Table of Contents

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2007

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: 000-50549

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, including zip code)

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

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 ☒ No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer.
Large accelerated filer o Accelerated filer ☒ Non-accelerated filer o

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

As of May 7, 2007, 34,884,871 shares of the registrant's Common Stock were outstanding.

GTx, INC.
FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2007
INDEX

PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

GTx, Inc.
CONDENSED BALANCE SHEETS
(in thousands, except share data)

	March 31, 2007 (unaudited)	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 111,431	$ 119,550
Accounts receivable, net	68	61
Inventory	180	207
Prepaid expenses and other current assets	2,857	1,882
Total current assets	114,536	121,700
Property and equipment, net	1,394	1,448
Intangible assets, net	4,649	4,714
Other assets	1,322	1,393
Total assets	$ 121,901	$ 129,255
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,748	$ 1,336
Accrued expenses	4,092	3,149
Deferred revenue — current portion	5,852	5,852
Total current liabilities	11,692	10,337
Deferred revenue, less current portion	20,091	21,554
Capital lease obligation	14	15
Other long term liability	282	300
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value: 60,000,000 shares authorized; 34,877,079 shares issued and outstanding at March 31, 2007 and 34,822,362 shares issued and outstanding at December 31, 2006	35	35
Additional paid-in capital	327,690	326,793
Accumulated deficit	(237,903)	(229,779)
Total stockholders' equity	89,822	97,049
Total liabilities and stockholders' equity	$ 121,901	$ 129,255

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 March 31,	
	2007	2006
Revenues:		
Product sales, net	$ 192	$ 876
Collaboration revenue	1,463	334
Total revenues	1,655	1,210
Costs and expenses:		
Cost of product sales	109	467
Research and development expenses	8,007	8,441
General and administrative expenses	3,117	2,950
Total costs and expenses	11,233	11,858
Loss from operations	(9,578)	(10,648)
Interest income	1,454	724
Net loss	$ (8,124)	$ (9,924)
Net loss per share:		
Basic	$ (0.23)	$ (0.32)
Diluted	$ (0.23)	$ (0.32)
Weighted average shares used in computing net loss per share:		
Basic	34,842,160	30,995,714
Diluted	34,842,160	30,995,714

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

GTx, Inc.
CONDENSED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Three Months Ended March 31,	
	2007	2006
Cash flows from operating activities:		
Net loss	$ (8,124)	$ (9,924)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	276	302
Share-based compensation	469	298
Directors' deferred compensation	38	35
Deferred revenue amortization	(1,463)	(334)
Foreign currency transaction gain	(31)	—
Changes in assets and liabilities:		
Accounts receivable, net	(7)	85
Inventory	27	(36)
Prepaid expenses and other assets	(873)	(700)
Accounts payable	412	560
Accrued expenses and other long term liability	925	1,252
Net cash used in operating activities	(8,351)	(8,462)
Cash flows from investing activities:		
Purchase of property and equipment	(93)	(223)
Purchase of intangible assets	(64)	(66)
Net cash used in investing activities	(157)	(289)
Cash flows from financing activities:		
Proceeds from exercise of employee stock options	390	16
Payments on capital lease obligation	(1)	(2)
Net cash provided by financing activities	389	14
Net decrease in cash and cash equivalents	(8,119)	(8,737)
Cash and cash equivalents, beginning of period	119,550	74,014
Cash and cash equivalents, end of period	$ 111,431	$ 65,277

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

GTx, Inc.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(in thousands, except share and per share data)
(unaudited)

1. Business and Basis of Presentation

Business

GTx, Inc. ("GTx," the "Company," or "we"), a Delaware corporation incorporated on September 24, 1997 and headquartered in Memphis, Tennessee, is a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules that selectively target hormone pathways to treat cancer, osteoporosis and bone loss, muscle wasting and other serious medical conditions. GTx operates in one business segment.

GTx is developing ACAPODENE® (toremifene citrate), a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: first, a pivotal Phase III clinical trial for the treatment of serious side effects of androgen deprivation therapy, or ADT, for advanced prostate cancer and second, a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia, or high grade PIN. GTx has licensed to Ipsen Limited ("Ipsen") exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein, and the Commonwealth of Independent States (collectively, the "European Territory") to develop and commercialize ACAPODENE® and other products containing toremifene for all indications which we have licensed from Orion Corporation ("Orion"). GTx is also developing Ostarine™, a selective androgen receptor modulator, or SARM, for the treatment of cancer wasting, which is known as cancer cachexia, and for the treatment of muscle wasting in chronic kidney disease and end-stage renal disease patients.

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 condensed financial statements. These interim condensed 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, 2006. Operating results for the three months ended March 31, 2007 are not necessarily indicative of the results that may be expected for the entire fiscal year ending December 31, 2007.

GTx, Inc.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(in thousands, except share and per share data)
(unaudited)

Use of Estimates

The preparation of condensed 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 condensed financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual amounts and results could differ from those estimates.

Revenue Recognition

The Company recognizes net product sales revenue from the sale of FARESTON® less deductions for estimated sales discounts and sales returns. Revenue from product sales is recognized when the goods are shipped and title and risk of loss pass to the customer and the other criteria outlined in Staff Accounting Bulletin ("SAB") No. 101, "Revenue Recognition in Financial Statements" as amended by SAB No. 104 (together, "SAB No. 104") and Statement of Financial Accounting Standards No. 48 "*Revenue Recognition When Right of Return Exists"* are satisfied. The Company accounts for rebates to certain governmental agencies as a reduction of product sales. The Company allows customers to return product within a specified time period prior to and subsequent to the product's labeled expiration date. The Company estimates its accrual for product returns, which is recorded as a reduction of product sales, based on factors which include historical product returns and estimated product in the distribution channel which is expected to exceed its expiration date. At March 31, 2007 and December 31, 2006, the Company's accrual for product returns was $386 and $415, respectively. If actual future results are different than the Company's estimates, the Company may need to adjust its estimated accrual for product returns, which could have a material effect on earnings in the period of the adjustment.

Collaboration revenue consists of non-refundable up-front payments and license fees associated with the Company's collaboration and license agreements discussed in Note 4. The Company recognized revenue in accordance with SAB No. 104 and Emerging Issues Task Force Issue 00-21, *"Revenue Arrangements with Multiple Deliverables"*. 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 recorded as deferred revenue in the balance sheet and amortized as collaboration revenue in the condensed statements of operations over the term of the performance obligation.

Recent Accounting Pronouncements

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes-an interpretation of FASB Statement No. 109 "(FIN 48)"*, which clarifies the accounting for uncertainty in tax positions. FIN 48 requires the recognition in the condensed financial statements, the impact of a tax position, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 were effective as of January 1, 2007. The adoption of the standard had no effect on the Company's financial condition or results of operations.

GTx, Inc.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(in thousands, except share and per share data)
(unaudited)

2. Share-Based Compensation

Effective January 1, 2006, the Company adopted SFAS No.123(R), "Share-Based Payment" ("SFAS 123R") and began recognizing compensation expense for its share-based payments based on the fair value of the awards. Share-based payments include stock option grants under the Company's stock option plans.

Total share-based compensation expense for the three months ended March 31, 2007 was $507, of which $234 and $273 were recorded in the condensed statement of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the three months ended March 31, 2006 was $333, of which $163 and $170 were recorded in the condensed statement of operations as research and development expenses and general and administrative expenses, respectively. Share-based compensation expense for the three months ended March 31, 2007 and 2006 included share-based compensation expense related to deferred compensation arrangements for the Company's directors of $38 and $35, respectively.

The Company grants options to purchase common stock to certain employees and directors under various plans at prices equal to the market value of the stock on the dates the options are granted. The options have a term of ten years from the grant date and vest three years from the grant date for director options and in periods up to five years from the grant date for employee options. Employees have 90 days after the employment relationship ends to exercise all vested options except in the case of retirement, permanent disability or death, where exercise periods are generally longer. The Company issues new shares of common stock upon the exercise of options. The fair value of each option grant is separately estimated for each vesting date. The fair value of each option is amortized into compensation expense on a straight-line basis between the grant date for the award and each vesting date. The Company estimates the fair value of certain stock option awards as of the date of the grant by applying the Black-Scholes-Merton option pricing valuation model. The application of this valuation model involves assumptions that are judgmental and highly sensitive in the determination of compensation expense. The weighted average for key assumptions used in determining the fair value of options granted for the periods presented and a summary of the methodology applied to develop each assumption are as follows:

	Three Months Ended March 31,	
	2007	2006
Expected price volatility	50.9%	66.5%
Risk-free interest rate	4.7%	4.5%
Weighted average expected life in years	7.0 years	6.0 years
Dividend yield	0%	0%
Forfeiture rate	12.0%	13.0%

GTx, Inc.
NOTES TO CONDENSED FINANCIAL STATEMENTS
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Expected Price Volatility — This is a measure of the amount by which a price has fluctuated or is expected to fluctuate. For the three months ended March 31, 2007, the Company based its determination of expected volatility on its historical stock price volatility. For the three months ended March 31, 2006, the Company used an average expected price volatility of other publicly traded biopharmaceutical companies as it was the Company's belief that it was the best indicator of future volatility as it had less than two years of its own historical stock price volatility. This change in estimate did not have a material effect on the Company's results from operations for the three months ended March 31, 2007. An increase in the expected price volatility will increase compensation expense.

Risk-Free Interest Rate — This is the U.S. Treasury rate for the week of the grant having a term approximating the expected life of the option. An increase in the risk-free interest rate will increase compensation expense.

Expected Life — This is the period of time over which the options granted are expected to remain outstanding and is based on management's estimate, taking into consideration vesting term, contractual term and historical actual life. Options granted have a maximum term of ten years. An increase in the expected life will increase compensation expense.

Dividend Yield — The Company has not made any dividend payments nor does it have plans to pay dividends in the foreseeable future. An increase in the dividend yield will decrease compensation expense.

Forfeiture Rate — This is the estimated percentage of options granted that are expected to be forfeited or canceled before becoming fully vested. This estimate is based on historical experience. An increase in the forfeiture rate will decrease compensation expense.

The following is a summary of stock option transactions for all of the Company's stock option plans since our most recent fiscal year end:

	Number of Shares	Weighted Average Exercise Price Per Share
Options outstanding at December 31, 2006	1,458,289	$ 8.33
Options granted	336,500	17.88
Options forfeited	(9,500)	12.02
Options exercised	(54,717)	7.15
Options outstanding at March 31, 2007	1,730,572	10.20

3. Basic and Diluted Net Loss Per Share

The Company computed net loss per share attributable to common stockholders according to SFAS No. 128, *"Earnings per Share,"* which requires disclosure of basic and diluted earnings (loss) per share.

GTx, Inc.
NOTES TO CONDENSED FINANCIAL STATEMENTS
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Basic net loss per share attributable to common stockholders is calculated based on the weighted average number of common shares outstanding during the period. Diluted net loss per share attributable to common stockholders gives effect to the dilutive potential of common stock consisting of stock options.

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

	Three Months Ended March 31,	
	2007	2006
Basic net loss per share		
Numerator:		
Net loss	$ (8,124)	$ (9,924)
Denominator (weighted average shares):		
Common stock outstanding at beginning of period	34,822,362	30,993,967
Exercise of employee stock options	19,798	1,747
Weighted average shares used in computing basic net loss per share	34,842,160	30,995,714
Basic net loss per share	$ (0.23)	$ (0.32)

	Three Months Ended March 31,	
	2007	2006
Diluted net loss per share		
Numerator:		
Net loss	$ (8,124)	$ (9,924)
Denominator (weighted average shares):		
Common stock outstanding at beginning of period	34,822,362	30,993,967
Exercise of employee stock options	19,798	1,747
Weighted average shares used in computing diluted net loss per share	34,842,160	30,995,714
Diluted net loss per share	$ (0.23)	$ (0.32)

Weighted average options outstanding to purchase shares of common stock of 1,760,674 and 1,442,447 for the three months ended March 31, 2007 and 2006, respectively, were excluded from the calculations of diluted net loss per share as inclusion of the options would have had an anti-dilutive effect on the net loss per share for the periods.

GTx, Inc.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(in thousands, except share and per share data)
(unaudited)

4. Collaboration and License Agreements

Ipsen Collaboration and License Agreement

In September 2006, the Company entered into a collaboration and license agreement with Ipsen pursuant to which the Company granted Ipsen exclusive rights in the European Territory to develop and commercialize ACAPODENE® and other products containing toremifene in all indications which the Company has licensed from Orion, which include all indications in humans except the treatment and prevention of breast cancer outside of the United States. In accordance with the terms of the license agreement, Ipsen has agreed to pay the Company €23,000 as a license fee and expense reimbursement, of which €1,500 will be paid in equal installments over a three year period. In October 2006, the Company received €21,500 (approximately $27,100) from Ipsen as the initial payment for the license fee and expense reimbursement. Pursuant to the agreement, GTx is also entitled to receive from Ipsen up to an aggregate of €39,000 in milestone payments depending on the successful development and launch of ACAPODENE® in certain countries of the European Territory for the high grade PIN indication, subject to certain conditions, and the ADT indication. Ipsen has agreed to be responsible for and to pay all clinical development, regulatory and launch activities to commercialize ACAPODENE® in the European Territory for both the high grade PIN indication and ADT indication. Ipsen has agreed to pay the Company a royalty equal to a graduating percentage of aggregate net sales of products containing toremifene (including ACAPODENE®) which rates will be dependent on whether such sales are for the high grade PIN indication or the ADT indication. The Company will remain responsible for paying upstream royalties on ACAPODENE® to both Orion and the University of Tennessee Research Foundation (“UTRF”) for the PIN indication and to Orion only for the ADT indication. Ipsen will purchase the bulk drug product supply directly from Orion and is responsible for the packaging and labeling of the final product.

The Company recorded deferred revenue of $29,259 related to the Ipsen up-front license fee and expense reimbursement which is expected to be amortized into revenue on a straight-line basis over the estimated five year development period for ACAPODENE® in the European Territory. The Company recognized as collaboration revenue $1,463 for the three months ended March 31, 2007 from the amortization of the Ipsen deferred revenue.

Ortho Biotech Collaboration and License Agreement

In March 2004, the Company entered into a joint collaboration and license agreement with Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson (Ortho Biotech) for andarine, and specified backup SARM compounds. Under the terms of the agreement, the Company received in April 2004 an up-front licensing fee and expense reimbursement totaling $6,687. The up-front licensing fee and expense reimbursement were deferred and amortized into revenue on a straight-line basis over the estimated five year andarine development period. The Company recognized revenue of $334 for the three months ended March 31, 2006 from the amortization of the up-front license fee and expense reimbursement. In December 2006, the Company reacquired full rights to develop and commercialize andarine and all backup compounds previously licensed to Ortho Biotech and the joint collaboration and license agreement was terminated by mutual agreement of the parties. In connection with the termination of the Ortho Biotech agreement, the Company recognized the associated $3.1 million balance of deferred revenue as additional collaboration revenue for the year ended December 31, 2006. Accordingly, the

Company did not recognize any collaboration revenue for the three months ended March 31, 2007 with respect to the Ortho Biotech deferred revenue.

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 Part 1, Item 1 of this Quarterly Report on Form 10-Q.

Forward-Looking Information

This Quarterly Report on Form 10-Q contains forward-looking statements. The forward-looking statements are contained principally in the sections entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors." These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements include statements about:

- the anticipated progress of our research, development and clinical programs, including whether future clinical trials will achieve similar results to clinical trials that we have successfully concluded;
- potential future licensing fees, milestone payments, and royalty payments including any milestone payments or royalty payments that we may receive under our collaboration and license agreement with Ipsen Limited;
- our and our collaborator's ability to market, commercialize and achieve market acceptance for our product candidates or products that we may develop;
- our ability to generate additional product candidates for clinical testing;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; and
- our estimates regarding the sufficiency of our cash resources.

In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would" and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events, are based on assumptions and are subject to risks and uncertainties. We discuss many of these risks in this Quarterly Report on Form 10-Q in greater detail in the section entitled "Risk Factors" under Part II, Item 1A below. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our estimates and assumptions only as of the date of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q and the documents that we incorporate by reference in and have filed as exhibits to this Quarterly Report on Form 10-Q, completely and with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update any forward-looking

statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, even if new information becomes available in the future.

Overview

We are a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules that selectively target hormone pathways to treat cancer, osteoporosis and bone loss, muscle wasting and other serious medical conditions. We are developing ACAPODENE® (toremifene citrate), a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: first, a pivotal Phase III clinical trial for the treatment of multiple serious side effects of androgen deprivation therapy, or ADT, for advanced prostate cancer, and second, a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia, or high grade PIN. We have licensed to Ipsen Limited, or Ipsen, exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States to develop and commercialize ACAPODENE® and other products containing toremifene in all indications which we have licensed from Orion Corporation, or Orion, which include all indications in humans except the treatment and prevention of breast cancer outside of the United States. We are also developing Ostarine™, a selective androgen receptor modulator, or SARM, for the treatment of cancer wasting, which is known as cancer cachexia, and for the treatment of muscle wasting in chronic kidney disease, (“or CKD”), and end-stage renal disease, (“or ESRD”) patients. We plan to initiate a Phase IIb clinical trial evaluating Ostarine™ for the treatment of cancer cachexia by the summer of 2007 and another Phase IIb clinical trial evaluating Ostarine™ for the treatment of muscle wasting in CKD patients by the end of the year. We believe that Ostarine™ and our other SARMs have the potential to treat a variety of other indications related to muscle wasting and bone loss, including sarcopenia and osteoporosis. Even though we will primarily maintain our focus in urology and oncology, GTx is evolving into a selective nuclear hormone receptor modulator company that can target hormone pathways to address a myriad of unmet medical needs in men and women.

We also have an extensive preclinical pipeline generated from our own discovery program that includes the potential product candidates GTx-838, a SARM for sarcopenia, and GTx-878, an estrogen receptor beta agonist for benign prostatic hyperplasia and chronic prostatitis.

We commenced a pivotal Phase III clinical trial of ACAPODENE® 80 mg under a Special Protocol Assessment, or a SPA, with the United States Food and Drug Administration, or FDA, for the treatment of multiple serious side effects of ADT in November 2003. We reached our enrollment goal in the fall of 2005 and have approximately 1,400 patients randomized into the trial. We anticipate that we will complete the ADT clinical trial in the fourth quarter of 2007 with a New Drug Application, or NDA, filing expected in 2008 if the results are favorable.

In January 2005, we initiated a pivotal Phase III clinical trial of ACAPODENE® 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, which is being conducted under a SPA with the FDA. We reached our enrollment goal of 1,260 patients in May 2006. We have enrolled approximately 300 additional patients into the trial who are also participating in bone and ocular substudies requested by the FDA under the SPA. We will evaluate efficacy endpoints for the clinical trial at 36 months after completion of enrollment, and we anticipate conducting an interim efficacy analysis after a certain number of cancer events have been recorded among study patients, which we currently expect to occur in the first quarter of 2008. If the efficacy results from the interim analysis achieve the statistical outcome specified in the SPA, we plan to file a NDA with the FDA. If we are able to file a NDA based on the results of the interim efficacy analysis, we will continue to collect efficacy data and safety data during the review process to satisfy the FDA’s safety requirements set forth in the SPA.

In our third clinical program, Ostarine™, a SARM, is being developed to treat a variety of medical conditions relating to muscle wasting and/or bone loss. In December 2006, we announced that Ostarine™ met its primary endpoint in a Phase II proof of concept, double-blind, randomized, placebo-controlled clinical trial in 60 elderly men and 60 postmenopausal women. The trial was designed to evaluate the activity of Ostarine™ on building muscle as well as to assess safety in both elderly men and postmenopausal women. We recently conducted discussions with various divisions of the FDA to investigate the required regulatory pathways for several indications under consideration for the ongoing clinical development of Ostarine™. With more clarity regarding the required regulatory pathway and with proof of concept Phase II clinical data, we have selected cancer cachexia as the initial indication for Ostarine™ development. We plan to initiate a Phase IIb Ostarine™ clinical trial for cancer cachexia by the summer of 2007. We also plan to initiate a Phase IIb clinical trial of Ostarine™ for the treatment of muscle wasting in CKD patients by the end of the year.

Out net loss for the three months ended March 31, 2007 was $8.1 million. Our net loss included FARESTON® net product sales of $192,000 and the recognition of collaboration revenue of $1.5 million. We have financed our operations and internal growth primarily through private placements of preferred stock and public offerings. On December 18, 2006, we completed a registered direct public offering of 3,799,600 shares of common stock and received net proceeds of approximately $57.4 million. 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, expand our sales and marketing capabilities and grow our operations.

Research and Development

Since our inception in 1997, we have been focused on drug discovery and development programs. Research and development expenses represented 72% of our total operating expenses for the three months ended March 31, 2007. Research and development expenses included 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 in future years due to (1) the continuation of the pivotal Phase III clinical trial of ACAPODENE® 80 mg for the treatment of multiple serious side effects of ADT for advance prostate cancer, (2) the continuation of the pivotal Phase III clinical trial of ACAPODENE® 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, (3) the continued clinical and preclinical development of Ostarine™, (4) the continued preclinical development of other product candidates, including GTx-838, a SARM for sarcopenia, and GTx-878, an estrogen receptor beta agonist for benign prostatic hyperplasia and chronic prostatitis and (5) increases in research and development personnel. We anticipate filing an Investigational New Drug (IND) application for GTx-838 by year end and an IND for GTx-878 in 2008.

There is a risk that any drug discovery and development program may not produce revenue. Moreover, because of uncertainties inherent in drug discovery and development, including those factors described in Part II, Item 1A “Risk Factors” of this Quarterly Report on Form 10-Q, we may not be able to successfully develop and commercialize any of our product candidates.

The following table identifies the development phase and status for each of our product candidates:

Program	Product Candidate/ Indication	Development Phase	Status
SERM	**ACAPODENE®** **80 mg** Multiple serious side effects of ADT	Pivotal Phase III clinical trial	Phase III clinical trial ongoing under a SPA; attained enrollment goal; obtained statistically significant results from a planned BMD interim analysis in fourth quarter of 2005 and from a lipid interim analysis in second quarter of 2006
	ACAPODENE® **20 mg** Prevention of prostate cancer in high risk men with high grade PIN	Pivotal Phase III clinical trial	Phase III clinical trial ongoing under a SPA; attained enrollment goal
SARM	**Ostarine™** Cancer cachexia	Phase IIb clinical trial	Phase II proof of concept clinical trial completed December 2006; Phase IIb trial to treat cancer cachexia planned to commence by summer of 2007
	Ostarine™ CKD/ESRD muscle wasting	Phase IIb clinical trial	Phase IIb trial to treat muscle wasting in CKD patients planned to commence by year end 2007
	Andarine	Phase I clinical trial	Four Phase I clinical trials completed

Sales and Marketing

We currently market FARESTON® (toremifene citrate 60 mg) tablets, which have been approved by the FDA, for the treatment of metastatic breast cancer in postmenopausal women in the United States. In January 2005, we acquired from Orion the right to market FARESTON® tablets in the United States for the metastatic breast cancer indication. We also acquired from Orion a license to toremifene for all indications in humans worldwide, except breast cancer outside of the United States. The active pharmaceutical ingredient in FARESTON® is the same as in ACAPODENE®, but in a different dose. We plan to build specialized sales and marketing capabilities to promote our product candidates to urologists and medical oncologists in the United States and to seek partners to commercialize our product candidates in broader markets in the United States and in the rest of the world.

General and Administrative Expenses

Our general and administrative expenses consisted primarily of salaries and other related costs for personnel serving executive, finance, legal, human resources, information technology, investor relations and marketing functions. Other costs include facility costs not otherwise included in research and

development expense and professional fees for legal, accounting, public relations, and marketing services. General and administrative expenses also included insurance costs and FARESTON® selling and distribution expenses. We expect that our general and administrative expenses will increase in future periods as we add personnel and infrastructure to support the planned growth of our business. In addition, we plan to expand our sales and marketing efforts which will result in increased sales and marketing expenses in future years.

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 condensed 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 condensed 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, 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, 2006 filed with the SEC, we believe that the following accounting policies are most critical to aid you in fully understanding and evaluating our reported financial results.

Revenue Recognition

Our revenues consist of product sales of FARESTON® and revenues derived from our collaboration and license agreements.

We use revenue recognition criteria outlined in Staff Accounting Bulletin ("SAB") No. 101, *"Revenue Recognition in Financial Statements"* as amended by SAB No. 104, (together, "SAB 104") and Statement of Financial Accounting Standards No. 48, *"Revenue Recognition When Right of Return Exists"* or SFAS No. 48 and Emerging Issues Task Force Issue 00-21, "*Revenue Arrangements with Multiple Deliverables"* or EITF 00-21. Accordingly, revenues from licensing and collaboration 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 as collaboration revenue in the condensed statements of operations over the term of the performance obligation. We estimate the performance obligation period to be five years for the development of ACAPODENE® for both the high grade PIN and ADT indications in the European Territory with Ipsen. 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.

We recognize net product sales revenue from sales of FARESTON® less deductions for estimated sales discounts and sales returns. We recognize revenue from product sales when the goods are shipped

and title and risk of loss pass to the customer and the other criteria of SAB No. 104 and SFAS No. 48 are satisfied. We account for rebates to certain governmental agencies as a reduction of product sales. We allow customers to return product within a specified time period prior to and subsequent to the product's labeled expiration date. As a result, we estimate an accrual for product returns, which is recorded as a reduction of product sales, based on factors which include historical product returns and estimated product in the distribution channel which is expected to exceed its expiration date. We retained substantially the same wholesale customers of, and the distribution channel that was used by, another pharmaceutical company that distributed FARESTON® for six years prior to our obtaining the rights to market FARESTON® in January 2005. We also obtained historical product return trend information that we continue to update with our own product return data. We estimate the amount of product in the distribution channel which is expected to exceed its expiration date and be returned by the customer by receiving information from our three largest wholesale customers about the levels of FARESTON® inventory held by these customers. These three largest wholesale customers accounted for 93% of the total sales of FARESTON® for the three months ended March 31, 2007. Based on this information, and other factors, we estimate the number of months of product on hand. At March 31, 2007 and December 31, 2006, our accrual for product returns was $386,000 and $415,000, respectively. If actual future results are different than our estimates, we may need to adjust our estimated accrual for product returns, which could have a material effect on earnings in the period of the adjustment.

Research and Development Expenses

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, development and clinical trial studies on our behalf.

Patent Costs

We expense patent costs, including legal fees, in the period in which they are incurred. Patent expenses are included in general and administrative expenses in our condensed statements of operations.

Share-Based Compensation

We have stock option plans that provide for the purchase of our common stock by certain of our employees and directors. Effective January 1, 2006, we adopted SFAS 123R, "Share-Based Payment," or SFAS 123R, and began recognizing compensation expense for our share-based payments based on the fair value of the awards. Share-based payments include stock option grants under our stock option plans. Under SFAS 123R, forfeitures are estimated at the time of valuation and reduce expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate.

Total share-based compensation expense for the three months ended March 31, 2007 was $507,000, of which $234,000 and $273,000 were recorded in the statement of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the three months ended March 31, 2006 was $333,000 of which $163,000 and $170,000 were recorded in the condensed statement of operations as research and development expenses and general and administrative expenses, respectively. Share-based compensation expense for the three months ended March 31, 2007 and 2006 included share-based compensation expense related to deferred compensation arrangements for our directors of $38,000 and $35,000, respectively.

Recent Accounting Pronouncements

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes-an interpretation of FASB Statement No. 109 "(FIN 48)"*, which clarifies the accounting for uncertainty in tax positions. FIN 48 requires the recognition in the condensed financial statements, the impact of a tax position, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 were effective as of January 1, 2007. The adoption of the standard had no effect on our financial condition or results of operations.

Results of Operations

Three Months Ended March 31, 2007 and 2006

Revenues

Revenues for the three months ended March 31, 2007 were $1.7 million, as compared to $1.2 million for the same period of 2006. Revenues include net sales of FARESTON® marketed for the treatment of metastatic breast cancer and collaboration income from Ipsen for ACAPODENE® in the first quarter of 2007 and from Ortho Biotech for andarine in the first quarter of 2006. During the three months ended March 31, 2007 and 2006, FARESTON® net sales were $192,000 and $876,000, respectively, while costs of products sales were $109,000 and $467,000, respectively. During the quarter ended March 31, 2006, the Company increased the price of FARESTON®, which resulted in an increase in the sales volume and revenues of FARESTON® reported for that period. During the quarter ended March 31, 2007, aromatase inhibitors continued to gain market share at the expense of SERMs, including FARESTON®. These two factors combined resulted in a decrease of net product sales revenue and sales volume of approximately 78% during the three months ended March 31, 2007, as compared to the same period of the prior year. Collaboration income was $1.5 million for the three months ended March 31, 2007, and $334,000 for the three months ended March 31, 2006.

Research and Development Expenses

Research and development expenses decreased by $434,000 to $8.0 million for the three months ended March 31, 2007 from $8.4 million for the same period of 2006. The following table identifies the research and development expenses for each of our product candidates, as well as research and development expenses pertaining to our other research and development efforts for each of the periods presented. Research and development spending for past periods is not indicative of spending in future periods.

Program	Product Candidate/ Indication	Three Months Ended March 31, 2007	2006
		(in thousands)	
SERM	**ACAPODENE** **80mg** Multiple serious side effects of ADT	$2,312	$2,358
	ACAPODENE **20 mg** Prevention of prostate cancer in high risk men with high grade PIN	2,333	3,073
SARM	**Ostarine™** Cancer cachexia and CKD/ESRD muscle wasting	1,304	1,107
	Andarine	—	14
Other research and development		2,058	1,889
Total research and development expenses		$8,007	$8,441

General and Administrative Expenses

General and administrative expenses increased during the three months ended March 31, 2007 to $3.1 million from $3.0 million for the three months ended March 31, 2006 was primarily the result of increased personnel related expenses.

Interest Income

Interest income increased to $1.5 million for the three months ended March 31, 2007 from $724,000 for the three months ended March 31, 2006. The increase was attributable to higher average interest rates in addition to higher average cash and cash equivalents balances during the three months ended March 31, 2007, as compared to the same period in 2006.

Liquidity and Capital Resources

At March 31, 2007, we had cash and cash equivalents of $111.4 million, compared to $119.6 million at December 31, 2006. Net cash used in operating activities was $8.4 million and $8.5 million for the three months ended March 31, 2007 and 2006, respectively. The use of cash in both periods resulted primarily from funding our net losses. Net cash used in investing activities was $157,000 and $289,000 for the three months ended March 31, 2007 and 2006, respectively. Net cash used in investing activities for both periods was primarily for the purchase of research and development equipment, software and information technology equipment. We currently expect to make capital expenditures of approximately $1 million for the remainder of 2007.

Net cash provided by financing activities was $389,000 for the three month period ended March 31, 2007 and included proceeds from the exercise of employee stock options of $390,000, offset by principal payments under a capital lease obligation of $1,000. Net cash provided by financing activities was $14,000 for the three month period ended March 31, 2006 and included proceeds from the exercise of employee stock options of $16,000, offset by principal payments under a capital lease obligation of $2,000.

We estimate 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 the first quarter of 2009. This estimate does not include funding from milestone payments that we may receive under our existing collaboration with Ipsen, potential future collaboration agreements with pharmaceutical companies, or the potential future issuances and sales of our securities. This estimate also does not include any potential product launch costs in connection with the potential marketing approval of ACAPODENE® by the FDA.

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 under Part II, Item 1A “Risk Factors” of this Quarterly Report on Form 10-Q. 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 achievement of certain milestone events under, and other matters related to, our collaboration and license agreement with Ipsen;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;

- potential future licensing fees, milestone payments and royalty payments, including any milestone payments or royalty payments that we may receive under our collaboration and license agreement with Ipsen;
- 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.

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 collaboration and licensing arrangements, such as our arrangement with Ipsen, as well as through interest income earned on the investment of our cash balances and revenues from the sale of FARESTON®. With the exception of payments that we may receive under our collaboration with Ipsen, 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 Ipsen, 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

During the three months ended March 31, 2007, there were no material changes to our market risk disclosures as set forth in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2006.

ITEM 4. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities and Exchange Act of 1934, as amended (the "Exchange Act") 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 for timely decisions regarding required disclosures.

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 Rules13a-15(e) and 15d-15(e) of the Exchange Act as of the end of the period covered by this report. Based on the evaluation of these disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective.

There were no changes in our internal control over financial reporting during the first quarter of 2007 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

ITEM 1A. RISK FACTORS

We have identified the following additional risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. Investors should carefully consider the risks described below before making an investment decision. Our business faces significant risks and the risks described below may not be the only risks we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. If any of these risks occur, our business, results of operations or financial condition could suffer, the market price of our common stock could decline and you could lose all or part of your investment in our common stock.

We have marked with an asterisk (*) those risks described below that reflect substantive changes from the risks described under Part I, Item 1A "Risk Factors" included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 9, 2007.

Risks Related to Our Financial Results and Need for Additional Financing

We have incurred losses since inception and anticipate that we will incur continued losses for the foreseeable future.*

We have a limited operating history. As of March 31, 2007, we had an accumulated deficit of $237.9 million, of which $96.3 million related to non-cash dividends and adjustments to the preferred stock redemption value. We have incurred losses in each year since our inception in 1997. Net losses were $8.1 million for the three months ended March 31, 2007, $35.5 million in 2006, $36.8 million in 2005 and $22.3 million in 2004. We expect to continue to incur significant and increasing operating losses for the foreseeable future. These losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Because of the numerous risks and uncertainties associated with developing small molecule drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. We have primarily financed our operations and internal growth through sales of common stock and preferred stock. In addition, we have received up-front license fees and payments pursuant to our collaboration agreement with Ortho Biotech for andarine and certain other selective androgen receptor modulator, or SARMs, which was terminated in December 2006, and our collaboration agreement with Ipsen Limited for European rights to ACAPODENE® and other toremifene-based products. FARESTON® is currently our only commercial product and, we expect, will account for all of our product revenue for the foreseeable future. For the three months ended March 31, 2007, we recognized $192,000 in net revenues from the sale of FARESTON®.

We expect our research and development expenses to increase in connection with our ongoing clinical trials. In addition, subject to regulatory approval of any of our product candidates, we expect to incur additional sales and marketing expenses and increased manufacturing expenses.

We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.*

We will need to raise additional capital to:

- fund our operations and clinical trials;
- continue our research and development; and
- commercialize our product candidates, if any such product candidates receive regulatory approval for commercial sale.

We estimate 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 the first quarter of 2009. This estimate does not include funding from milestone payments that we may receive under our existing collaboration with Ipsen, potential future collaboration agreements with pharmaceutical companies, or potential future issuances and sales of our securities. This estimate does not include any potential product launch costs in connection with the potential marketing approval of ACAPODENE by the FDA.

- 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 achievement of certain milestone events under, and other matters related to, our collaboration and license agreement with Ipsen;
- the terms and timing of any future collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- potential future licensing fees, milestone payments and royalty payments, including any milestone payments or royalty payments that we may receive under our collaboration and license agreement with Ipsen;
- 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.

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 collaboration and licensing arrangements, as

well as through interest income earned on the investment of our cash balances and revenues from the sale of FARESTON®.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, may involve restrictive covenants. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and/or licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our product candidates, or we may be required to grant licenses on terms that may not be favorable to us.

Risks Related to Development of Product Candidates

We will not be able to commercialize our product candidates if our preclinical studies do not produce successful results or our clinical trials do not demonstrate safety and efficacy in humans.

Preclinical and clinical testing is expensive, can take many years and has an uncertain outcome. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. Typically, the failure rate for development candidates is high. Significant delays in clinical testing could materially impact our product development costs. We do not know whether planned clinical trials will begin on time, will need to be restructured or will be completed on schedule, if at all.

Several patients in our Phase III clinical trial of ACAPODENE® 80 mg for the side effects of androgen deprivation therapy have withdrawn from the trial, in accordance with the trial protocol, to seek treatment for a significant loss in bone mineral density. Even if these patients are receiving a placebo, their withdrawal from the trial may result in delays or an inability to achieve the proscribed statistical endpoint. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent our ability to commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- our preclinical or clinical trials may produce negative or inconclusive results, which may require us to conduct additional preclinical or clinical testing or to abandon projects that we expect to be promising;
- registration or enrollment in our clinical trials may be slower than we currently anticipate, resulting in significant delays;
- we might have to suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks;
- regulators or institutional review boards may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; and
- our product candidates may not have the desired effects or may include undesirable side effects.

If any of these events were to occur and, as a result, we have significant delays in or termination of clinical trials, our costs could increase and our ability to generate revenue could be impaired, which would adversely impact our financial results.

For some of the indications for which we intend to conduct or are currently conducting clinical trials for our product candidates, we do not have evidence from prior preclinical studies in animals or clinical trials in humans of the potential effectiveness of such product candidates for such indications. In the absence of preclinical or clinical data, our beliefs regarding the potential effectiveness of our product candidates for these indications is generally based on pharmacokinetic data and analyses and pharmacological rationales. For example, our belief that ACAPODENE® has the potential to reduce hot flashes is based, in part, on our second Phase II clinical trial in which a higher percentage of the subjects in the placebo group experienced worsening in the frequency of hot flashes compared to the subjects treated with ACAPODENE®. Although this observation suggests that ACAPODENE® does not cause hot flashes or the worsening of hot flashes in men on androgen deprivation therapy, this trial was too small to establish the potential effects of ACAPODENE® on the reduction in incidence or severity of hot flashes. Similarly, an assessment of the potential to treat gynecomastia with ACAPODENE® in this second Phase II clinical trial was inconclusive. We are assessing the effect of ACAPODENE® on gynecomastia and hot flashes in our Phase III clinical trial. Our preclinical or clinical trials may produce negative or inconclusive results that would not support our belief regarding the potential effectiveness of our product candidates.

If we observe serious or other adverse events during the time our product candidates are in development or after our products are approved and on the market, we may be required to perform lengthy additional clinical trials, may be denied regulatory approval of such products, may be forced to change the labeling of such products or may be required to withdraw any such products from the market, any of which would hinder or preclude our ability to generate revenues.

To date, in our two Phase III clinical trials for ACAPODENE®, some patients have experienced venous thromboembolic events, such as deep vein thromboses and pulmonary embolisms, as well as myocardial infarctions, one of which resulted in a patient's death, which were considered by investigators as possibly related to treatment with ACAPODENE®. Because these trials are blinded, we cannot establish whether these patients received placebo or ACAPODENE® in the trial. There have been no drug-related serious adverse events related to our other product candidates. A drug safety monitoring board meets every six months to review unblinded data from the ACAPODENE® Phase III clinical trials. In January 2007, the drug safety monitoring board reviewed safety data from in excess of 2,900 patients, including the venous thromboembolic events and myocardial infarctions referred to above, and recommended continuing both clinical trials with no changes to the trial protocols. In addition, in our Phase II clinical trial for Ostarine™, we observed a dose-related elevation of hepatic enzymes, and in our preclinical studies for Ostarine™, we observed expected effects on the reproductive organs in the male population, since our drug targets the androgen receptor which is located on these organs.

If the incidence of these events increases in number or severity, if a regulatory authority believes that these events constitute an adverse effect caused by the drug, or if other effects are identified during clinical trials that we are currently conducting, during clinical trials that we may conduct in the future or after any of our product candidates are approved and on the market:

- we may be required to conduct additional preclinical or clinical trials, make changes in labeling of any such approved products, reformulate any such products, or implement changes to or obtain new approvals of our or our contractors' manufacturing facilities;
- regulatory authorities may be unwilling to approve our product candidates or may withdraw approval of our products;
- we may experience a significant drop in the sales of the affected products;

- our reputation in the marketplace may suffer; and
- we may become the target of lawsuits, including class action suits.

Any of these events could prevent approval or harm sales of the affected product candidates or products or could substantially increase the costs and expenses of commercializing and marketing any such products.

Risks Related to Our Dependence on Third Parties

If third parties do not manufacture our product candidates in sufficient quantities and at an acceptable cost, clinical development and commercialization of our product candidates would be delayed.*

We do not currently own or operate manufacturing facilities, and we rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to develop product candidates and commercialize any product candidates on a timely and competitive basis.

We have agreed to purchase from Orion Corporation our worldwide requirements of toremifene, the active pharmaceutical ingredient in ACAPODENE®, in finished tablet form at specified transfer prices under a license and supply agreement. Similarly, Ipsen has agreed to purchase from Orion ACAPODENE® tablets for clinical testing and commercial sale in the European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States, which we refer to collectively as the European Territory, under an amended supply agreement with Orion. As such, both we and Ipsen rely on Orion as the single source supplier of ACAPODENE®.

In the event that Orion terminates our license and supply agreement due to our uncured material breach or bankruptcy, we would not be able to manufacture ACAPODENE® until the expiration of Orion's patents with respect to the composition of matter of toremifene, the active pharmaceutical ingredient in ACAPODENE®. Although Orion's composition of matter patents within the European Territory have expired, and as such, would not prevent Ipsen from manufacturing ACAPODENE® within the European Territory, there is no obligation on the part of Orion to transfer its manufacturing technology to Ipsen or to assist Ipsen in developing manufacturing capabilities to meet Ipsen's supply needs if Ipsen is in material breach of its supply agreement with Orion. Although we and Ipsen have agreed to collaborate with each other in the event either of our supply rights are terminated by Orion for any reason, a disruption in the supply of ACAPODENE® could delay the development of and impair our and Ipsen's ability to commercialize ACAPODENE®. In addition, Orion may terminate its obligation to supply us and Ipsen with toremifene if Orion ceases its manufacture of toremifene permanently, or Orion may terminate its obligation to supply us with toremifene if ACAPODENE® is not approved for commercial sale in the United States by December 31, 2009. If such termination occurs because Orion is no longer manufacturing toremifene, or because such regulatory approval is not obtained prior to the specified date, we and Ipsen will have the right to manufacture ACAPODENE®, but any arrangements we make for an alternative supply would still have to be made with a qualified alternative supplier with appropriate FDA approval in order for us to obtain our supply requirements for ACAPODENE®. We and Ipsen have mutually agreed to cooperate in the manufacture of ACAPODENE® in the event Orion ceases manufacture of toremifene for any of the above-mentioned reasons.

We also rely on Orion to cooperate with us in the filing and maintenance of regulatory filings with respect to the manufacture of ACAPODENE®. Orion may terminate its obligation to assist us in obtaining and maintaining regulatory approval of ACAPODENE® if we do not receive regulatory approval for ACAPODENE® in the United States by December 31, 2009. If Orion terminates its obligation to cooperate in these activities, or does not cooperate with us or otherwise does not successfully file or maintain these regulatory filings, we would be required to make arrangements with a qualified alternative supplier, which could delay or prevent regulatory approval of ACAPODENE®.

We have relied on third party vendors for Ostarine™. We recently executed agreements with third party contractors for the manufacture of Ostarine™ drug substance and the supply of Ostarine™ drug product for our planned clinical trials for cancer cachexia and CKD. We continue to assess our manufacturing needs for additional clinical trial materials and commercial supply of Ostarine™ as we execute our clinical strategy for Ostarine™. We will evaluate whether to continue to rely on the manufacturing capabilities of these third party contractors or whether some or all of the manufacturing process should be transferred to other contract manufacturers as we plan our additional clinical trials and the potential commercial launch of Ostarine™ and other SARM product candidates. If our current supply of Ostarine™ becomes unusable, if our Ostarine™ supply is not sufficient to complete our clinical trials, or if we are unsuccessful in identifying a contract manufacturer or negotiating a manufacturing agreement on a timely basis for our clinical trials and potential commercial launch, we could experience a delay in receiving an adequate supply of Ostarine™.

We may not be able to maintain or renew our existing or any other third-party manufacturing arrangements on acceptable terms, if at all. If we are unable to continue relationships with Orion for ACAPODENE® and third party vendors for Ostarine™, or to do so at an acceptable cost, or if these or other suppliers fail to meet our requirements for these product candidates or other SARM product candidates for any reason, we would be required to obtain alternate suppliers. However, we may not be permitted to obtain alternate suppliers for ACAPODENE® under our license agreement with Orion if Orion terminates its supply of ACAPODENE® due to our uncured material breach or bankruptcy. Any inability to obtain alternate suppliers, including an inability to obtain approval from the FDA of an alternate supplier, would delay or prevent the clinical development and commercialization of these product candidates.

Use of third-party manufacturers may increase the risk that we will not have adequate supplies of our product candidates.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party because of factors beyond our control;
- the possible termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us; and
- the possible exercise by Orion of its right to terminate its obligation to supply us with toremifene:
  - if it permanently ceases manufacture of toremifene or if we do not obtain regulatory approval of ACAPODENE® in the United States prior to December 31, 2009; or

- if Orion terminates due to our uncured material breach or bankruptcy.

If we are not able to obtain adequate supplies of our product candidates, it will be more difficult for us to develop our product candidates and compete effectively. Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. For example, the active pharmaceutical ingredient in ACAPODENE® is also the active pharmaceutical ingredient in FARESTON®. Further, Orion has agreed to supply ACAPODENE® tablets to Ipsen for clinical trials and commercial supply in the European Territory. Orion also manufactures toremifene for third parties for sale outside the United States for the treatment of advanced breast cancer in postmenopausal women.

Our present or future manufacturing partners may not be able to comply with FDA-mandated current Good Manufacturing Practice regulations, other FDA regulatory requirements or similar regulatory requirements outside the United States. Failure of our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates.

If third parties on whom we rely do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or to commercialize our product candidates.

We do not have the ability to independently conduct clinical trials for our product candidates, and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials. In addition, we rely on third parties to assist with our preclinical development of product candidates. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

We are dependent on our collaborative arrangement with Ipsen to develop and commercialize ACAPODENE® in the European Territory. We may also be dependent upon additional collaborative arrangements to complete the development and commercialization of some of our other product candidates. These collaborative arrangements may place the development and commercialization of our product candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

The loss of Ipsen as a collaborator in the development or commercialization of ACAPODENE®, any dispute over the terms of our collaboration with Ipsen, or any other adverse development in our relationship with Ipsen could materially harm our business and might accelerate our need for additional capital. For example, Ipsen is obligated to initiate and conduct appropriate clinical studies as required by the appropriate regulatory authorities in order to obtain marketing approvals of ACAPODENE® within the European Territory. Any failure on the part of Ipsen to initiate these studies could delay the commercialization of ACAPODENE® within the European Territory.

We may not be successful in entering into additional collaborative arrangements with other third parties. If we fail to enter into additional collaborative arrangements on favorable terms, it could delay or

impair our ability to develop and commercialize our other product candidates and could increase our costs of development and commercialization.

Dependence on collaborative arrangements, including our arrangement with Ipsen for the development and commercialization of ACAPODENE®, subjects us to a number of risks, including:

- we are not able to control the amount and timing of resources that Ipsen devotes to ACAPODENE®;
- we may not be able to control the amount and timing of resources that our potential future partners may devote to our product candidates;
- our partners may experience financial difficulties or changes in business focus;
- under certain circumstances, Ipsen may not be required to commercialize ACAPODENE® in certain countries of the European Territory if it is determined that it is not commercially reasonable for it to do so;
- pricing reimbursement constraints within the European Territory may diminish the prospects of our receiving royalty payments from Ipsen on aggregate net sales of ACAPODENE® in some or all of the countries within the European Territory;
- should a collaborator fail to develop or commercialize one of our compounds or product candidates, we may not receive any future milestone payments and will not receive any royalties for this compound or product candidate;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- a collaborator could move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors;
- collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our product candidates; and
- we may be required to relinquish important rights such as marketing and distribution rights.

Additionally, we and Ipsen have agreed that neither party will seek to commercialize, promote, market or sell certain products within the European Territory for an agreed period of time subsequent to the time of the first commercial launch of ACAPODENE® within the European Territory. We and Ipsen have also agreed to grant to the other a right of first negotiation with respect to the development, marketing, sale and distribution of any new SERM-based products for the field of the prevention and treatment of prostate cancer or related side effects, or any other indication the parties agree on. Furthermore, our royalty rates under our collaboration agreement with Ipsen are subject to a possible reduction if a generic version of toremifene achieves specified sales levels in a major country within the European Territory or if Ipsen licenses patent rights from a third party that would otherwise be infringed by Ipsen's use, manufacture, sale or import of toremifene. Ipsen has the right to terminate the collaboration agreement with 12 months prior written notice for any reason and with 30 days prior written notice as a result of legitimate and documented safety concerns. If the royalty rates under our collaboration agreement are reduced or if Ipsen terminates the collaboration agreement, the anticipated benefits to us from this agreement would be significantly reduced or eliminated. In addition, if Ipsen

terminates the collaboration agreement, the development of ACAPODENE® in the European Territory could be delayed and our costs of development would increase.

Risks Related to Our Intellectual Property

Our license agreement with Orion excludes the use of toremifene in humans to treat breast cancer outside the United States and may limit our ability to market ACAPODENE® for human uses of toremifene outside the United States.

Our exclusive license and supply agreement from Orion excludes the use of toremifene for the treatment of breast cancer outside the United States. Orion has licensed to other parties the right to market, sell and distribute toremifene for the treatment of advanced breast cancer outside the United States and could license additional parties to market, sell and distribute toremifene for this indication outside the United States.

Under the terms of our license agreement with Orion, Orion may require us and Ipsen to modify our final ACAPODENE® development plans for specified major markets outside the United States if those development plans could adversely affect Orion's or Orion's other licensees' activities related to FARESTON® for breast cancer outside the United States or toremifene-based animal health products. Although we do not believe that our or Ipsen's development plans adversely affect these activities, any future modifications to our or Ipsen's plans imposed by Orion may limit our and Ipsen's ability to maximize the commercial potential of ACAPODENE®.

Furthermore, we and our affiliates are prohibited from marketing or selling products containing toremifene or related SERM compounds for human use in the United States and other major countries located outside the European Union during the term of Orion's patents covering toremifene in such countries, which in the United States expire in September 2009. The binding effect of this noncompetition provision on us and our affiliates may make it more difficult for us to be acquired by some potential buyers during the relevant time periods even if we determine that a sale of the company would be in the best interests of our stockholders.

If some or all of our, or our licensors', patents expire or are invalidated or are found to be unenforceable, or if some or all of our patent applications do not yield issued patents or yield patents with narrow claims, or if we are estopped from asserting that the claims of an issued patent cover a product of a third party, we may be subject to competition from third parties with products with the same active pharmaceutical ingredients as our product candidates.

Our commercial success will depend in part on obtaining and maintaining patent and trade secret protection for our product candidates, the methods for treating patients in the product indications using these product candidates and the methods used to synthesize these product candidates. We will be able to protect our product candidates and the methods for treating patients in the product indications using these product candidates from unauthorized use by third parties only to the extent that we or our exclusive licensors own or control such valid and enforceable patents or trade secrets. Additionally, Ipsen's ability to successfully market ACAPODENE® within a substantial portion of the European Territory may depend on having marketing and data exclusivity from the appropriate regulatory authorities.

Our rights to certain patent applications relating to SARM compounds that we have licensed from the University of Tennessee Research Foundation, or UTRF, are subject to the terms of UTRF's interinstitutional agreements with The Ohio State University, or OSU, and our rights to future related improvements in some instances are subject to UTRF's exercise of exclusive options under its agreements with OSU for such improvements, which UTRF can exercise at no additional cost to UTRF. In addition,

under the terms of our agreements with the diagnostic companies to which we provide clinical samples from our Phase IIb and Phase III clinical trial of ACAPODENE®, we will not obtain any intellectual property rights in any of their developments, including any test developed to detect high grade PIN or prostate cancer.

Even if our product candidates and the methods for treating patients for prescribed indications using these product candidates are covered by valid and enforceable patents and have claims with sufficient scope and support in the specification, the patents will provide protection only for a limited amount of time. For example, the patent that we have licensed from Orion covering the composition of matter of toremifene expires in the United States in September 2009. Foreign counterparts of this patent have either already expired or will expire in Australia, Italy, Sweden and Switzerland in 2008, that is, before we or Ipsen will receive regulatory approval to commercialize ACAPODENE®. As a result, outside the United States and in the United States after 2009, we will need to rely primarily on the protection afforded by method of use patents relating to the use of ACAPODENE® for the relevant product indications that have been issued or may be issued from our owned or licensed patent applications. Within the European Union, Ipsen may need to rely primarily on the protection afforded by marketing and data exclusivity for the ACAPODENE® products to be sold within the countries comprising the European Union. To date, most of our applications for method of use patents filed for ACAPODENE® outside of the United States are still pending and have not yielded issued patents. Although we intend to apply, if appropriate, for extensions of patent terms under applicable United States laws pertaining to our method of use patents, we may not be able to secure any such regulatory exclusivity or extension of patent term. Loss of marketing and data exclusivity for the ACAPODENE® products to be commercialized within the European Union could adversely affect its ability to successfully commercialize these products, and our failure to obtain any extension of patent terms for our method of use patents could adversely affect our prospects for protecting our ACAPODENE® products from competitive pressures in the United States for the time periods we currently expect. We are not eligible for any such exclusivity or further extension of the composition of matter patent of toremifene licensed to us by Orion in the United States.

Our and our licensors' ability to obtain patents can be highly uncertain and involve complex and in some cases unsettled legal issues and factual questions. Furthermore, different countries have different procedures for obtaining patents, and patents issued in different countries provide different degrees of protection against the use of a patented invention by others. Therefore, if the issuance to us or our licensors, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Even if patents are issued to us or our licensors regarding our product candidates or methods of using them, those patents can be challenged by our competitors who can argue such patents are invalid or unenforceable or that the claims of the issued patents should be limited or narrowly construed. Patents also will not protect our product candidates if competitors devise ways of making or using these product candidates without legally infringing our patents. The Federal Food, Drug, and Cosmetic Act and FDA regulations and policies create a regulatory environment that encourages companies to challenge branded drug patents or to create noninfringing versions of a patented product in order to facilitate the approval of abbreviated new drug applications for generic substitutes. These same types of incentives encourage competitors to submit new drug applications that rely on literature and clinical data not prepared for or by the drug sponsor, providing another less burdensome pathway to approval.

We also rely on trade secrets to protect our technology, especially where we do not believe that patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time-consuming, and the outcome is unpredictable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

If we lose our licenses from Orion and UTRF, we may be unable to continue our business.

We have licensed intellectual property rights and technology from Orion and UTRF under our license agreements with each of Orion and UTRF. Each of these license agreements may be terminated by the other party if we are in breach of our obligations under, or fail to perform any terms of, the agreement and fail to cure that breach. If any of these agreements were terminated, then we may lose our rights to utilize the technology and intellectual property covered by that agreement to market, distribute and sell our licensed products, which may prevent us from continuing our business. For example, on November 28, 2006, we received correspondence from counsel representing UTRF claiming we owed additional annual license maintenance fees and residual alliance royalties under two exclusive license agreements we entered into with UTRF granting us worldwide exclusive licenses under UTRF's composition of matter and method of use patents relating to SARM compounds, including andarine and Ostarine™, to market, distribute and sell licensed products. In December 2006, we entered into a letter of intent with UTRF agreeing to modify each of the license agreements between us and UTRF including the two SARM license agreements. Upon execution of the revised license agreements, we will pay UTRF an aggregate consideration of $600,000. Under our exclusive license agreements with UTRF, in the event of a default or failure by us to perform any of the terms, covenants or provisions of these agreements, we have 30 days after the giving of written notice of any default to correct the default. If the default is not corrected within this 30-day period, UTRF has the right, at its option, to cancel and terminate these exclusive license agreements. In the event that we and UTRF do not execute revised license agreements or we do not pay the $600,000 consideration for the new license agreements, UTRF may elect to continue its claims against us, which if not resolved, could result in a termination of the existing SARM license agreements. If we did not prevail in our position that we are not in default under these license agreements or otherwise establish that UTRF did not have a right to terminate them, then the loss of these licenses would have a material adverse effect on the continued development of our SARM program and our business prospects would suffer.

Off-label sale or use of toremifene products could decrease sales of ACAPODENE® and could lead to pricing pressure if such products become available at competitive prices and in dosages that are appropriate for the indications for which we and Ipsen are developing ACAPODENE®.

In all countries in which we hold or have licensed rights to patents or patent applications related to ACAPODENE®, the composition of matter patents we license from Orion will expire before our method of use patents, and in some countries outside the United States, the composition of matter patents have already expired. Our method of use patents may not protect ACAPODENE® from the risk of off-label sale or use of other toremifene products in place of ACAPODENE®. Physicians are permitted to prescribe legally available drugs for uses that are not described in the drug's labeling and that differ from those uses tested and approved by the FDA or its equivalent. Such off-label uses are common across medical specialties and are particularly prevalent for cancer treatments. Any off-label sales of toremifene may adversely affect our or Ipsen's ability to generate revenue from the sale of ACAPODENE®, if approved for commercial sale.

Even in the event that patents are issued from our pending method of use patent applications, after the expiration of the patent covering the composition of matter of toremifene in a particular country, competitors could market and sell toremifene products for uses for which FARESTON® has already been approved. Thus, physicians in such countries would be permitted to prescribe these other toremifene products for indications that are protected by our method of use patents or patents issuing from pending patent applications, even though these other toremifene products would not have been approved for those uses, and in most cases, the physician would not be liable for contributing to the infringement of our patents. Moreover, because Orion has licensed and could further license other parties to market, sell and distribute toremifene for breast cancer outside the United States, physicians in such countries could prescribe these products sold pursuant to another Orion license off-label. This further increases the risk of off-label competition developing for ACAPODENE® for the indications for which we and Ipsen are developing this product candidate. In addition, if no patents are issued with respect to our pending method of use patent applications related to the use of ACAPODENE® in the countries outside of the United States where these applications are currently pending, after the expiration of the patent covering the composition of matter of toremifene in a particular country, we would have no patent to prevent competitors from marketing and selling generic versions of toremifene at doses and in formulations equivalent to ACAPODENE® for the indications covered by our pending method of use patent applications. Also, regulatory authorities may not recognize marketing and data exclusivity for ACAPODENE® in the European Union for the treatment of prostate cancer and the multiple side effects resulting from androgen deprivation therapy. If generic versions of toremifene are able to be sold in countries within the European Territory for the indications for which Ipsen anticipates marketing ACAPODENE®, the royalties to be paid to us by Ipsen will be reduced if the total generic sales exceed a certain threshold for a certain period of time. Similarly, the royalties we will be paying to Orion for its licensing and supply of toremifene will be reduced if generic sales thresholds are reached.

If we infringe intellectual property rights of third parties, it may increase our costs or prevent us from being able to commercialize our product candidates.

There is a risk that we are infringing the proprietary rights of third parties because numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields that are the focus of our drug discovery and development efforts. Others might have been the first to make the inventions covered by each of our or our licensors' pending patent applications and issued patents and might have been the first to file patent applications for these inventions. In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us or our licensors, which may later result in issued patents that cover the production, manufacture, commercialization, formulation or use of our product candidates. In addition, the production, manufacture, commercialization, formulation or use of our product candidates may infringe existing patents of which we are not aware. Defending ourselves against third-party claims, including litigation in particular, would be costly and time consuming and would divert management's attention from our business, which could lead to delays in our development or commercialization efforts. If third parties are successful in their claims, we might have to pay substantial damages or take other actions that are adverse to our business.

As a result of intellectual property infringement claims, or to avoid potential claims, we might:

- be prohibited from selling or licensing any product that we may develop unless the patent holder licenses the patent to us, which the patent holder is not required to do;
- be required to pay substantial royalties or grant a cross license to our patents to another patent holder; or

- be required to redesign the formulation of a product candidate so it does not infringe, which may not be possible or could require substantial funds and time.

In addition, under our collaboration and license agreement with Ipsen, Ipsen may be entitled to offset a portion of any royalties due to us in any calendar year on account of ACAPODENE® sales to pay for costs incurred by Ipsen to obtain a license to any dominant intellectual property rights that are infringed by such ACAPODENE® sales.

Risk Related to Regulatory Approval of Our Product Candidates

If we or our collaborators are not able to obtain required regulatory approvals, we or our collaborators will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization are subject to comprehensive regulation by the FDA, and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing our product candidate and will prevent our collaborators from commercializing the product candidate in the licensed territories. We have not received regulatory approval to market any of our product candidates in any jurisdiction and have only limited experience in preparing and filing the applications necessary to gain regulatory approvals. In addition, we will not receive a substantial majority of the milestone payments provided under our collaboration and license agreement with Ipsen or any royalty payments if Ipsen is unable to obtain the necessary regulatory approvals to commercialize ACAPODENE® within the European Territory. The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved.

Changes in the regulatory approval policy during the development period, changes in or the enactment of additional regulations or statutes, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Even if the FDA approves a product candidate, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product, and may impose ongoing requirements for post-approval studies, including additional research and development and clinical trials. The FDA also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

Furthermore, the approval procedure and the time required to obtain approval varies among countries and can involve additional testing beyond that required by the FDA. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions.

The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. For example, we are conducting our Phase III clinical trials of ACAPODENE® to treat the side effects of androgen deprivation therapy and for the reduction in the incidence of prostate cancer in high risk men with high grade PIN under Special Protocol Assessments, or SPAs, from the FDA. A SPA is designed to facilitate the FDA's review and approval of drug products by allowing the FDA to evaluate the proposed design and size of clinical trials that are intended to form the primary basis for determining a drug product's efficacy. If agreement is reached with the FDA, a SPA documents the terms and conditions under which the design of the subject trial will be adequate for submission of the efficacy and human safety portion of a NDA. However, there are circumstances under which we may not receive the

benefits of a SPA, notably including if the FDA subsequently identifies a substantial scientific issue essential to determining the product's safety or efficacy. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Furthermore, even if we file an application with the FDA for marketing approval of a product candidate, it may not result in marketing approval from the FDA.

We do not expect to receive regulatory approval for the commercial sale of any of our product candidates that are in development for the next few years. Similarly, it is not anticipated that Ipsen will receive the appropriate regulatory approvals to market ACAPODENE® within the European Territory any sooner than we will achieve regulatory approval in the United States, and it may be thereafter. The inability to obtain FDA approval or approval from comparable authorities in other countries for our product candidates would prevent us or our collaborators from commercializing these product candidates in the United States or other countries. See the section entitled "Business — Government Regulation" under Part I, Item 1 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2006 filed with the Securities and Exchange Commission for additional information regarding risks associated with approval, as well as risks related to post-approval requirements.

Risks Related to Commercialization

The commercial success of any products that we may develop will depend upon the degree of market acceptance among physicians, patients, healthcare payors and the medical community.

Any products that we may develop may not gain market acceptance among physicians, patients, health care payors and the medical community. If these products do not achieve an adequate level of acceptance, we may not generate material product revenues, and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the prevalence and severity of any side effects;
- potential advantages over alternative treatments;
- the ability to offer our product candidates for sale at competitive prices;
- relative convenience and ease of administration;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

Our only marketed product generating revenue is FARESTON®. FARESTON® is subject to a number of risks that may cause sales of FARESTON® to continue to decline.

FARESTON® is currently our only marketed product. Sales of FARESTON® in the United States have been declining and we anticipate that they will continue to do so. Continued sales of FARESTON® could be impacted by many factors. The occurrence of one or more of the following risks may cause sales of FARESTON® to decline more than we currently anticipate:

- the loss of the availability of Orion's website to market FARESTON®, which is an important source of advertising;

- the loss of one or more of our three largest wholesale drug distributors, which accounted for approximately 93% of our revenue generated from the sale of FARESTON® for the three months ended March 31, 2007;
- the continued success of competing products, including aromatase inhibitors;
- the loss of coverage or reimbursement for FARESTON® from Medicare and Medicaid, private health insurers or other third-party payors;
- exposure to product liability claims related to the commercial sale of FARESTON®, which may exceed our product liability insurance;
- the failure of Orion to maintain regulatory filings or comply with applicable FDA requirements with respect to FARESTON®;
- the ability of third parties to market and sell generic toremifene products that will compete with FARESTON® for the treatment of breast cancer after the composition of matter patents that we license from Orion expire in the United States in September 2009;
- the loss of Orion, upon which we rely as a single source, as our supplier of FARESTON®; and
- our inability to manufacture FARESTON® until Orion's patents with respect to the composition of matter of toremifene expire if Orion terminates our license and supply agreement due to our uncured material breach or bankruptcy.

Sales of pharmaceuticals for breast cancer in the SERM class have declined in recent years as aromatase inhibitors have gained market share. We believe that aromatase inhibitors will continue to capture breast cancer market share from SERMs, including from FARESTON®, resulting in a continued decline in FARESTON® sales.

If we are unable to expand our sales and marketing capabilities or enter into and maintain agreements with third parties to market and sell our product candidates, we may be unable to generate product revenue from such candidates.

We have limited experience as a company in the sales, marketing and distribution of pharmaceutical products. There are risks involved with building our own sales and marketing capabilities, as well as entering into arrangements with third parties to perform these services. For example, building a sales force is expensive and time-consuming and could delay any launch of a product candidate. Similarly, we are relying on Ipsen to market and distribute our ACAPODENE® product candidates through Ipsen's established sales and marketing network within the European Territory. If our collaboration and license agreement with Ipsen is terminated for any reason, our ability to sell our ACAPODENE® product candidates in the European Territory would be adversely affected, and we may be unable to develop or engage an effective sales force to successfully market and sell our ACAPODENE® product candidates in the European Territory. In addition, to the extent that we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues are likely to be lower than if we market and sell any products that we develop ourselves.

If we are unable to obtain adequate coverage and reimbursement from third-party payors for products we sell at acceptable prices, our revenues and prospects for profitability will suffer.

Many patients will not be capable of paying for any products that we may develop and will rely on Medicare and Medicaid, private health insurers and other third-party payors to pay for their medical needs. If third-party payors do not provide coverage or reimbursement for any products that we may develop, our revenues and prospects for profitability may suffer. In December 2003, the President of the United States signed into law the Medicare Prescription Drug, Improvement and Modernization Act of 2003, legislation creating a prescription drug benefit program for Medicare recipients. The prescription drug program established by the legislation may have the effect of reducing the prices that we are able to charge for products we develop and sell through the program. This prescription drug legislation may also cause third-party payors other than the federal government, including the states under the Medicaid program, to discontinue coverage for products that we may develop or to lower the amount that they pay.

State Medicaid programs generally have outpatient prescription drug coverage, subject to state regulatory restrictions, for the population eligible for Medicaid. The availability of coverage or reimbursement for prescription drugs under private health insurance and managed care plans varies based on the type of contract or plan purchased.

A primary trend in the United States health care industry is toward cost containment. In addition, in some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization. Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly-approved health care products. In particular, third-party payors may limit the indications for which they will reimburse patients who use any products that we may develop or products we sell. Cost-control initiatives could decrease the price we might establish for products that we may develop or that we sell, which would result in lower product revenues to us.

Another development that may affect the pricing of drugs is proposed Congressional action regarding drug reimportation into the United States. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 gives discretion to the Secretary of Health and Human Services to allow drug reimportation into the United States under some circumstances from foreign countries, including countries where the drugs are sold at a lower price than in the United States. Proponents of drug reimportation may attempt to pass legislation which would directly allow reimportation under certain circumstances. If legislation or regulations were passed allowing the reimportation of drugs, they could decrease the price we receive for any products that we may develop, negatively affecting our revenues and prospects for profitability.

If product liability lawsuits are brought against us, we will incur substantial liabilities and may be required to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any product that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or

products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products for which we obtain or hold marketing approvals.

We have product liability insurance that covers our clinical trials and commercial products up to a $25.0 million annual aggregate limit. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

If our competitors are better able to develop and market products than any products that we may develop, our commercial opportunity will be reduced or eliminated.

We face competition from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we may develop. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before us and impair our ability to commercialize our product candidates.

Various products are currently marketed or used off-label for some of the diseases and conditions that we are targeting, and a number of companies are or may be developing new treatments. The occurrence of such off-label uses could significantly reduce our ability to market and sell any products that we may develop. For example, although there are no products that have been approved by the FDA to treat multiple side effects of androgen deprivation therapy, we are aware of a number of drugs marketed by Eli Lilly (Evista®), Merck (Fosamax®), Sanofi-Aventis and Procter & Gamble (Actonel®), Wyeth Pharmaceuticals (Effexor®), Boehringer Ingelheim (Catapres®), Novartis (Zometa®) and Bristol Myers Squibb (Megace®) that are prescribed off-label to treat single side effects of this therapy; that external beam radiation is used to treat breast pain and enlargement; and that Amgen is developing a product candidate for the treatment of osteoporosis in prostate cancer patients. While we have the only pharmaceutical product in clinical development to prevent prostate cancer in high risk men with high grade PIN, GlaxoSmithKline is conducting a Phase III study for Avodart® on prostate cancer prevention which purposely excludes the high risk patient group of men with high grade PIN. In addition, there are nutritional supplement studies (for example, selenium) investigating prostate cancer prevention in men with high grade PIN. Similarly, while there are no drugs that have been approved by the FDA for the treatment of muscle wasting from cancer, there are drugs marketed by Steris Laboratories and Savient Pharmaceuticals that are being prescribed off-label for the treatment of some types of muscle wasting from cancer. Testosterone and other anabolic agents are used to treat involuntary weight loss in patients

who have acute muscle wasting. Also, TAP Pharmaceuticals and Ligand Pharmaceuticals have entered into a collaboration agreement to develop a SARM and may be initiating Phase II studies in 2007. In addition, there are other SARM product candidates at an earlier stage of development that may compete with our product candidates. Wyeth and Amgen have myostatin inhibitors in development which may compete for similar patients as Ostarine™. This could result in reduced sales and pricing pressure on our product candidates, if approved, which in turn would reduce our ability to generate revenue and have a negative impact on our results of operations.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

Risks Related to Employees and Growth

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop or commercialize our product candidates.

Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. If we are not able to attract and keep senior management and key scientific personnel, particularly Dr. Mitchell S. Steiner, we may not be able to successfully develop or commercialize our product candidates. All of our employees are at-will employees and can terminate their employment at any time. We do not carry “key person” insurance covering members of senior management, other than $25 million of insurance covering Dr. Steiner.

We will need to hire additional employees in order to continue our clinical trials and commercialize our product candidates. Any inability to manage future growth could harm our ability to commercialize our product candidates, increase our costs and adversely impact our ability to compete effectively.

In order to continue our clinical trials and commercialize our product candidates, we will need to expand the number of our managerial, operational, financial and other employees. We currently anticipate that we will need between 150 and 250 additional employees by the time that ACAPODENE® or Ostarine™ is initially commercialized, including 50 to 100 sales representatives. The competition for qualified personnel in the biotechnology field is intense.

Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

Risks Related to Our Common Stock

Market volatility may cause our stock price and the value of your investment to decline.

The market prices for securities of biotechnology companies in general have been highly volatile and may continue to be so in the future. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- Adverse results or delays in our clinical trials;
- the timing of achievement of our clinical, regulatory and other milestones, such as the commencement of clinical development, the completion of a clinical trial or the receipt of regulatory approval;
- announcement of FDA approval or non-approval of our product candidates or delays in the FDA review process;
- actions taken by regulatory agencies with respect to our product candidates or products, our clinical trials or our sales and marketing activities;
- the commercial success of any product approved by the FDA or its foreign counterparts;
- developments with respect to our collaboration with Ipsen;
- the terms and timing of any collaborative, licensing or other arrangements that we may establish;
- regulatory developments in the United States and foreign countries;
- changes in the structure of health care payment systems;
- any intellectual property infringement lawsuit involving us;
- announcements of technological innovations or new products by us or our competitors;
- market conditions for the biotechnology or pharmaceutical industries in general;
- actual or anticipated fluctuations in our results of operation;
- changes in financial estimates or recommendations by securities analysts;
- sales of large blocks of our common stock;
- sales of our common stock by our executive officers, directors and significant stockholders;
- changes in accounting principles; and
- the loss of any of our key scientific or management personnel.

The stock markets in general, and the markets for biotechnology stocks in particular, have experienced significant volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock. In the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs, which would hurt our financial condition and results of operations and divert

management's attention and resources, which could result in delays of our clinical trials or commercialization efforts.

Our officers, directors and largest stockholders will maintain the ability to control all matters submitted to stockholders for approval.*

As of March 31, 2007, our officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 79.9% of our outstanding common stock and our officers and directors alone owned approximately 49.6% of our outstanding common stock. As a result, these stockholders, acting together, will be able to control all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and our bylaws may delay or prevent an acquisition of us or a change in our management. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a classified Board of Directors;
- a prohibition on actions by our stockholders by written consent;
- the ability of our Board of Directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board of Directors; and
- limitations on the removal of directors.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Finally, these provisions establish advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted upon at stockholder meetings. These provisions would apply even if the offer may be considered beneficial by some stockholders.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.*

For the 12 month period ended March 31, 2007, the average daily trading volume of our common stock on the NASDAQ Global Market was approximately 111,354 shares. As a result, future sales of a

substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the then-prevailing market price of our common stock. As of March 31, 2007, we had 34,877,079 shares of common stock outstanding.

Moreover, J.R. Hyde, III, and Oracle Partners, L.P., two of our largest stockholders, and their affiliates, have rights, subject to some conditions, to require us to file registration statements covering the approximately 10.8 million shares of common stock they hold in the aggregate which are subject to registration rights or to include these shares in registration statements that we may file for ourselves or other stockholders. Additionally, all shares of common stock that we may issue under our employee benefit plans can be freely sold in the public market upon issuance.

ITEM 5. OTHER INFORMATION

Employment Agreement with James T. Dalton

We entered into an employment agreement with James T. Dalton, dated as of April 12, 2007, pursuant to which Mr. Dalton will continue to serve as our Vice President, Preclinical Research & Development. Under the employment agreement, Mr. Dalton will serve in such capacity on a full-time basis, subject to his limited right to continue to work part-time as a professor at The Ohio State University. The employment agreement provides for an annual base salary of $260,000, which may be adjusted from time to time by mutual agreement of Mr. Dalton and our chief executive officer, as well as his participation in our employee benefit plans. The employment agreement is terminable by either us or Mr. Dalton at any time. If we experience a change of control and Mr. Dalton's employment is terminated by us without cause, or if Mr. Dalton terminates his employment for good reason, at any time within six months after the change of control, then Mr. Dalton will continue to receive his then current base salary for a period of one year after the termination date. Mr. Dalton agreed to certain non-competition and non-solicitation covenants that generally apply during the term of his employment and for a period of two years after his employment ends. However, if we experience a change of control and Mr. Dalton's employment is terminated by us without cause, or if Mr. Dalton terminates his employment for good reason, at any time within six months after the change of control, then the two-year period will be reduced to one year. The agreement imposes certain obligations on Mr. Dalton with respect to maintaining the confidentiality of our confidential and proprietary information, and provides that we have exclusive ownership rights to employee inventions. The foregoing is a brief description of the terms and conditions of Mr. Dalton's employment agreement with us and does not purport to be complete, and is qualified in its entirety by reference to Mr. Dalton's employment agreement with us, which will be filed as an exhibit to our quarterly report on Form 10-Q for the quarter ending June 30, 2007.

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.

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: May 7, 2007

By: /s/ Mitchell S. Steiner
Mitchell S. Steiner, Chief Executive Officer
and Vice-Chairman of the Board of Directors

Date: May 7, 2007

By: /s/ Mark E. Mosteller
Mark E. Mosteller, Vice President
and Chief Financial Officer

EXHIBIT INDEX

Number	Description
3.1	Restated Certificate of Incorporation of GTx, Inc.(1)
3.2	Amended and Restated Bylaws of GTx, Inc.(2)
4.1	Reference is made to Exhibits 3.1 and 3.2
4.2	Specimen of Common Stock Certificate(3)
4.3	Amended and Restated Registration Rights Agreement between Registrant and Oracle Partners, L.P. dated August 7, 2003(3)
4.4	Amended and Restated Registration Rights Agreement between Registrant and J. R. Hyde, III dated August 7, 2003(3)
4.5	Amended and Restated Registration Rights Agreement between Registrant and Memphis Biomed Ventures dated August 7, 2003(3)
10.28*	Compensation Information for Registrant's Executive Officers, effective as of January 1, 2007
10.37	2007 Executive Bonus Compensation Plan(4)
31.1*	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a)
31.2*	Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a)
32.1*	Certification of Chief Executive Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350) (5)
32.2*	Certification of Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350) (5)

* Filed herewith.

(1) Filed as Exhibit 4.1 to the Registrant's registration statement on Form S-3 (File No. 333-127175), filed with the SEC on August 4, 2005, and incorporated herein by reference.

(2) Filed as Exhibit 3.4 to the Registrant's registration statement on Form S-1 (File No. 333-109700), filed with the SEC on October 15, 2003, as amended, and incorporated herein by reference.

(3) Filed as the like numbered Exhibit to the Registrant's registration statement on Form S-1 (File No. 333-109700), filed with the SEC on October 15, 2003, as amended, and incorporated herein by reference.

(4) Filed as Exhibit 10.2 to the Registrant's current report on Form 8-K (File No. 000-50549), filed with the SEC on November 3, 2006, and incorporated herein by reference.

(5) This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 10.28

COMPENSATION INFORMATION FOR EXECUTIVE OFFICERS

The table below provides information regarding the base salary of each executive officer of GTx, Inc.effective as of January 1, 2007:

Executive Officer	Title	Base Compensation
Mitchell S. Steiner, M.D., F.A.C.S.	Chief Executive Officer and Vice-Chairman of the Board of Directors	$446,250
Marc S. Hanover	President and Chief Operating Officer	$306,600
Henry P. Doggrell	Vice President, General Counsel and Secretary	$265,650
Mark E. Mosteller	Vice President, Chief Financial Officer and Treasurer	$246,750
James T. Dalton	Vice President, Preclinical Research & Development	$252,000
K. Gary Barnette	Vice President, Clinical Research & Development Strategy	$239,200
Gregory A. Deener	Vice President, Sales & Marketing, Product Commercialization	$234,000

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 the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(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 the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2007

/s/ Mitchell S. Steiner
Mitchell S. Steiner, M.D., F.A.C.S.
Chief Executive Officer and
Vice-Chairman of the Board of Directors

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 the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(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 the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2007

/s/ Mark E. Mosteller
Mark E. Mosteller, CPA
Vice President and 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 three months ended March 31, 2007, 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 Rule 13a-14(b) or Rule 15d-14(b) and 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.

Date: May 7, 2007

/s/ Mitchell S. Steiner
Mitchell S. Steiner, M.D., F.A.C.S.
Chief Executive Officer and
Vice-Chairman of the Board of Directors

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934 (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

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 three months ended March 31, 2007, 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 Rule 13a-14(b) or Rule 15d-14(b) and 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.

Date: May 7, 2007

/s/ Mark E. Mosteller
Mark E. Mosteller, CPA
Vice President and Chief Financial Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934 (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.