GTX INC /DE/
Form 10-Q/A
August 03, 2005

Table of Contents

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

FORM 10-Q/A

Amendment No. 2

(Mark One)

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

For the quarterly period ended March 31, 2005

OR

o **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
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 þ No o

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

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 25, 2005, 24,664,716 shares of the Registrant s Common Stock were outstanding.

Table of Contents

EXPLANATORY NOTE

GTx, Inc. (the Company) is filing this Amendment No. 2 to its Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, as filed with the Securities and Exchange Commission on April 29, 2005, as amended by Amendment No. 1 filed on July 28, 2005 to (1) restate the full text of the Quarterly Report as originally filed, (2) amend and restate the Exhibit Index in Item 6, and (3) correct an inadvertent, single word error in and refile Exhibits 31.1 and 31.2.

TABLE OF CONTENTS

Table of Contents

PART I
FINANCIAL INFORMATION

GTx, Inc.

CONDENSED BALANCE SHEETS
(in thousands, except share data)

	March 31, 2005 (unaudited)	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 55,578	$ 64,528
Inventory	594	448
Prepaid expenses and other current assets	2,314	1,176
Total current assets	58,486	66,152
Property and equipment, net	1,612	1,537
Purchased intangible assets, net	4,901	4,943
Other assets	672	450
Total assets	$ 65,671	$ 73,082
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 2,049	$ 900
Accrued expenses	3,201	2,617
Deferred revenue	1,337	1,337
Total current liabilities	6,587	4,854
Deferred revenue	3,961	4,295
Capital lease obligation	22	24
Stockholders equity:		
Common stock, $0.001 par value: 60,000,000 shares authorized; 24,664,716 shares issued and outstanding at March 31, 2005 and December 31, 2004	25	25
Deferred stock compensation	(2,516)	(2,701)
Additional paid-in capital	224,102	224,015
Accumulated deficit	(166,510)	(157,430)
Total stockholders equity	55,101	63,909
Total liabilities and stockholders equity	$ 65,671	$ 73,082

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

Table of Contents

GTx, Inc.

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

	Three Months Ended March 31,	
	2005	**2004**
Revenues:		
Product sales, net	$ 353	$
Collaboration revenue	334	52
Total revenues	687	52
Costs and expenses:		
Cost of goods sold	245	
Research and development expenses	7,326	4,411
General and administrative expenses	2,520	1,612
Total costs and expenses	10,091	6,023
Loss from operations	(9,404)	(5,971)
Interest income	324	150
Net loss	(9,080)	(5,821)
Accrued preferred stock dividends		(455)
Adjustments to preferred stock redemption value		17,125
Net (loss) income attributable to common stockholders	$ (9,080)	$ 10,849
Net (loss) income per share attributable to common stockholders:		
Basic	$ (0.37)	$ 0.60
Diluted	$ (0.37)	$ (0.26)
Weighted average shares used in computing net (loss) income per share attributable to common stockholders:		
Basic	24,664,716	17,962,871
Diluted	24,664,716	22,456,489

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

Table of Contents

GTx, Inc.

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

	Three Months Ended March 31,	
	2005	**2004**
Cash flows from operating activities:		
Net loss	$ (9,080)	$ (5,821)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	238	87
Stock-based compensation expense	185	250
License fee amortization	(334)	(52)
Changes in assets and liabilities:		
Inventory	(146)	125
Prepaid expenses and other current assets	(1,138)	(7,773)
Other assets	(255)	
Accounts payable	1,149	650
Accrued expenses	671	366
Deferred revenue		6,687
Net cash used in operating activities	(8,710)	(5,481)
Cash flows from investing activity:		
Purchases of property and equipment	(238)	(71)
Net cash used in investing activity	(238)	(71)
Cash flows from financing activities:		
Proceeds from initial public offering		71,403
Payments on capital lease obligation	(2)	
Net cash (used) provided by financing activities	(2)	71,403
Net (decrease) increase in cash and cash equivalents	(8,950)	65,851
Cash and cash equivalents, beginning of period	64,528	14,769
Cash and cash equivalents, end of period	$ 55,578	$ 80,620
Supplemental schedule of non-cash investing and financing activities:		
Preferred stock dividends	$	$ 455
Preferred stock adjustment to redemption value	$	$ 17,125
Deferred initial public offering costs reclassified to additional paid-in capital	$	$ 1,471

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

Table of Contents

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

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 and oncology. GTx s drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens, two essential classes of hormones.

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, 2004. Operating results for the three months ended March 31, 2005 are not necessarily indicative of future results that may be expected for the year ending December 31, 2005.

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, the disclosure of contingent assets and liabilities at the date of the financial statements, 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.

Property and Equipment

Property and equipment is stated at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the assets which range from three to five years. Amortization of leasehold improvements is recognized over the shorter of the estimated useful life of the leasehold improvement or the lease term.

Table of Contents

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

Impairment of Long-Lived Assets

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 March 31, 2005. 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.

Purchased Intangible Assets

The Company accounts for its purchased intangible assets in accordance with Statement of Financial Accounting Standards (SFAS) No. 142, *Goodwill and Other Intangible Assets*, which requires that purchased intangible assets with finite lives be amortized over their estimated economic lives. The Company s purchased intangible asset, license fee, represents the value of a license and supply agreement purchased by the Company. The license fee is being amortized on a straight-line basis over the term of the agreement which the Company estimates to be 16 years. Other purchased intangible assets represent the costs incurred to acquire software used by the Company. The Company amortizes the cost of purchased software on a straight-line basis over the estimated useful lives of the software, generally three years.

Fair Value of Financial Instruments

The carrying amounts of the Company s financial instruments, which include cash and cash equivalents, accounts payable and capital lease obligation approximate their 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 March 31, 2005, net of the valuation allowance, the net deferred tax assets 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.

Table of Contents

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

Revenue Recognition

Revenues associated with the Company s collaboration and license agreement consist of non-refundable, up-front license fees and reimbursement of development expenses.

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 EITF 99-19, in transactions where the Company acts as a principal, has 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.

Net product sales revenue represents gross revenue from the sale of Fareston® less deductions for estimated sales rebates, sales discounts and sales returns.

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.

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 SFAS 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.

Table of Contents

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

SFAS No. 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 (IPO) 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 2005 and 2004, respectively: risk free interest rates of 3.7% and 3.8%, expected volatility of 56.3% and 60.6%, no expected dividend yield, and expected option life of 5 years and 6 years. If compensation cost for stock-based compensation plans had been determined under SFAS No. 123, the Company s net (loss) income attributable to common stockholders would have been the pro forma amounts indicated as follows:

	Three Months Ended March 31,	
	2005	**2004**
Net (loss) income attributable to common stockholders, as reported	$ (9,080)	$ 10,849
Add: Deferred compensation amortization included in reported net (loss) income	185	250
Deduct: Stock-based employee compensation determined under fair value based method for all awards	(410)	(277)
Pro forma net (loss) income attributable to common stockholders	$ (9,305)	$ 10,822
Pro forma SFAS No. 123 disclosure:		
Net (loss) income per share attributable to common stockholders as reported:		
Basic	$ (0.37)	$ 0.60
Diluted	$ (0.37)	$ (0.26)
Net (loss) income per share attributable to common stockholders pro forma:		
Basic	$ (0.38)	$ 0.60
Diluted	$ (0.38)	$ (0.26)

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 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 $185 and $250 for the three months ended March 31, 2005 and 2004, respectively. Of

Table of Contents

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

these amounts, $133 and $133 for the respective periods were included in research and development expenses and $52 and $117, respectively, were included in general and administrative expenses in the condensed statements of operations.

Comprehensive Loss

The Company has adopted the provisions of SFAS No. 130, *Comprehensive Income* (SFAS No. 130). SFAS No. 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.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R), which replaces SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123), and supercedes APB Opinion No. 25, *Accounting for Stock Issued to Employees.* SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. The pro forma disclosures previously permitted under SFAS 123 no longer will be an alternative to financial statement recognition. The Company is required to adopt SFAS 123R in the first quarter of fiscal 2006, beginning January 1, 2006. Under SFAS 123R, the Company must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. The transition methods include prospective and retroactive adoption options. Under the retroactive option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS 123R, while the retroactive methods would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated. The Company is evaluating the requirements of SFAS 123R. The Company has not yet determined the method of adoption or the effect of adopting SFAS 123R, and it has not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS 123.

3. 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 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

Table of Contents

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

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 (loss) income attributable to common stockholders.

4. 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 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 expenses are expected to be amortized into revenue on a straight-line basis through March 2009. The Company recognized revenue of $334 and $52 for the three months ended March 31, 2005 and 2004, respectively, from the amortization of the up-front license fee and expense reimbursement.

5. BASIC AND DILUTED NET (LOSS) INCOME PER SHARE

The Company computed net (loss) income 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.

Table of Contents

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

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

	Three Months Ended March 31,	
	2005	**2004**
Basic net (loss) income per share		
Numerator:		
Net (loss) income attributable to common stockholders	$ (9,080)	$ 10,849
Denominator:		
Common stock outstanding at beginning of period	24,664,716	7,735,848
Conversion of preferred stock to common stock		6,963,287
Issuance of common stock in initial public offering		3,263,736
Other share activity		
Weighted average shares used in computing basic net (loss) income per share	24,664,716	17,962,871
Basic net (loss) income per share attributable to common stockholders	$ (0.37)	$ 0.60

	Three Months Ended March 31,	
	2005	**2004**
Diluted net loss per share		
Numerator:		
Net loss	$ (9,080)	$ (5,821)
Denominator:		
Common stock outstanding at beginning of period	24,664,716	7,735,848
Conversion of preferred stock to common stock		11,456,905
Issuance of common stock in initial public offering		3,263,736
Other share activity		
Weighted average shares used in computing diluted net loss per share	24,664,716	22,456,489
Diluted net loss per share attributable to common stockholders	$ (0.37)	$ (0.26)

Outstanding options to purchase shares of common stock of 1,199,207 and 904,750 were excluded from the calculation of diluted loss per share attributable to common stockholders for the periods ended March 31, 2005 and 2004, respectively, as inclusion of the options would have an anti-dilutive effect on the net loss for the periods. Of the 1,199,207 options outstanding at March 31, 2005, 934,207 had an exercise price less than the market price of the common stock at March 31, 2005.

12

Table of Contents

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 product sales, potential future licensing fees and milestone and royalty payments and GTx s current and anticipated marketed products, 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; and the commercial success of our current marketed product or any product that we may develop depends upon the degree of market acceptance among physicians, patients, healthcare payors and the medical community. 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 (the SEC) on March 24, 2005 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.

Table of Contents

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

OVERVIEW

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 and oncology. Our lead drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens, two essential classes of hormones.

We have four clinical programs. We are developing ACAPODENE® (toremifene citrate) for two separate indications in men: (1) a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men and (2) a pivotal Phase III clinical trial for the treatment of serious side effects of androgen deprivation therapy (ADT) for advanced prostate cancer. In our third clinical program, we and our partner, Ortho Biotech Products, L.P. (Ortho Biotech), a subsidiary of Johnson & Johnson, are developing andarine, a selective androgen receptor modulator (SARM). We are working with Ortho Biotech to progress andarine into a Phase II clinical trial in the second half of this year. In our fourth clinical program, we are developing our second SARM, ostarine, for andropause and other chronic conditions related to aging, including sarcopenia. We also have a marketed product, FARESTON® (toremifene citrate 60mg) tablets, for the treatment of metastatic breast cancer. The active pharmaceutical ingredient in FARESTON is the same as in ACAPODENE, but a different dose.

In addition, we have an extensive preclinical pipeline generated from our own discovery program, which includes the specific product candidates prostarine, a SARM for benign prostatic hyperplasia (BPH), and andromustine, an anticancer drug, for hormone refractory prostate cancer. We believe our four promising clinical programs along with our discovery pipeline create for us attractive long term commercial opportunities.

In January 2005, we acquired from Orion Corporation the rights to distribute FARESTON for the treatment of metastatic breast cancer in the U.S. and a license to toremifene for all indications worldwide except breast cancer outside the U.S. FARESTON has been commercially available for over 15 years.

Based on the positive data from our Phase IIb clinical trial for ACAPODENE in men with diagnosed high grade prostatic intraepithelial neoplasia, or high grade PIN, in January 2005, we initiated a pivotal Phase III clinical trial of ACAPODENE for the prevention of prostate cancer in men with high grade PIN. We held an investigators meeting in January, 2005 for approximately 100 U.S. clinical sites for the Phase III PIN trial. The pivotal Phase III trial is a double blind, placebo controlled, multicenter study. Patients with high grade PIN, the precancerous lesion in prostate cancer, will be randomized into two treatment groups: 20 mg toremifene or placebo. The primary endpoint of the clinical trial is the incidence of prostate cancer. We submitted our plan for the pivotal Phase III clinical trial to the FDA in October 2004 under a Special Protocol Assessment (SPA). An SPA, which is provided for in the Food and Drug Administration Modernization Act, allows a sponsor to obtain a written agreement from the FDA on the evaluation of issues related to the adequacy of the design of proposed clinical protocols. We have refiled a revised SPA in response to the FDA s input to our initial filing.

Table of Contents

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

In March 2005, we successfully completed a Phase I single ascending dose clinical trial for ostarine, our second SARM compound to be moved from discovery into clinical trials. Ostarine is a nonsteroidal SARM that is designed to have positive anabolic effects without having an impact on the prostate and is being developed for andropause as well as other conditions associated with aging, such as sarcopenia. Sarcopenia is defined as the loss of muscle mass associated with aging leading to frailty and loss of independence.

As people age they undergo hormonal and metabolic changes. Each year after age 30 people gain an average of a pound of fat every year and lose a half a pound of muscle every year. Men may lose 50% of muscle between the ages of 30 and 90. Muscle provides strength and endurance and supports the skeletal system. Loss of muscle can cause frailty and loss of independence. In addition, muscle loss can worsen other conditions such as osteoarthritis and osteoporosis. There are 17 million Americans alive over the age of 75 who suffer from sarcopenia, and currently, there are no approved treatment options available.

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, a SARM, and specified backup compounds. Under the terms of the agreement, we received an up-front licensing fee and reimbursement of expenses totaling $6,687. The up-front licensing fee and expense reimbursement are 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.

On February 6, 2004, we successfully completed an initial public offering (IPO) of 5,400,000 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 March 31, 2005, we had outstanding 24,664,716 shares of common stock.

Our net loss for the three month period ended March 31, 2005 was $9,080. Our net loss was reduced by FARESTON product sales of $353 and the recognition of collaboration revenue of $334 for the three-month period ended March 31, 2005. We have financed our operations and internal growth almost exclusively through private placements of preferred stock and our initial public offering. We expect to

Table of Contents

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

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 74% of our total operating expenses for the three months ended March 31, 2005. 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 serious side effects of androgen deprivation therapy for advanced prostate cancer, (2) the pivotal Phase III clinical trial of ACAPODENE for the prevention of prostate cancer in high risk men, (3) the continued clinical development of ostarine, (4) the continued development of other product candidates in the Company s SARM program that are not included in our collaboration with Ortho Biotech, including prostarine, (5) the continued preclinical development of other product candidates including andromustine, an anticancer drug, for hormone refractory prostate cancer and other research development efforts, and (6) the increase in research and development personnel. 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, marketing expenses, patent costs and professional fees for accounting and public relations services. We expect that our general and administrative expenses will increase as we add personnel, facilities (including our office space expansion) and infrastructures to support the planned growth of our business as well as additional expenses associated with operating as a public company.

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

Our management s discussion and analysis of our financial condition and results of operations is based on our condensed 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, income taxes, intangible assets,

Table of Contents

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

long-term service contracts and other contingencies. 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 financial statements appearing in our Annual Report on Form 10-K for the year ended December 31, 2004 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

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 we have 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. We estimated the performance obligation period to be five years for the development of andarine. The factors that drive the actual development period of a pharmaceutical product are inherently uncertain, and include determining the timing and expected costs to complete the project, projecting regulatory approvals and anticipating potential delays. We use all of these factors in initially estimating the economic useful lives of our performance obligations, and we also continuously monitor these factors for indications of appropriate revisions.

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 EITF
99-19, in transactions where we act as a principal, have discretion to choose suppliers, bear credit risk and perform part of the services required in the transaction, we have 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.

Table of Contents

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

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 our IPO on February 6, 2004, we determined that, for financial reporting purposes, the estimated value of our common stock was in excess of the exercise price for stock options issued to employees from June 30, 2003 to December 31, 2003. Accordingly, we recorded non-cash deferred stock-based compensation expense of $4,100 in 2003, and are 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.

Purchased Intangible Assets

We account for our purchased intangible assets in accordance with Statement of Financial Accounting Standards (SFAS) No. 142, *Goodwill and Other Intangible Assets*, which requires that purchased intangible assets with finite lives be amortized over their estimated economic lives. Our purchased intangible asset, license fee, represents a license fee paid to Orion in connection with entering into an Amended and Restated License and Supply Agreement. The license fee is being amortized on a straight-line basis over the term of the agreement which we estimate to be 16 years. Other purchased intangible assets represent the costs incurred to acquire software used by us. We amortize the cost of purchased software on a straight-line basis over the estimated useful lives of the software, generally three years. We use a discounted cash flow model to value our license fee. The discounted cash flow model requires assumptions about the timing and amount of future cash inflows and outflows, risk and the cost of capital. Each of these factors can significantly affect the value of the license fee. We review our license fee for impairment on a periodic basis using an undiscounted net cash flows approach. If the undiscounted cash flows of our license fee are less than its carrying value, it is written down to the discounted cash flow value. If we are unsuccessful in obtaining regulatory approval for ACAPODENE, we may not be able to recover the carrying amount of our license fee.

Table of Contents

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

Results of Operations

Three Months Ended March 31, 2005 and 2004

Revenues

Revenues for the quarter ended March 31, 2005 were $687 as compared to $52 for the first quarter of 2004. The first quarter revenues for 2005 were comprised of net sales of Fareston marketed for the treatment of metastatic breast cancer and collaboration income from our partner, Ortho Biotech, L.P., a subsidiary of Johnson & Johnson, for andarine, one of our proprietary SARM compounds. Fareston net sales were $353 and cost of goods sold was $245 while the collaboration income from Ortho Biotech, L.P. was $334.

Research and Development Expenses

Research and development expenses increased by $2,915 to $7,326 for the three months ended March 31, 2005 from $4,411 for the same period of 2004. The net increase in research and development expenses by R&D program are as follows:

Program	Product Candidate/ Indication	Development Phase	Status	Increase (Decrease) in R&D Expense (in thousands)
SERM	**ACAPODENE**			
	- Prevention of prostate cancer in men with high grade PIN	Pivotal Phase III clinical trial	Phase III trial initiated first quarter 2005	$ 1,016
	- Side effects of androgen deprivation therapy	Pivotal Phase III clinical trial	Phase III trial initiated fourth quarter 2003	1,671
SARM	**Andarine**			
	- Cachexia from various types of cancer	Four Phase I clinical trials completed	Planning Phase II trial second half of 2005	(2,057)
	Ostarine			
	- Andropause and sarcopenia	Phase I	Phase I single ascending dose (SAD) trial completed first quarter 2005	1,138

		Planning Phase I multiple ascending dose (MAD) trial second quarter of 2005	
Other research and development	Preclinical	Preclinical studies	1,147
Total increase in research and development expenses			$ 2,915

Table of Contents

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

General and Administrative Expenses

General and administrative expenses increased during the three months ended March 31, 2005 to $2,520 from $1,612 for the three months ended March 31, 2004. The increase of $908 was primarily the result of increased personnel costs, insurance costs, patent costs, medical education costs, professional fees and other administrative costs to support the Company s planned growth, as well as additional expenses associated with operating as a public company.

Interest Income

Interest income increased to $324 for the three months ended March 31, 2005 from $150 for the three months ended March 31, 2004. The increase was attributable to higher average cash and cash equivalents balances during the three months ended March 31, 2005, as compared to the same period in 2004, primarily resulting from the IPO net proceeds received on February 6, 2004 and the license fee and expense reimbursement received from Ortho Biotech in April 2004.

Adjustment to 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 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 net income attributable to common stockholders.

Liquidity and Capital Resources

At March 31, 2005, we had cash and cash equivalents of $55,578, compared to $64,528 at December 31, 2004. Net cash used in operating activities was $8,710 and $5,481 for the three months ended March 31, 2005 and 2004, respectively. The use of cash in both periods resulted primarily from funding our net losses. Net cash used in investing activities was $238 and $71 for the three months ended March 31, 2005 and 2004, respectively. The use of cash in both periods was primarily for the purchase of research and development and office equipment. We currently expect to make expenditures for capital equipment and leasehold improvements of up to $2,500 for the remaining nine months of 2005.

Net cash used in financing activities was $2 for the three month period ended March 31, 2005 and related to principal payments under a capital lease obligation. Net cash provided by financing activities for the three months ended March 31, 2004 was $71,403 excluding approximately $1,038 of IPO related

Table of Contents

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

expenses paid in 2003. Net cash provided by financing activities for the three months ended March 31, 2004 reflected net proceeds from the Company s IPO, which closed February 6, 2004, less underwriters commission and offering expenses paid during the period.

We believe that our current cash resources, interest on these funds, and product revenue from the sale of FARESTON will be sufficient to meet our projected operating requirements through at least the end of 2005. This estimate does not include additional funding that we may receive as milestone payments under our joint collaboration and license agreement with Ortho Biotech as well as funding from potential collaboration agreements with pharmaceutical companies or from the issuance and sale of securities.

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 24, 2005. 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 product sales, 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 expanding 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;

Table of Contents

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

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.

Until we can generate a sufficient amount of product revenue, we expect to finance future cash needs through current product sales, public or private equity offerings 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 and Fareston product sales, 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.

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 operate primarily in the United States. Through March 31, 2005, we have not had any material exposure to foreign currency rate fluctuations. Our exposure to foreign currency rate fluctuations results from our obligation to pay Orion Corporation, our supplier of ACAPODENE and FARESTON, in Euros; however such exposure is not expected to be material.

Table of Contents

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

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 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.

We have carried out an evaluation, under the supervision and with the participation of our management, including, our Chief Executive Officer and Chief Financial Officer of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Exchange Act) 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 during the first quarter of 2005 that have materially affected, or are reasonably likely to materially affect, our 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.

As indicated on the cover page of this report, we are not an accelerated filer within the meaning of Rule 12b-2 under the Exchange Act. We must reassess our status of non-accelerated filer on June 30, 2005, based on our market capitalization as of that date. We will be required to include in our periodic filings under the Exchange Act the disclosures contemplated by Section 404 of the Sarbanes-Oxley Act beginning with our Annual Report on Form 10-K for the year ending December 31, 2005 if we are an accelerated filer as of June 30, 2005 or for the year ending December 31, 2006 if we are not an accelerated filer as of June 30, 2005. Section 404 will require us to include an internal control report of management in our Annual Report on Form 10-K. The internal control report must contain (1) a statement of management s responsibility for establishing and maintaining adequate internal control over financial reporting, (2) a statement identifying the framework used by management to conduct the required evaluation of the effectiveness of our internal control over financial reporting, (3) management s assessment of the effectiveness of our internal control over financial reporting as of the end of our most recent fiscal year, including a statement as to whether or not internal control over financial reporting is effective, and (4) a statement that our registered public accounting firm has issued an attestation report on management s assessment of internal control over financial reporting.

Table of Contents

PART II
OTHER INFORMATION

ITEM 1 LEGAL PROCEEDINGS

None.

ITEM 2 UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

The Company s common stock began trading on The Nasdaq National Market under the trading symbol GTXI on February 3, 2004. The Company sold 5,400,000 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. After deducting the underwriter s commission and the offering expenses, the Company received net proceeds of $70,365. From the time of receipt through March 31, 2005, we have invested the available net proceeds in short-term securities. In addition, approximately $23,110 of the proceeds were used to fund our operations through March 31, 2005 and approximately $1,338 of the proceeds were used for capital expenditures and $4.8 million of the proceeds were used to acquire a license from Orion Corporation. We plan to use the balance of the 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 proceeds to acquire products, technologies or businesses, although we currently have no binding commitments or agreements relating to any of these types of transactions.

ITEM 3 DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4 SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

ITEM 5 OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The exhibits listed on the accompanying Exhibit Index are filed or incorporated by reference (as stated therein) as part of this Quarterly Report on Form 10-Q.

Table of Contents

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: August 3, 2005 By: /s/ Mitchell S. Steiner

Mitchell S. Steiner, Chief Executive Officer
(Principal Executive Officer)

Date: August 3, 2005 By: /s/ Mark E. Mosteller

Mark E. Mosteller, Chief Financial Officer
(Principal Financial and Accounting Officer)

Table of Contents

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)

Table of Contents

Number	Description
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.(2)
10.25	Purchase Agreement dated December 13, 2004, between Registrant and Orion Corporation(3)
10.26	Amended and Restated License and Supply Agreement effective January 1, 2005, between Registrant and Orion Corporation(3)
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 Form 10-Q for the period ended March 31, 2004 filed May 7, 2004.

(3) Incorporated by reference to GTx s Form 8-K filed March 7, 2005.