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, 2006

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 5, 2006, 30,998,217 shares of the Registrant's Common Stock were outstanding.

GTx, INC.
FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2006
INDEX

PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2006 (unaudited)	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 65,277	$ 74,014
Accounts receivable	68	153
Inventory	171	135
Prepaid expenses and other current assets	2,430	1,702
Total current assets	67,946	76,004
Property and equipment, net	1,790	1,746
Purchased intangible assets, net	4,921	4,978
Other assets	55	83
Total assets	$ 74,712	$ 82,811
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,967	$ 1,407
Accrued expenses	4,391	3,230
Deferred revenue — current portion	1,337	1,337
Total current liabilities	7,695	5,974
Deferred revenue, less current portion	2,624	2,958
Other long term liability	371	280
Capital lease obligation	18	20
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value: 60,000,000 shares authorized; 30,998,217 shares issued and outstanding at March 31, 2006 and 30,993,967 shares issued and outstanding at December 31, 2005	31	31
Deferred stock compensation	—	(1,725)
Additional paid-in capital	268,166	269,542
Accumulated deficit	(204,193)	(194,269)
Total stockholders' equity	64,004	73,579
Total liabilities and stockholders' equity	$ 74,712	$ 82,811

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,	
	2006	2005
Revenues:		
Product sales, net	$ 876	$ 353
Collaboration revenue	334	334
Total revenues	1,210	687
Costs and expenses:		
Costs of product sales	467	245
Research and development expenses	8,441	7,326
General and administrative expenses	2,950	2,520
Total costs and expenses	11,858	10,091
Loss from operations	(10,648)	(9,404)
Interest income	724	324
Net loss	$ (9,924)	$ (9,080)
Net loss per share:		
Basic	$ (0.32)	$ (0.37)
Diluted	$ (0.32)	$ (0.37)
Weighted average shares used in computing net loss per share:		
Basic	30,995,714	24,664,716
Diluted	30,995,714	24,664,716

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,	
	2006	2005
Cash flows from operating activities:		
Net loss	$ (9,924)	$ (9,080)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	302	238
Stock-based compensation	298	153
Directors' deferred compensation	35	32
Deferred revenue amortization	(334)	(334)
Changes in assets and liabilities:		
Accounts receivable	85	(228)
Inventory	(36)	(146)
Prepaid expenses and other current assets	(728)	(910)
Other assets	28	(255)
Accounts payable	560	1,149
Accrued expenses	1,252	671
Net cash used in operating activities	(8,462)	(8,710)
Cash flows from investing activities:		
Purchase of property and equipment	(223)	(238)
Purchase of intangible assets	(66)	—
Net cash used in investing activities	(289)	(238)
Cash flows from financing activities:		
Proceeds from exercise of employee stock options	16	—
Payments on capital lease obligation	(2)	(2)
Net cash provided by (used in) financing activities	14	(2)
Net decrease in cash and cash equivalents	(8,737)	(8,950)
Cash and cash equivalents, beginning of period	74,014	64,528
Cash and cash equivalents, end of period	$ 65,277	$ 55,578

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"), headquartered in Memphis, Tennessee, is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for cancer and serious conditions related to men's health. GTx's lead drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens, two essential classes of hormones. 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 also is developing ostarine, a selective androgen receptor modulator, or SARM. We believe that ostarine has the potential to treat a variety of indications, including muscle wasting and bone loss in frail elderly patients, osteoporosis, muscle wasting in end stage renal disease patients, and severe burn wounds and associated muscle wasting. We have licensed to Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, (Ortho Biotech), andarine, another of GTx's SARMs, under a joint collaboration and license agreement.

GTx also has an extensive preclinical pipeline generated from its own discovery program, which includes the specific product candidates prostarine, a SARM for benign prostatic hyperplasia, and andromustine, an anticancer product candidate, for hormone refractory prostate cancer.

Basis of Presentation

The accompanying unaudited condensed financial statements reflect, in the opinion of management, all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation of GTx's financial position, results of operations and cash flows for each period presented in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted from the accompanying statements. These interim financial statements should be read in conjunction with the audited financial statements and related notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2005. Operating results for the three months ended March 31, 2006 are not necessarily indicative of the results that may be expected for the entire fiscal year ending December 31, 2006.

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

Use of Estimates

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

2. STOCK-BASED COMPENSATION

Effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards ("SFAS") No. 123(R) "Share-Based Payment" 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. SFAS No. 123(R) requires stock-based compensation expense recognized since January 1, 2006 to be based on the following: a) grant date fair value estimated using the minimum value method in accordance with the original provisions of SFAS No. 123 "Accounting for Stock-Based Compensation" for unvested options granted prior to the Company's initial public offering ("IPO") in February 2004; b) grant date fair value estimated using the intrinsic value method for unvested options granted prior to the Company's IPO and previously accounted for using Accounting Principles Board Opinion ("APB") No. 25, "Accounting for Stock Issued to Employees"; c) grant date fair value estimated in accordance with the original provisions of SFAS No.123 for unvested options granted after the Company's IPO and prior to the adoption date and d) grant date fair value estimated in accordance with the provisions of SFAS No. 123(R) for unvested options granted on or after the adoption date. Prior to January 1, 2006, the Company accounted for stock-based compensation expense using the intrinsic value recognition method prescribed by APB No. 25 and SFAS No.123. Since the Company adopted SFAS No. 123(R) under the modified prospective and the prospective transition methods, results from prior periods have not been restated. The following table illustrates the effect on net loss and net loss per share if the Company had not adopted SFAS No. 123(R) and applied the fair value recognition provisions of SFAS No.123 and the intrinsic value recognition provisions of APB No. 25 to options granted under the Company's stock option plans in all periods presented. For purposes of this pro forma disclosure, the fair value of the options granted is estimated using the Black-Scholes-Merton option pricing model, the minimum value method and the intrinsic value method.

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

	Three Months Ended March 31,	
	2006	2005
Net loss, as reported	$ (9,924)	$ (9,080)
Add: Stock-based compensation expense included in reported net loss	333	185
Deduct: Stock-based compensation expense determined under the fair value based method	(333)	(410)
Pro forma net loss	$ (9,924)	$ (9,305)
Net loss per share:		
Basic — as reported	$ (0.32)	$ (0.37)
Basic — pro forma	$ (0.32)	$ (0.38)
Diluted — as reported	$ (0.32)	$ (0.37)
Diluted — pro forma	$ (0.32)	$ (0.38)

Under SFAS No. 123(R) 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. Under SFAS No.123 and APB No. 25, the Company elected to account for forfeitures when awards were actually forfeited, at which time all previous pro forma expense was reversed to reduce pro forma expense for that period.

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 statements of operations as research and development expenses and general and administrative expenses, respectively. Prior to the adoption of SFAS No. 123(R), the Company accounted for share-based compensation expense under APB No. 25. For the quarter ended March 31, 2005, the Company recorded amortization of deferred stock-based compensation expense of $185, of which $133 and $52 were included in research and development expenses and general and administrative expenses, respectively. On the date of adoption of SFAS No. 123(R), the unamortized balance of deferred stock-based compensation of $1,725 was reduced to zero with an offsetting adjustment to additional paid-in capital.

SFAS No. 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required prior to SFAS No. 123(R). The impact of adopting SFAS No. 123(R) on future results will depend on, among other things, levels of share-based options granted in the future, actual forfeiture rates and the timing of option exercises.

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

The Company grants options to purchase common stock to some of its 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 10 years from grant date and vest three years from grant date for director options and in periods up to five years from 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 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 has estimated 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 in the quarter ended March 31, 2006 and a summary of the methodology applied to develop each assumption are as follows:

Expected price volatility	66.5%
Risk-free interest rate	4.5%
Weighted average expected lives in years	6.0
Forfeiture rate	13.0%
Dividend yield	0.0%

Expected Price Volatility — This is a measure of the amount by which a price has fluctuated or is expected to fluctuate. We use an average expected price volatility of other publicly traded biopharmaceutical companies as it is management's belief that this is the best indicator of future volatility due to the limited period of time the Company's stock has been publicly traded. 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 Lives — 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 lives. Options granted have a maximum term of ten years. An increase in the expected life will increase 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.

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.

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

A summary of stock option activity since our most recent fiscal year end is as follows:

	Options	Weighted Average Exercise Price
Outstanding at December 31, 2005	1,301,750	$ 8.27
Granted	148,500	$ 7.74
Exercised	(4,250)	$ 3.75
Forfeited	(5,000)	$ 11.12
Outstanding at March 31, 2006	1,441,000	$ 8.22

At March 31, 2006, the average remaining contractual term of all outstanding options was 7.71 years, with an aggregate intrinsic value of $4,405, with 336,008 of the outstanding options being exercisable with an average exercise price of $7.47, an average remaining contractual term of 6.27 years and an aggregate intrinsic value of $1,334. Shares reserved for future option grants were 1,574,506 at March 31, 2006. For the quarters ended March 31, 2006 and 2005, the weighted average grant date fair value of options granted was $4.94 and $6.67, respectively. The total intrinsic value of options exercised during the three months ended March 31, 2006 was $33. There were no stock options exercised during the quarter ended March 31, 2005. At March 31, 2006, the total compensation cost related to non-vested awards not yet recognized was $3,125 with a weighted average expense recognition period of 2.14 years.

Under the Company's Amended and Restated 2004 Non-Employee Directors' Stock Option Plan, on the day immediately following the Annual Meeting of Stockholders each year, each non-employee director receives an option to purchase shares of common stock. The number of shares of common stock subject to these annual grants is currently set at 8,000, and such number of shares may be increased or decreased by the Board of Directors in its sole discretion. If an individual has not been serving as a non-employee director for the entire period since the preceding annual meeting of the Company's stockholders, the number of shares subject to such individual's annual grant will be reduced pro rata for each full month prior to the date of grant during which such individual did not serve as a non-employee director. In addition, each new director receives an option to purchase shares of common stock upon his or her election to the Board of Directors. The number of shares of common stock subject to these new director grants is currently set at 10,000, and such number of shares may be increased or decreased by the Board of Directors in its sole discretion. These stock option grants are made at the fair market value as of the grant date. At March 31, 2006, there were 68,000 outstanding options under this plan with 182,000 shares of common stock remaining available for future issuance under this plan.

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

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.

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 effect of potential 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,	
	2006	2005
Basic net loss per share		
Numerator:		
Net loss	$ (9,924)	$ (9,080)
Denominator (weighted average shares):		
Common stock outstanding at beginning of period	30,993,967	24,664,716
Exercise of employee stock options	1,747	—
Weighted average shares used in computing basic net loss per share	30,995,714	24,664,716
Basic net loss per share	$ (0.32)	$ (0.37)

	Three Months Ended March 31,	
	2006	2005
Diluted net loss per share		
Numerator:		
Net loss	$ (9,924)	$ (9,080)
Denominator (weighted average shares):		
Common stock outstanding at beginning of period	30,993,967	24,664,716
Exercise of employee stock options	1,747	—
Weighted average shares used in computing diluted net loss per share	30,995,714	24,664,716
Diluted net loss per share	$ (0.32)	$ (0.37)

Weighted average options outstanding to purchase shares of common stock of 1,442,447 and 1,190,318 were excluded from the calculation of diluted net loss per share for the three months ended March 31, 2006 and 2005, respectively, as inclusion of the options would have an anti-dilutive effect on the net loss per share for the periods.

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. 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;
- potential future licensing fees, milestone payments and royalty payments;
- our 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 therapeutics for cancer and serious conditions related to men's health. Our lead drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens, two essential classes of hormones. We 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 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 are also developing ostarine, a selective androgen receptor modulator, or SARM. We believe that ostarine has the potential to treat a variety of indications, including muscle wasting and bone loss in frail elderly patients, osteoporosis, muscle wasting in end stage renal disease patients, and severe burn wounds and associated muscle wasting. We are currently planning a Phase II clinical trial of ostarine for the treatment of muscle wasting and bone loss in 120 elderly men and postmenopausal women. We have licensed to Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson (Ortho Biotech), andarine, another one of our SARMs, under a joint collaboration and license agreement.

We plan to build a specialized sales and marketing capability to market our product candidates directly to the relatively small and concentrated community of urologists and medical oncologists in the United States and to seek partners to commercialize our product candidates outside the United States and to broader target physician markets within the United States.

We currently market FARESTON (toremifene citrate 60 mg) tablets, which have been approved by the U.S. Food and Drug Administration, or FDA, for the treatment of metastatic breast cancer in post-menopausal women in the United States. The active pharmaceutical ingredient in FARESTON is the same as in ACAPODENE, but at a different dose. In January 2005, we acquired from Orion Corporation the right to market FARESTON tablets in the United States for the metastatic breast cancer indication. We also acquired a license to toremifene, the active pharmaceutical ingredient in FARESTON and ACAPODENE, for all indications in humans worldwide, except breast cancer outside of the United States.

In addition, we have an extensive preclinical pipeline generated from our own discovery program that includes the specific product candidates prostarine, a SARM for benign prostatic hyperplasia, and andromustine, an anticancer product candidate, for hormone refractory prostate cancer.

Our most advanced product candidate, ACAPODENE, is being developed to treat both the multiple side effects of ADT and to prevent prostate cancer in high risk men with high grade PIN. ADT is the standard medical treatment for patients who have advanced, recurrent or metastatic prostate cancer, and we believe that there will be approximately one million prostate cancer survivors who are expected to be treated with ADT by 2008. We commenced a pivotal Phase III clinical trial of ACAPODENE under a Special Protocol Assessment, or SPA, with the FDA for this indication in November 2003. We reached our enrollment goal in the fall of 2005 with approximately 1,400 patients randomized for the trial. We anticipate that we will complete this clinical trial in the fourth quarter of 2007. If the results are favorable, we expect to file a New Drug Application, or NDA, with the FDA in the first half of 2008. We will conduct a one-year blinded Phase IIIb extension trial in the same patients to gather additional fracture and safety data.

In January 2005, we initiated a pivotal Phase III clinical trial of ACAPODENE for the prevention of prostate cancer in men with high grade PIN, which is being conducted under a SPA with the FDA. We reached our total enrollment goal of 1,260 patients in May 2006. The trial is designed as a 36 month study, but provides for an interim analysis after a sufficient number of events have occurred to determine if the efficacy of the study drug has been statistically established. Management believes an interim analysis of the trial results will occur 18 to 24 months from completion of enrollment of the trial. If the efficacy endpoint is achieved, we plan to file an NDA during 2008. If we are able to file an NDA based on the results of the interim analysis, we will need to continue to collect 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. Ostarine is a novel non-steroidal agent designed to have anabolic activity like testosterone without unwanted side effects on the prostate and skin and in a once daily oral dose. We plan to initiate in the second quarter a proof of concept Phase II clinical trial in 120 elderly men and postmenopausal women. The trial is designed to obtain broad data demonstrating ostarine's effects on building muscle and promoting bone and to evaluate dose and safety in both men and women. Endpoints of the trial will include measurements of changes in muscle, bone, fat, and performance. GTx anticipates receiving data from the trial in the second half of 2006.

In March 2004, we entered into a joint collaboration and license agreement with Ortho Biotech for andarine for indications related to men's health and other licensed SARM compounds meeting specified criteria which Ortho Biotech may ultimately choose to develop instead of, or in addition to, andarine. We retain the right to independently develop specific SARM compounds which are excluded from the collaboration, including ostarine. Under the terms of the agreement, we received an up-front licensing fee and reimbursement of certain andarine development expenses totaling approximately $6.7 million, which are being amortized into revenue over five years. We are entitled to receive additional licensing fees, milestone payments and royalty payments on any sales of licensed products. Johnson & Johnson Pharmaceutical Research & Development, an affiliate of Ortho Biotech, is responsible for further clinical development and related expenses for andarine and other licensed SARM compounds. Ortho Biotech may terminate the development or commercialization of andarine or any other licensed SARM compound under the agreement upon 90 days' notice, or 30 days' notice if there are safety issues, or may terminate the agreement for our uncured material breach.

Our net loss for the three month period ended March 31, 2006 was $9.9 million. Our net loss included FARESTON net product sales of $876,000 and the recognition of collaboration revenue of $334,000 for the three months ended March 31, 2006. We have financed our operations and internal growth almost exclusively through private placements of preferred stock and our public offerings of common stock. 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 of our product candidates, establish sales and marketing capabilities and grow our operations. We believe that our current cash resources, interest on these funds and product revenue from the sale of FARESTON will be sufficient to meet our projected operating requirements through the first half of 2007.

Since our inception in 1997, we have been focused on drug discovery and development programs. Research and development expenses represented 74.1% of our total operating expenses for the three months ended March 31, 2006. Research and development expenses include our expenses for personnel associated with our research activities, screening and identification of product candidates, formulation and synthesis activities, manufacturing, preclinical studies, toxicology studies, clinical trials, regulatory affairs, and quality assurance activities.

We expect that research and development expenditures will continue to increase during the remainder of the year and in subsequent years due to (1) the continuation of the pivotal Phase III clinical trial of ACAPODENE for the treatment of serious side effects of ADT for advance prostate cancer and a one-year Phase IIIb extension trial, (2) the continuation of the pivotal Phase III clinical trial of ACAPODENE for the prevention of prostate cancer in men with high grade PIN, (3) the continued clinical and preclinical development of ostarine, (4) the continued development of other product candidates in the Company's SARM program that are not included in our collaboration with Ortho Biotech, including prostarine, (5) the continued preclinical development of other product candidates, including andromustine, and (6) the increase in research and development personnel.

Our general and administrative expenses consist primarily of salaries and other related costs for personnel serving executive, finance, legal, human resources, information technology, public 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 include 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 for interim financial information. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments related to revenue recognition, income taxes, intangible assets, 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, 2005 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

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 ("SFAS") No. 48 "Revenue Recognition When Right of Return Exists" ("FAS 48") and Emerging Issues Task Force ("EITF") Issue 00-21, "*Revenue Arrangements with Multiple Deliverables*" ("EITF 00-21"). Accordingly, revenues from licensing agreements are recognized based on the performance requirements of the agreement. Non-refundable up-front fees, where we have an ongoing involvement or performance obligation, are generally recorded as deferred

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

We recognize net product sales revenue from the sale of FARESTON less deductions for estimated sales rebates, 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 104 and FAS 48 are satisfied. We accept returns of products near their expiration date.

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

Research and Development Costs

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

Patent Costs

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

Stock-Based Compensation

Effective January 1, 2006, we adopted SFAS No. 123(R) "Share-Based Payment" 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. Prior to January 1, 2006, we accounted for stock-based compensation expense using the intrinsic value recognition method prescribed by Accounting Principles Board Opinion ("APB") No. 25 and SFAS No. 123. Since we adopted SFAS No. 123(R) under the modified prospective and the prospective transition methods, results from prior periods have not been restated. Under SFAS No. 123(R), 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, 2006 was $333,000 of which $163,000 and $170,000 were recorded in the condensed statements of operations as research and development expenses and general and administrative expenses, respectively. Prior to the adoption of SFAS No.123(R), we accounted for share-based compensation expense under APB No. 25. For the quarter ended March 31, 2005, we recorded amortization of deferred stock-based compensation expense of $185,000, of which $133,000 and $52,000 were included in research and development expenses and general and administrative expenses, respectively. On the date of adoption of SFAS No.123(R), the unamortized balance of deferred stock-based compensation of $1.7 million was reduced to zero with an offsetting adjustment to additional paid-in capital.

Results of Operations

Three Months Ended March 31, 2006 and 2005

Revenues

Revenues for the three months ended March 31, 2006 were $1.2 million as compared to $687,000 for the same period of 2005. Revenues included net sales of FARESTON marketed for the treatment of metastatic breast cancer. During the three months ended March 31, 2006 and 2005, FARESTON net sales were $876,000 and $353,000, respectively, while costs of products sales were $467,000 and $245,000, 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. We do not believe that FARESTON net sales for the first quarter of 2006 are indicative of the FARESTON net sales for the remaining quarters of the fiscal year ending December 31, 2006. In each of the three months ended March 31, 2006 and 2005, revenues also included collaboration income of $334,000 from our partner Ortho Biotech for andarine, one of our proprietary SARM compounds.

Research and Development Expenses

Research and development expenses increased by $1.1 million to $8.4 million for the three months ended March 31, 2006 from $7.3 million for the same period of 2005. The following table identifies the development phase, the status, and research and development expenses for each of our product candidates as well as information 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	Development Phase	Status	Three Months Ended March 31, 2006	2005
				(in thousands)	
SERM	**ACAPODENE 80mg** Side effects of ADT	Pivotal Phase III clinical trial	Phase III clinical trial ongoing under a SPA; fully enrolled; obtained statistically significant BMD results from a planned interim analysis in fourth quarter of 2005	$ 2,358	$ 2,288
	ACAPODENE 20 mg Prevention of prostate cancer in men with high grade PIN	Pivotal Phase III clinical trial	Phase III clinical trial ongoing under a SPA; attainment of enrollment goal in May 2006	3,073	1,533
SARM	**Ostarine** Muscle wasting and bone loss in elderly men and postmenopausal women	Phase II clinical trial	Planning to initiate Phase II clinical trial in second quarter of 2006	1,107	1,671
	Andarine Cachexia from various types of cancer	Phase I clinical trial	Four Phase I clinical trials completed	14	51
Other research and development		Preclinical	Preclinical studies	1,889	1,783
Total research and development expenses				$ 8,441	$ 7,326

General and Administrative Expenses

General and administrative expenses increased during the three months ended March 31, 2006 to $3.0 million from $2.5 million for the three months ended March 31, 2005. The increase of $430,000 was primarily the result of increased personnel related expenses, intellectual property related expenses, professional fees and other administrative costs to support our planned growth.

Interest Income

Interest income increased to $724,000 for the three months ended March 31, 2006 from $324,000 for the three months ended March 31, 2005. 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, 2006, as compared to the same period in 2005.

Liquidity and Capital Resources

At March 31, 2006, we had cash and cash equivalents of $65.3 million, compared to $74.0 million at December 31, 2005. Net cash used in operating activities was $8.5 million and $8.7 million for the three months ended March 31, 2006 and 2005, respectively. The use of cash in both periods resulted primarily from funding our net losses. Net cash used in investing activities was $289,000 and $238,000 for the three months ended March 31, 2006 and 2005, respectively. Net cash used in investing activities for both periods was primarily for the purchase of research and development equipment, computer equipment, and furniture and fixtures. We currently expect to make capital expenditures of approximately $1.2 million for the remainder of 2006.

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. Net cash used in financing activities for the three months ended March 31, 2005 was $2,000 and related to principal payments made under a capital lease obligation.

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 half of 2007. This estimate does not include funding that we may receive under our existing collaboration, potential future collaboration agreements with pharmaceutical companies, or the potential future issuance and sale of our securities.

Our forecast of the period of time through which our financial resources will be adequate to support our projected operating requirements is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed in the section entitled “Risk Factors” under Part II, Item 1A below. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development of our product candidates and other research and development activities, including risks and uncertainties that could impact the rate of progress of our development activities, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials and other research and development activities. Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;

- future clinical trial results;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the achievement of certain milestone events under, and other matters related to, our joint collaboration and license agreement with Ortho Biotech;
- the cost and timing of regulatory approvals;
- potential future licensing fees, milestone payments and royalty payments;
- 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 financing or corporate collaboration and licensing arrangements, as well as through interest income earned on cash balances. With the exception of payments that we may receive under our collaboration with Ortho Biotech, we do not currently have any commitments for future external funding. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or to obtain funds through collaborations with others that are on unfavorable terms or that may require us to relinquish rights to some of our technologies or product candidates that we would otherwise seek to develop on our own.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk for changes in interest rates relates to our cash equivalents on deposit in highly liquid money market funds. The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. We do not use derivative financial instruments in our investment portfolio. Our cash and investments policy emphasizes liquidity and preservation of principal over other portfolio considerations. The effect of a hypothetical 20% change in all interest rates on our investments would have resulted in a change in interest income of $145,000 for the quarter ended March 31, 2006.

We operate primarily in the United States. Through March 31, 2006, we had not experienced any material exposure to foreign currency rate fluctuations. Our exposure to foreign currency rate fluctuations will increase because we are obligated to pay Orion Corporation, our supplier of ACAPODENE and FARESTON, in Euros; however, such exposure is not expected to be material. We do not currently use derivative financial instruments to mitigate this exposure.

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 that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities and Exchange Act of 1934 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) under the Securities and Exchange Act of 1934) 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 2006 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.

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, 2006, we had an accumulated deficit of $204.2 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 $36.8 million in 2005, $22.3 million in 2004, and $14.2 million in 2003. For the three months ended March 31, 2006, net losses were $9.9 million. 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 financed our operations and internal growth almost exclusively through sales of common stock and preferred stock. In addition, we received an upfront license fee from Ortho Biotech in March 2004 for our joint collaboration for the development and commercialization of andarine and other licensed SARM compounds that Ortho Biotech may choose to develop. 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, 2006, we recognized $876,000 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 half of 2007. This estimate does not include funding we may receive under our existing collaboration, potential future collaboration agreements with pharmaceutical companies, or the potential future issuance and sale of our securities.

Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- future clinical trial results;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the achievement of certain milestone events under, and other matters related to, our joint collaboration and license agreement with Ortho Biotech;
- the cost and timing of regulatory approvals;
- potential future licensing fees, milestone payments and royalty payments;
- 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 cash balances.

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 or licensing arrangements with third parties, it will 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. 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.

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 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. We rely on Orion as a single source supplier for ACAPODENE. In the event that Orion terminates the agreement due to our uncured material breach or bankruptcy, we would not be able to manufacture ACAPODENE until Orion's patents with respect to the composition of matter of toremifene, the active pharmaceutical ingredient in ACAPODENE, expire. This could delay the development of and impair our ability to commercialize ACAPODENE. In addition, Orion may terminate its obligation to supply us with toremifene if Orion ceases its manufacture of toremifene permanently, or 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 will have the right to manufacture ACAPODENE, but we would be required to make arrangements with a qualified alternative supplier and obtain FDA approval of such supplier to do so.

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 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.

Under our joint collaboration and license agreement with Ortho Biotech, Ortho Biotech is responsible for the manufacture, packaging and supply of andarine for both clinical trials and commercialization. We relied on EaglePicher Pharmaceutical Services as our single supplier for ostarine, but currently have sufficient supply to complete our planned Phase II clinical trials. EaglePicher Technologies, LLC, the parent company of EaglePicher Pharmaceutical Services, had previously filed for protection under the bankruptcy code, but has secured new financing and expects to emerge from bankruptcy in 2006. We are evaluating whether to transfer the manufacturing process to another contract manufacturer and expect to make a decision the first half of this year. If our current supply of ostarine becomes unusable, if our ostarine supply is not sufficient to complete our planned Phase II clinical trials, or if we are unsuccessful in identifying a contract manufacturer or negotiating a manufacturing agreement on a timely basis, we could experience a delay in receiving an adequate supply of ostarine for use in our clinical trials.

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 EaglePicher or Ortho Biotech for andarine or ostarine respectively, or to do so at an acceptable cost, or if these or other suppliers fail to meet our requirements for these product candidates or for ostarine 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 of an alternate supplier from the FDA, 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 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. Orion also manufactures toremifene for third parties for sale outside the United States for the treatment of advanced breast cancer in post-menopausal 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 Ortho Biotech to develop and commercialize andarine, and we may 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 of our product candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

Any loss of Ortho Biotech as a collaborator in the development or commercialization of andarine, dispute over the terms of the collaboration or other adverse development in our relationship with Ortho Biotech could materially harm our business and might accelerate our need for additional capital. While we initially anticipated proceeding with Phase II clinical studies of andarine within a reasonable period subsequent to entering into our collaboration agreement with Ortho Biotech, to date Ortho Biotech has not initiated a Phase II clinical trial. We do not know when, or if, Ortho Biotech will initiate a Phase II clinical trial of andarine, and any failure to do so could have an adverse effect on our business, including with respect to our potential receipt of related milestone payments.

We may not be successful in entering into additional collaborative arrangements with 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 product candidates and could increase our costs of development and commercialization.

Dependence on collaborative arrangements, including our arrangement with Ortho Biotech for the development of andarine, subjects us to a number of risks, including:

- we are not able to control the amount and timing of resources that Ortho Biotech devotes to andarine;
- we may not be able to control the amount and timing of resources that our potential future partners may devote to product candidates;
- our partners may experience financial difficulties or changes in business focus;
- we may be required to relinquish important rights such as marketing and distribution rights;
- 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; and
- the collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our product candidates.

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 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 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 development plans adversely affect these activities, any future modifications to our plans imposed by Orion may limit our 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 (1) 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 and (2) in major countries in the European Union through October 2006, other than in the dosage forms or formulations which are, or may in the future be, manufactured by Orion under our agreement with Orion. 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. Our rights to specified 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 license with The Ohio State University Research Foundation, or OSURF, and our rights to future related improvements are subject to UTRF's exercise of an exclusive option under its agreement with OSURF for such improvements, which UTRF can exercise at no additional cost to it. In addition, under the terms of our agreements with the diagnostic companies to which we provide clinical samples from our Phase IIb 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 in the product 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 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 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. 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 regulatory market exclusivity and extensions of patent term under applicable European and United States laws, we might not be able to secure any such regulatory exclusivity or extension of patent term. We are not eligible for any such exclusivity or further extension of the composition of matter patent of toremifene 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.

Off-label sale or use of toremifene products could decrease our 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 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 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 toremifene products would not have been approved for those uses, and in most cases the competitor would not be liable for infringing 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 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, 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.

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.

Risk Related to Regulatory Approval of Our Product Candidates

If we are not able to obtain required regulatory approvals, we 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 the product candidate. 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. 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 believe that if the results of our ongoing Phase III clinical trial of ACAPODENE for the reduction in the incidence of prostate cancer in men with high grade PIN are sufficiently positive, that trial will be sufficient to serve as a single pivotal Phase III clinical trial for this indication. In September 2005, we received a Special Protocol Assessment from the FDA. A SPA is designed to facilitate the FDA's review and approval of drug products by allowing the agency 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 the 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. The inability to obtain FDA approval or approval from comparable authorities in other countries for such candidates would prevent us from commercializing our 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, 2005 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, health care 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 generating sales. Sales of FARESTON in the United States have been declining. 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:

- 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 96% of our revenue generated from the sale of FARESTON for the three months' ended March 31, 2006;
- 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 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.

If we are unable to expand our sales and marketing capabilities or enter into 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. 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 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 approvals.

We have product liability insurance that covers our clinical trials and commercial products up to a $20.0 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 sold and 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 advanced prostate cancer therapy, we are aware of a number of drugs marketed by Eli Lilly, Merck, Sanofi-Aventis, Procter & Gamble, Wyeth Pharmaceuticals, Boehringer Ingelheim and Bristol Myers Squibb 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 Inc. is developing a product candidate for the treatment of prostate cancer patients. 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 2006. In addition, there may be product candidates of which we are not aware at an earlier stage of development that may compete with our product candidates. If any are successfully developed and approved, they could compete directly with our product candidates. 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 $15.0 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 highly volatile 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 Ortho Biotech;

- 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 January 31, 2006, our officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 67.2% 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, 2006, the average daily trading volume of our common stock on the NASDAQ National Market was less than 72,000 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, 2006, we had 30,998,217 shares of common stock outstanding.

Based on information currently available to us, all of the shares of our common stock currently outstanding are eligible for sale in the public market, subject in some cases to volume and other limitations under federal securities laws.

Moreover, J.R. Hyde, III, Oracle Partners, L.P. and Memphis Biomed Ventures I, L.P., three of our largest stockholders, and their affiliates, have rights, subject to some conditions, to require us to file registration statements covering the approximately 11.1 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 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Our common stock began trading on The NASDAQ National Market under the trading symbol “GTXI” on February 3, 2004. We sold 5,400,000 shares of common stock in our initial public offering at $14.50 per share. Our Registration Statement on Form S-1 (333-109700) was declared effective by the SEC on February 2, 2004. The offering terminated after the sale of all of the securities registered on the registration statement and the expiration of the underwriters’ over-allotment option. After deducting the underwriting discounts and the offering expenses, we received net proceeds of $70.4 million. From the time of receipt through March 31, 2006, we had invested the available net proceeds in short-term securities. In addition, approximately $57.7 million of the proceeds were used to fund our operations through March 31, 2006, approximately $2.8 million of the proceeds were used for capital expenditures and approximately $4.8 million of the proceeds were used to acquire a license from Orion Corporation. The application of the net proceeds from our initial public offering as set forth above represents our best estimate and does not represent a material change from the use of proceeds as described in the prospectus for our initial public offering. No such payments were made to directors, officers or persons owning 10 percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for Board or Board committee service. We plan to use the balance of the proceeds to fund our clinical trials and other research and development activities and for general corporate purposes. In addition, we may use a portion of the proceeds to acquire products, technologies or businesses, although we currently have no binding commitments or agreements relating to any of these types of transactions.

ITEM 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 5, 2006

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

Date: May 5, 2006

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

Table of Contents

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)
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) (4)
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) (4)

* 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) 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 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 5, 2006

/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 5, 2006

/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-0XLEY 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, 2006, 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 5, 2006

/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-0XLEY 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, 2006, 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 5, 2006

/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.