the difference between the deemed fair value of our common stock for financial reporting purposes on the date such options were granted and the applicable exercise price. Such amount is included as a reduction of stockholders' equity and is being amortized on the straight-line basis. We recorded amortization of deferred stock compensation

of approximately $184 and $434 for the three and six month periods ended June 30, 2004, respectively. Of these amounts, $133 and $266 for the respective periods were included in research and development expenses and $51 and $168, respectively, were included in general and administrative expenses in our statement of operations. No amortization of deferred stock compensation was recorded for the three or six month periods ended June 30, 2003. At June 30, 2004, we had approximately $3,071 to be amortized over the remaining vesting periods of the stock options.

Results of Operations

Three Months Ended June 30, 2004 and 2003

Revenue

We recognized collaboration revenue of $1,094 for the three months ended June 30, 2004. Collaboration revenue included $334 of revenue recognized from the amortization of the up-front license fee received in April 2004 in connection with the collaboration and license agreement with Ortho Biotech Products L.P. In addition, revenue for the second quarter of 2004 included revenue from the reimbursement of andarine development costs under our collaboration and license agreement of $760. No revenue was recognized for the three months ended June 30, 2003.

Research and Development Expenses

Research and development expenses increased by $1,549 to $4,139 for the three months ended June 30, 2004 from $2,590 for the three months ended June 30, 2003. The increase in research and development expenses included a planned increase in expenditures of approximately $1,077 related to the pivotal Phase III clinical trial of ACAPODENE™ for the treatment of side effects of androgen deprivation therapy. In addition, we incurred additional expenses of $292 related to the continued clinical development of andarine and continued preclinical development of other selective androgen receptor modulator (SARM) compounds, including ostarine and andromustine. We also increased research and development spending on other product candidates by approximately $238. These increases were offset by a reduction in clinical trial expenses for the Phase IIb clinical trial of ACAPODENE™ for the reduction of prostate cancer in men with PIN of $58 which was completed during the quarter.

General and Administrative Expenses

General and administrative expenses increased during the three months ended June 30, 2004 to $1,585 from $801 for the three months ended June 30, 2003. The increase of $784 was primarily the result of increases in personnel costs, insurance costs, legal fees, as well as increases in other administrative costs to support our planned growth as well as increased expenses associated with operating as a public company.

Interest Income

Interest income increased to $212 for the three months ended June 30, 2004 from $14 for the three months ended June 30, 2003. The increase was attributable to higher average cash and cash equivalents balances during the three months ended June 30, 2004, as compared to the three months ended June 30, 2003, resulting from the IPO net proceeds of $70,365 received on February 6, 2004 and the net proceeds of $19,986 received in August 2003 from the issuance of Series E preferred stock.

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Adjustment to Preferred Stock Redemption Value

The adjustment to the preferred stock redemption value consists of the amount of the change in the redemption value, which is the greater of the liquidation value or fair value, of the preferred stock. For the three months ended June 30, 2003, the amount of the adjustment to the preferred stock redemption value was an increase to net income attributable to common stockholders of $4,809. No adjustment to the preferred stock redemption value was recorded for the three months ended June 30, 2004 as all outstanding preferred stock was converted to common stock on February 6, 2004. See “Critical Accounting Policies and Significant Judgments and Estimates – Preferred Stock Redemption Value.”

Six Months Ended June 30, 2004 and 2003

Revenue

We recognized collaboration revenue of $1,146 for the six months ended June 30, 2004. Collaboration revenue included $386 of revenue recognized from the amortization of the up-front license fee received in April 2004 in connection with the collaboration and license agreement with Ortho Biotech Products L.P. In addition, revenue for the first six months of 2004 included revenue from the reimbursement of andarine development costs under our collaboration and license agreement of $760. No revenue was recognized for the six months ended June 30, 2003.

Research and Development

Research and development expenses increased by $3,772 to $8,475 for the six months ended June 30, 2004 from $4,703 for the six months ended June 30, 2003. The increase in research and development expenses included a planned increase in expenditures of approximately $2,028 related to the pivotal Phase III clinical trial of ACAPODENE™ for the treatment of side effects of androgen deprivation therapy. In addition, we incurred additional expenses of $1,444 related to the continued clinical development of andarine and continued preclinical development of other SARM compounds including ostarine and andromustine. We also increased research and development spending on other product candidates by approximately $550. These increases were offset by a reduction of $250 in clinical trial expenses for the Phase IIb clinical trial of ACAPODENE™ for the reduction of prostate cancer in men with PIN which was completed during the period.

General and Administrative

General and administrative expenses increased during the first six months of 2004 to $3,185 from $1,411 for the first six months of 2003. The increase of $1,774 was primarily the result of increases in personnel costs, legal fees, insurance costs, marketing and investor relations costs and professional fees, as well as increases in other administrative costs to support our planned expansion of our business as well as additional expenses associated with operating as a public company.

Interest Income

Interest income increased to $362 for the six months ended June 30, 2004 from $43 for the six months ended June 30, 2003. The increase was attributable to higher average cash and cash equivalents balances during the six months ended June 30, 2004, as compared to the six months ended June 30, 2003, resulting from the IPO net proceeds of $70,365 received on February 6, 2004 and the net proceeds of $19,986 received in August 2003 from the issuance of Series E preferred stock.

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Adjustment to Preferred Stock Redemption Value

The adjustment to the preferred stock redemption value for the six months ended June 30, 2004 was an increase to net income attributable to common stockholders of $17,125, as compared to $4,736 for the six months ended June 30, 2003. Our preferred stock was recorded at its redemption value. The per share redemption price was equal to the greater of liquidation value, which included accrued dividends, or the fair value calculated on an as-if converted to common stock basis. At December 31, 2003, the per share redemption value was determined based on the estimated projected midpoint of the range of our initial public offering price per common share of approximately $14.50 per share. At February 6, 2004, the date of the closing of the Company's IPO and automatic conversion of all outstanding preferred stock, and accrued dividends thereon, into common stock, the market price for our common stock was $12.90 per share. Prior to conversion into common stock, the carrying value of the preferred stock and accrued dividends was adjusted to reflect the per share redemption value on the date of conversion resulting in a decrease in the carrying value of preferred stock of $17,125 and an offsetting increase in stockholders' equity.

Liquidity and Capital Resources

At June 30, 2004, we had cash and cash equivalents of $81,444, compared to $14,769 at December 31, 2003. On February 6, 2004, we successfully completed an initial public offering of 5.4 million shares of common stock at an offering price to the public of $14.50 per share, resulting in net proceeds of $70,365.

Net cash used in operating activities was $3,916 and $5,774 for the six months ended June 30, 2004 and 2003, respectively. The use of cash in both periods resulted primarily from funding our net losses.

Net cash used in investing activities was $812 and $39 for the six months ended June 30, 2004 and 2003, respectively. The use of cash in both periods was primarily for the purchase of office and research and development equipment. We currently expect to make expenditures for capital equipment and leasehold improvements of up to $2,000 for the remaining six months of 2004.

Net cash provided by financing activities, was $71,403 and $0 for the six months ended June 30, 2004 and 2003, respectively. Net cash provided by financing activities for the six months ended June 30, 2004 reflected the proceeds from the Company's IPO, which closed February 6, 2004, less underwriters' commission and offering expenses paid during the period and did not include offering expenses paid in 2003 of $1,038.

We believe that our current cash resources, which include the net proceeds from our initial public offering, license fees and reimbursement of development costs received under our research collaborative agreement, and interest on these funds, will be sufficient to meet our projected operating requirements through at least the end of 2005. This estimate does not include payments that we may receive as milestone payments under our joint collaboration and license agreement with Ortho Biotech.

Our forecast of the period of time through which our financial resources will be adequate to support our projected operating requirements is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed in the "Additional Factors That May Affect Future Results" section of the annual report filed on Form 10-K with the U.S. Securities and Exchange Commission on March 26, 2004. We have based this estimate on assumptions that may prove to be wrong, and we

could utilize our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development of our product candidates and other research and development activities, including risks and uncertainties that could impact the rate of progress of our development activities, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials and other research and development activities. Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- future clinical trial results;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the achievement of certain milestone events under our joint collaboration and license agreement with Ortho Biotech;
- the cost and timing of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop;
- the effect of competing technological and market developments;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

We do not anticipate that we will generate product revenue for a number of years. Until we can generate a sufficient amount of product revenue, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, such as our arrangement with Ortho Biotech, as well as through interest income earned on cash balances. With the exception of payments that we may receive under our collaboration with Ortho Biotech, we do not currently have any commitments for future external funding. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, such as our arrangement with Ortho Biotech, it may be necessary to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or to obtain funds through collaborations with others that are on unfavorable terms or that may require us to relinquish rights to some of our technologies or product candidates that we would otherwise seek to develop on our own.

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ITEM 3 QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk for changes in interest rates relates to our cash equivalents on deposit in highly liquid money market funds. The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. We do not use derivative financial instruments in our investment portfolio. Our cash and investments policy emphasizes liquidity and preservation of principal over other portfolio considerations.

We have operated primarily in the United States. Accordingly, we do not have any material exposure to foreign currency rate fluctuations. However, if we are successful in our efforts to commercialize ACAPODENE™, our exposure to foreign currency rate fluctuations may increase because we are obligated to pay Orion Corporation, our supplier of ACAPODENE™, in Euros.

ITEM 4 EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Our Chief Executive Officer and Chief Financial Officer carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the evaluation of these disclosure controls and procedures, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective. There have been no significant changes in internal control over financial reporting for the period covered by this report that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting. It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system are met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of future events. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

PART II
OTHER INFORMATION

ITEM 2 CHANGES IN SECURITIES, USE OF PROCEEDS AND ISSUER PURCHASES OF EQUITY SECURITIES

The Company's common stock began trading on The Nasdaq National Market under the trading symbol "GTXI" on February 3, 2004. The Company sold 5,400` shares of common stock in our initial public offering at $14.50 per share. The Company's Registration Statement on Form S-1 (333-109700) was declared effective by the SEC on February 2, 2004. The offering terminated after the sale of all of the securities registered on the registration statement and the expiration of the underwriters' over-allotment option. The aggregate gross proceeds from the shares of common stock sold were $78,300. The Company paid the underwriters a commission of $5,481 and incurred offering expenses of $2,454. After deducting the underwriters' commission and the offering expenses, the Company received net proceeds of $70,365. We invested the net proceeds in short-term securities and expect to use the net proceeds to fund our clinical trials and other research and development activities and for general corporate purposes. In addition, we may use a portion of the net proceeds to acquire equipment, products, technologies or businesses, although we currently have no commitments or agreements relating to any of these types of transactions.

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ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

Number	Description
3.1	Restated Certificate of Incorporation of GTx, Inc. filed February 6, 2004, as amended(1)
3.2	Amended and Restated Bylaws of GTx, Inc.(1)
4.1	Reference is made to Exhibits 3.1 and 3.2
4.2	Specimen of Common Stock Certificate(1)
4.3	Amended and Restated Registration Rights Agreement between Registrant and Oracle Partners, L.P. dated August 7, 2003(1)
4.4	Amended and Restated Registration Rights Agreement between Registrant and J. R. Hyde, III dated August 7, 2003(1)
4.5	Amended and Restated Registration Rights Agreement between Registrant and Memphis Biomed Ventures dated August 7, 2003(1)
10.1	Genotherapeutics, Inc. 1999 Stock Option Plan(1)
10.2	GTx, Inc. 2000 Stock Option Plan(1)
10.3	GTx, Inc. 2001 Stock Option Plan(1)
10.4	GTx, Inc. 2002 Stock Option Plan(1)
10.5	2004 Equity Incentive Plan and Form of Stock Option Agreement(1)
10.6	2004 Non-Employee Directors' Stock Option Plan and Form of Stock Option Agreement(1)
10.7	Reserved
10.8	Employment Agreement dated October 1, 2003, between Registrant and Mitchell S. Steiner, M.D.(1)
10.9	Employment Agreement dated October 1, 2003, between Registrant and Marc S. Hanover(1)
10.10	Employment Agreement dated October 1, 2003, between Registrant and Mark E. Mosteller(1)
10.11	Employment Agreement dated October 1, 2003, between Registrant and Henry P. Doggrell(1)
10.12	Form of Indemnification Agreement(1)
10.13	Lease Agreement, dated March 7, 2001, between The University of Tennessee and TriStar Enterprises, Inc.(1)
10.14	Sublease Agreement dated October 1, 2000, as amended, between Registrant and TriStar Enterprises, Inc.(1)
10.15†	Amended and Restated License and Supply Agreement dated October 22, 2001, between Registrant and Orion Corporation(1)
10.16†	Amendment No. 1 to the License and Supply Agreement dated March 5, 2003, between Registrant and Orion Corporation(1)
10.17†	Production and Manufacturing Agreement dated September 9, 2002, between Registrant and ChemSyn Laboratories (Department of EaglePicher Technologies, LLC)(1)
10.18†	Amendment No. 1 to the Production and Manufacturing Agreement dated September 30, 2003, between Registrant and ChemSyn Laboratories (Department of EaglePicher Technologies, LLC)(1)
10.19†	Quotation Agreement dated August 8, 2003 between Registrant and EaglePicher Pharmaceutical Services(1)
10.20†	Amended and Restated Exclusive License Agreement dated June 3, 2002, between Registrant and University of Tennessee Research Foundation(1)
10.21†	Amended and Restated Exclusive License Agreement dated June 14, 2003, between Registrant and University of Tennessee Research Foundation(1)

10.22†	Amended and Restated Exclusive License Agreement dated August 30, 2003, between Registrant and University of Tennessee Research Foundation[1]
10.23	Amendment No. 2 to the License and Supply Agreement dated December 29, 2003, between Registrant and Orion Corporation[1]
10.24†	Joint Collaboration and License Agreement dated March 16, 2004, between Registrant and Ortho Biotech Products, L.P.[3]

(a) Exhibits

Number	Description
14.1	Code of Ethics(2)
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer Pursuant to 18. U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

† Confidential treatment requested. The redacted portions have been filed separately with the SEC as required by Rule 406 of Regulation C.

(1) Incorporated by reference to the same exhibit filed with GTx's Registration Statement on Form S-1 (File No. 333-109700).

(2) Incorporated by reference to the same exhibit filed with GTx's Annual Report on Form 10-K for the year ended December 31, 2003.

(3) Incorporated by reference to the same exhibit filed with GTx's Form 10-Q for the period ended March 31, 2004 filed May 7, 2004

(b) Reports on Form 8-K:

On April 20, 2004, GTx filed a Current Report on Form 8-K, to furnish under Item 12 its April 19, 2004 public announcement of GTx's earnings release for the first quarter ending March 31, 2004.

On June 3, 2004, GTx filed a Current Report on Form 8-K, to furnish under Item 9 its June 2, 2004 public announcement regarding the positive results of its Phase IIb clinical trials of Acapodene™ for the prevention of prostate cancer in high risk men.

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 thereunto duly authorized.

GTx, Inc.

Date: July 30, 2004

By: /s/ Mitchell S. Steiner
Mitchell S. Steiner, Chief Executive Officer

Date: July 30, 2004

By: /s/ Mark E. Mosteller
Mark E. Mosteller, Chief Financial Officer
(Principal Financial and Accounting Officer)

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EXHIBIT INDEX

Number	Description
3.1	Restated Certificate of Incorporation of GTx, Inc. filed February 6, 2004, as amended(1)
3.2	Amended and Restated Bylaws of GTx, Inc.(1)
4.1	Reference is made to Exhibits 3.1 and 3.2
4.2	Specimen of Common Stock Certificate(1)
4.3	Amended and Restated Registration Rights Agreement between Registrant and Oracle Partners, L.P. dated August 7, 2003(1)
4.4	Amended and Restated Registration Rights Agreement between Registrant and J. R. Hyde, III dated August 7, 2003(1)
4.5	Amended and Restated Registration Rights Agreement between Registrant and Memphis Biomed Ventures dated August 7, 2003(1)
10.1	Genotherapeutics, Inc. 1999 Stock Option Plan(1)
10.2	GTx, Inc. 2000 Stock Option Plan(1)
10.3	GTx, Inc. 2001 Stock Option Plan(1)
10.4	GTx, Inc. 2002 Stock Option Plan(1)
10.5	2004 Equity Incentive Plan and Form of Stock Option Agreement(1)
10.6	2004 Non-Employee Directors' Stock Option Plan and Form of Stock Option Agreement(1)
10.7	Reserved
10.8	Employment Agreement dated October 1, 2003, between Registrant and Mitchell S. Steiner, M.D.(1)
10.9	Employment Agreement dated October 1, 2003, between Registrant and Marc S. Hanover(1)
10.10	Employment Agreement dated October 1, 2003, between Registrant and Mark E. Mosteller(1)
10.11	Employment Agreement dated October 1, 2003, between Registrant and Henry P. Doggrell(1)
10.12	Form of Indemnification Agreement(1)
10.13	Lease Agreement, dated March 7, 2001, between The University of Tennessee and TriStar Enterprises, Inc.(1)
10.14	Sublease Agreement dated October 1, 2000, as amended, between Registrant and TriStar Enterprises, Inc.(1)
10.15†	Amended and Restated License and Supply Agreement dated October 22, 2001, between Registrant and Orion Corporation(1)
10.16†	Amendment No. 1 to the License and Supply Agreement dated March 5, 2003, between Registrant and Orion Corporation(1)
10.17†	Production and Manufacturing Agreement dated September 9, 2002, between Registrant and ChemSyn Laboratories (Department of EaglePicher Technologies, LLC)(1)
10.18†	Amendment No. 1 to the Production and Manufacturing Agreement dated September 30, 2003, between Registrant and ChemSyn Laboratories (Department of EaglePicher Technologies, LLC)(1)
10.19†	Quotation Agreement dated August 8, 2003 between Registrant and EaglePicher Pharmaceutical Services(1)
10.20†	Amended and Restated Exclusive License Agreement dated June 3, 2002, between Registrant and University of Tennessee Research Foundation(1)
10.21†	Amended and Restated Exclusive License Agreement dated June 14, 2003, between Registrant and University of Tennessee Research Foundation(1)
10.22†	Amended and Restated Exclusive License Agreement dated August 30, 2003, between Registrant and University of Tennessee Research Foundation(1)
10.23	Amendment No. 2 to the License and Supply Agreement dated December 29, 2003, between Registrant and Orion Corporation(1)

10.24†	Joint Collaboration and License Agreement dated March 16, 2004, between Registrant and Ortho Biotech, L.P.[3]
14.1	Code of Ethics[2]
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

Number	Description
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer Pursuant to 18. U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

† Confidential treatment requested. The redacted portions have been filed separately with the SEC as required by Rule 406 of Regulation C.

(1) Incorporated by reference to the same exhibit filed with GTx's Registration Statement on Form S-1 (File No. 333-109700).

(2) Incorporated by reference to the same exhibit filed with GTx's Annual Report on Form 10-K for the year ended December 31, 2003.

(3) Incorporated by reference to the same exhibit filed with GTx's Form 10-Q for the period ended March 31, 2004 filed May 7, 2004

EXHIBIT 31.1

Chief Executive Officer Certification

I, Mitchell S. Steiner, certify that:

1. I have reviewed this quarterly report on Form 10-Q of GTx, 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(s) 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 reliability of financial reporting and the preparation of financial statement 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.

5. The registrant's other certifying officer(s) 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 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, 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.

Dated: July 30, 2004

/s/ Mitchell S. Steiner

Mitchell S. Steiner
Chief Executive Officer

EXHIBIT 31.2

Chief Financial Officer Certification

I, Mark E. Mosteller, certify that:

1. I have reviewed this quarterly report on Form 10-Q of GTx, 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(s) 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 reliability of financial reporting and the preparation of financial statement 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.

5. The registrant's other certifying officer(s) 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 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, 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.

Dated: July 30, 2004

/s/ Mark E. Mosteller

Mark E. Mosteller
Chief Financial Officer

EXHIBIT 32.1

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 of GTx, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2004, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mitchell S. Steiner, Chief Executive Officer of the Company certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 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.

/s/ Mitchell S. Steiner
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Mitchell S. Steiner
Chief Executive Officer

July 30, 2004

EXHIBIT 32.2

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 of GTx, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2004, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mark E. Mosteller, Chief Financial Officer of the Company certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 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.

/s/ Mark E. Mosteller
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Mark E. Mosteller
Chief Financial Officer

July 30, 2004