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 June 30, 2010

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.)
175 Toyota Plaza 7th Floor Memphis, Tennessee	**38103**
(Address of principal executive offices)	(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 has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer ☑	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company 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 August 4, 2010, 36,420,901 shares of the registrant's Common Stock were outstanding.

GTx, INC.
FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2010
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PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2010 (unaudited)	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,990	$ 40,219
Short-term investments	8,374	8,825
Accounts receivable, net	369	406
Inventory	124	116
Prepaid expenses and other current assets	6,326	1,109
Total current assets	35,183	50,675
Property and equipment, net	2,680	3,291
Intangible and other assets, net	1,915	3,755
Total assets	$ 39,778	$ 57,721
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 851	$ 1,268
Accrued expenses	4,150	4,730
Deferred revenue — current portion	1,344	9,954
Total current liabilities	6,345	15,952
Deferred revenue, less current portion	7,394	49,898
Other long term liabilities	598	621
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock, $0.001 par value: 60,000,000 shares authorized; 36,420,901 shares issued and outstanding at June 30, 2010 and December 31, 2009	37	36
Additional paid-in capital	362,180	359,388
Accumulated deficit	(336,776)	(368,174)
Total stockholders' equity (deficit)	25,441	(8,750)
Total liabilities and stockholders' equity (deficit)	$ 39,778	$ 57,721

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	**2009**	**2010**	**2009**
Revenues:				
Product sales, net	$ 599	$ 949	$ 1,398	$ 1,708
Collaboration revenue	336	2,873	56,114	5,745
Total revenue	935	3,822	57,512	7,453
Costs and expenses:				
Cost of product sales	134	431	285	779
Research and development expenses	9,477	7,746	17,127	16,058
General and administrative expenses	4,325	6,981	8,834	13,492
Total costs and expenses	13,936	15,158	26,246	30,329
Income (loss) from operations	(13,001)	(11,336)	31,266	(22,876)
Other income, net	60	76	132	121
Income (loss) before income taxes	(12,941)	(11,260)	31,398	(22,755)
Income tax benefit	—	—	—	194
Net income (loss)	$ (12,941)	$ (11,260)	$ 31,398	$ (22,561)
Net income (loss) per share:				
Basic and diluted	$ (0.36)	$ (0.31)	$ 0.86	$ (0.62)
Weighted average shares used in computing net income (loss) per share:				
Basic and diluted	36,420,901	36,417,056	36,420,901	36,410,866

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

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

	Six Months Ended June 30,	
	2010	**2009**
Cash flows from operating activities:		
Net income (loss)	$ 31,398	$ (22,561)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	849	903
Share-based compensation	2,697	2,039
Directors' deferred compensation	96	84
Deferred revenue amortization	(51,114)	(5,745)
Impairment of intangible assets	1,687	—
Changes in assets and liabilities:		
Short-term investments, trading	—	744
Accounts receivable, net	37	76
Inventory	(8)	(23)
Prepaid expenses and other current assets	(5,217)	(846)
Accounts payable	(417)	(1,322)
Accrued expenses and other long term liabilities	(557)	(1,227)
Net cash used in operating activities	(20,549)	(27,878)
Cash flows from investing activities:		
Purchase of property and equipment	(85)	(248)
Purchase of short-term investments, held to maturity	(6,939)	—
Proceeds from maturities of short-term investments, held to maturity	7,390	—
Net cash provided by (used in) investing activities	366	(248)
Cash flows from financing activities:		
Proceeds from exercise of employee stock options	—	116
Payments on capital lease and financed equipment obligations	(46)	(2)
Net cash (used in) provided by financing activities	(46)	114
Net decrease in cash and cash equivalents	(20,229)	(28,012)
Cash and cash equivalents, beginning of period	40,219	95,510
Cash and cash equivalents, end of period	$ 19,990	$ 67,498

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

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

1. Business and Basis of Presentation

Business

GTx, Inc. ("GTx" or the "Company"), a Delaware corporation incorporated on September 24, 1997 and headquartered in Memphis, Tennessee, is a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules that selectively target hormone pathways for the treatment and prevention of cancer, the treatment of side effects of anticancer therapy, cancer supportive care, and other serious medical conditions. GTx operates in one business segment.

GTx is developing toremifene 80 mg, a selective estrogen receptor modulator ("SERM") for the reduction of fractures and treatment of other estrogen deficiency side effects of androgen deprivation therapy ("ADT") in men with prostate cancer. GTx has completed a pivotal Phase III clinical trial evaluating toremifene 80 mg for this indication. In December 2008, the Company submitted a New Drug Application ("NDA") for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT to the U.S. Food and Drug Administration ("FDA"). In October 2009, the Company received a Complete Response Letter from the FDA regarding its NDA for toremifene 80 mg notifying the Company that the FDA would not approve the Company's NDA in its present form as a result of certain clinical deficiencies identified in the Complete Response Letter. The Company met with the FDA in December 2009 to better understand the Company's options for addressing the deficiencies identified by the FDA in the Complete Response Letter. In April 2010, the Company submitted to the FDA a proposed protocol for a second pivotal Phase III clinical trial evaluating toremifene 80 mg to reduce fractures in men with prostate cancer on ADT to address in a single clinical trial the deficiencies identified by the FDA in the Complete Response Letter. In July 2010, the Company met with the FDA and is continuing to work with the FDA to finalize the protocol for a second pivotal Phase III clinical trial. GTx has licensed to Ipsen Biopharm Limited ("Ipsen") exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein, the Commonwealth of Independent States, Australia, and certain countries in North Africa, the Middle East and Asia, excluding Japan, (collectively, the "Ipsen Territory") to develop and commercialize toremifene in all indications which the Company has licensed from Orion Corporation ("Orion"), which include all indications except the treatment and prevention of breast cancer outside of the United States. In March 2010, the Company amended its collaboration and license agreement with Ipsen primarily to expand its partnership for the development and commercialization of toremifene 80 mg to reduce fractures in men with prostate cancer on ADT and to fund a second pivotal Phase III clinical trial of toremifene 80 mg. See Note 4, *Collaboration and License Agreements*, for further discussion.

The Company also has been developing toremifene 20 mg for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia ("high grade PIN"). In May 2010, the Company announced that toremifene 20 mg failed to meet the primary efficacy endpoint in a recently completed Phase III clinical trial evaluating toremifene 20 mg for this indication. In the Phase III clinical trial, toremifene 20 mg treatment compared to placebo resulted in a reduction in prostate cancer incidence, but the results were not statistically significant. The Company is reviewing all data from the Phase III clinical trial to better understand the trial results and the ability of toremifene 20 mg to reduce cancer among high risk men, but the Company does not currently expect to conduct additional clinical trials evaluating toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN or to submit a NDA to the FDA for this indication.

Additionally, the Company is developing selective androgen receptor modulators ("SARMs"), a new class of drugs with the potential to treat cancer cachexia (cancer induced muscle loss) and chronic sarcopenia, which is the loss of skeletal muscle mass resulting in reduced physical strength and ability to perform activities of daily living, as well as other musculoskeletal wasting or muscle loss conditions. In March 2010, the Company reacquired full rights to its SARM program, including ostarine™, following the termination by the Company and Merck & Co., Inc. ("Merck") of their exclusive license and collaboration agreement for SARM compounds and related SARM products. See Note 4, *Collaboration and License Agreements*, for further discussion.

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

GTx is also developing GTx-758 which is a selective estrogen receptor alpha agonist for the first line treatment of advanced prostate cancer. In February 2010, the Company initiated a Phase II proof of concept clinical trial evaluating the ability of GTx-758 to reduce testosterone to castrate levels in healthy male volunteers.

The Company markets FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of metastatic breast cancer in postmenopausal women in the United States.

Basis of Presentation

The accompanying unaudited condensed financial statements reflect, in the opinion of management, all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation of GTx's financial position, results of operations and cash flows for each period presented in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted from the accompanying condensed financial statements. These interim condensed financial statements should be read in conjunction with the audited financial statements and related notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2009. Operating results for the three and six months ended June 30, 2010 are not necessarily indicative of the results that may be expected for the entire fiscal year ending December 31, 2010.

Use of Estimates

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

Revenue Recognition

The Company recognizes revenue from product sales of FARESTON® less deductions for estimated sales discounts and sales returns. Revenue from product sales is recognized when persuasive evidence of an arrangement exists, title passes, the price is fixed or determinable, and collectability is reasonably assured. The Company accounts for rebates to certain governmental agencies as a reduction of product sales. The Company allows customers to return product within a specified time period prior to and subsequent to the product's labeled expiration date. The Company estimates an accrual for product returns, which is recorded as a reduction of product sales, based on factors which include historical product returns and estimated product in the distribution channel which is expected to exceed its expiration date. At June 30, 2010 and December 31, 2009, the Company's accrual for product returns was $797 and $494, respectively.

Collaboration revenue consists of non-refundable upfront payments, license fees, reimbursements for research and development activities, and milestone payments associated with the Company's collaboration and license agreements discussed in Note 4. Revenues from licensing agreements are recognized based on the performance requirements of the specific agreements. The Company analyzes agreements with multiple element arrangements to determine whether the deliverables under the agreement, including license and performance obligations such as joint steering committee participation and research and development activities, can be separated or whether all of the deliverables must be accounted for as a single unit of accounting. For these arrangements for which the Company is not able to identify evidence of fair value for the undelivered elements, the Company will recognize any consideration for a single unit of accounting in the same manner as revenue is recognized for the final deliverable, which is ratable over the performance period. The performance period is estimated at the inception of each agreement and is reevaluated at each reporting period. Revenues from milestone payments for which the Company has no continuing performance obligations are recognized upon achievement of the performance milestone, as defined in the related agreement, provided the milestone is substantive and a culmination of the earnings process has occurred. Performance obligations typically consist of significant milestones in the development life cycle of the related product candidates and technology, such as initiation of clinical trials, achievement of specified clinical trial endpoints, filing for approval with regulatory agencies and approvals by regulatory agencies. Due to the termination of the Company's license and collaboration agreement with Merck in March 2010, the Company recognized collaboration revenue of $54,856 in the first quarter of 2010 as the agreement was terminated and the Company has no further performance obligations. See Note 4, *Collaboration and License Agreements*, for further discussion.

GTx, Inc.
NOTES TO THE CONDENSED FINANCIAL STATEMENTS
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Research and Development Expenses

Research and development expenses include, but are not limited to, the Company's expenses for personnel, supplies, and facilities associated with research activities, screening and identification of product candidates, formulation and synthesis activities, manufacturing, preclinical studies, toxicology studies, clinical trials, regulatory and medical affairs, quality assurance activities and license and royalty fees. The Company expenses these costs in the period in which they are incurred. The Company estimates its liabilities for research and development expenses in order to match the recognition of expenses to the period in which the actual services are received. As such, accrued liabilities related to third party research and development activities are recognized based upon the Company's estimate of services received and degree of completion of the services in accordance with the specific third party contract.

Cash, Cash Equivalents and Short-term Investments

The Company considers highly liquid investments with initial maturities of three months or less to be cash equivalents.

At June 30, 2010, short-term investments consisted of U.S. treasury securities and certificates of deposit with original maturities of greater than three months and less than one year. At December 31, 2009, short-term investments consisted solely of certificates of deposit. As the Company has the positive intent and ability to hold these investments until maturity, the investments have been classified as held to maturity investments and are stated at cost, which approximates fair value.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in facts and circumstances, both internally and externally, may indicate that an impairment of long-lived assets held for use are present. An impairment loss is recognized when estimated future cash flows are less than the carrying amount. The cash flow estimates are based on management's best estimates, using appropriate and customary assumptions and projections at the time.

During the three months ended June 30, 2010, the Company determined that, based on the results of the Phase III clinical trial evaluating toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, it does not currently expect to conduct additional clinical trials or submit a NDA to the FDA for toremifene 20 mg for this indication. Based upon this determination, a triggering event occurred requiring the Company to perform an impairment review of the toremifene 20 mg intangible assets. After analyzing future cash flows and estimates of fair market value from a market participant perspective, the Company determined that an impairment existed and recorded an impairment charge of $1,687 during the three months ended June 30, 2010. The impaired intangible assets consisted of the unamortized portions of capitalized license fees paid to Orion and the University of Tennessee Research Foundation ("UTRF") related to the Company's toremifene 20 mg program. Of the $1,687 impairment charge, $1,515 related to unamortized license fees paid to Orion under the amended and restated license and supply agreement for the Company's exclusive license from Orion to develop and commercialize toremifene-based products, as approximately half of the original payment to Orion was allocated to the Company's toremifene 20 mg program. The remaining impairment charge of $172 related to the Company's amended and restated license agreement with UTRF with respect to the Company's toremifene 20 mg program.

GTx, Inc.
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The impairment charge was included in research and development expenses in the condensed statement of operations for the three and six months ended June 30, 2010.

Income Taxes

The Company accounts for deferred taxes by recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. Accordingly, at June 30, 2010 and December 31, 2009, net of the valuation allowance, the net deferred tax assets were reduced to zero. Income taxes are described more fully in Note 9 to the Company's financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2009.

For the six months ended June 30, 2009, the Company recognized a federal income tax benefit of $194 due to the adoption of a provision in the Housing and Economic Recovery Act of 2008 that allowed the Company to claim a refund for a portion of its pre-2006 research and development tax credits.

Other Income, Net

Other income, net consists of interest earned on the Company's cash, cash equivalents and short-term investments, interest expense, and foreign currency transaction gains and losses.

Reclassification

The prior period foreign currency transaction gains and losses and interest expense have been reclassified to other income, net from general and administrative expenses in the condensed statement of operations.

Subsequent Events

The Company has evaluated all events or transactions that occurred after June 30, 2010 up through the date the condensed financial statements were issued. There were no material recognizable or nonrecognizable subsequent events during the period evaluated.

2. Share-Based Compensation

Share-based payments include stock option grants under the Company's stock option and equity incentive plans and deferred compensation arrangements for the Company's non-employee directors. The Company recognizes compensation expense for its share-based payments based on the fair value of the awards over the period during which an employee or non-employee director is required to provide service in exchange for the award. The Company's share-based compensation plans are described more fully in Note 3 to the Company's financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2009.

GTx, Inc.
NOTES TO THE CONDENSED FINANCIAL STATEMENTS
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Total share-based compensation expense for the three months ended June 30, 2010 was $1,079, of which $454 and $625 were recorded in the condensed statement of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the three months ended June 30, 2009 was $1,064, of which $389 and $675 were recorded in the condensed statement of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the six months ended June 30, 2010 was $2,793, of which $1,300 and $1,493 were recorded in the condensed statement of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the six months ended June 30, 2009 was $2,123, of which $769 and $1,354 were recorded in the condensed statement of operations as research and development expenses and general and administrative expenses, respectively. Share-based compensation expense for the three months ended June 30, 2010 and 2009 included share-based compensation expense related to deferred compensation arrangements for the Company's non-employee directors of $46 and $39, respectively. Share-based compensation expense for the six months ended June 30, 2010 and 2009 included share-based compensation expense related to deferred compensation arrangements for the Company's non-employee directors of $96 and $84, respectively.

The Company uses the Black-Scholes-Merton option pricing valuation model to value stock options. The expected life of options is determined by calculating the average of the vesting term and the contractual term of the options. The expected price volatility is based on the Company's historical stock price volatility. The risk-free interest rate is determined using U.S. Treasury rates where the term is consistent with the expected life of the stock options. Expected dividend yield is not considered as the Company has not made any dividend payments and has no plans of doing so in the foreseeable future. The amount of share-based compensation expense recognized is reduced ratably over the vesting period by an estimate of the percentage of options granted that are expected to be forfeited or canceled before becoming fully vested. The fair value of options granted was estimated using the following assumptions for the periods presented:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Expected price volatility	64.2%	58.9%	64.6%	54.7%
Risk-free interest rate	3.3%	2.3%	3.4%	1.9%
Weighted average expected life in years	6.0 years	6.4 years	6.5 years	6.9 years

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

	Number of Shares	Weighted Average Exercise Price Per Share
Options outstanding at December 31, 2009	3,364,871	$ 13.55
Options granted	1,288,500	4.16
Options forfeited or expired	(116,832)	13.06
Options outstanding at June 30, 2010	4,536,539	10.89

3. Basic and Diluted Net Income (Loss) Per Share

Basic and diluted net income (loss) per share attributable to common stockholders is calculated based on the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share also gives effect to the dilutive potential of common stock consisting of stock options. The weighted average shares for the three and six months ended June 30, 2009 included 5,547 and 18,423 shares, respectively, related to the exercise of employee stock options and issuance of common stock under deferred compensation arrangements. Weighted average options outstanding to purchase shares of common stock of 4,536,821 and 3,587,530 for the three months ended June 30, 2010 and 2009, respectively, and 4,526,796 and 3,544,501 for the six months ended June 30, 2010 and 2009, respectively, were excluded from the calculations of diluted net income (loss) per share as inclusion of the options would have had an anti-dilutive effect on the net income (loss) per share for the periods.

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

4. Collaboration and License Agreements

Ipsen Collaboration and License Agreement

In September 2006, the Company entered into a collaboration and license agreement with Ipsen (the "Ipsen Collaboration Agreement") pursuant to which the Company granted Ipsen exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein, and the Commonwealth of Independent States (the "European Territory") to develop and commercialize toremifene in all indications which the Company has licensed from Orion, which include all indications in humans except the treatment and prevention of breast cancer outside of the United States.

In accordance with the terms of the Ipsen Collaboration Agreement, Ipsen agreed to pay the Company €23,000 as a license fee and expense reimbursement, of which €1,500 was paid in equal installments over a three year period from the date of the Ipsen Collaboration Agreement. In October 2006, the Company received €21,500 (approximately $27,100) from Ipsen as the initial payment for the license fee and expense reimbursement. In September 2009, 2008, and 2007, the Company received €500 (approximately $726, $711, and $688, respectively) from Ipsen for the three annual installment payments. In February 2008, the Company earned a milestone of €1,000 (approximately $1,482) with the achievement of the primary endpoint in the toremifene 80 mg ADT Phase III clinical trial. This amount was recognized as collaboration revenue in the first quarter of 2008.

In March 2010, the Company amended the Ipsen Collaboration Agreement primarily to expand its collaboration for the development and commercialization of toremifene 80 mg to reduce fractures in men with prostate cancer on ADT and to fund a second pivotal Phase III clinical trial of toremifene 80 mg. In accordance with the terms of the Ipsen Collaboration Agreement, as amended (the "Amended Ipsen Collaboration Agreement"), Ipsen agreed to pay the Company up to €42,000 in clinical development milestones for the purpose of conducting a second pivotal Phase III clinical trial evaluating toremifene 80 mg to reduce fractures in men with prostate cancer on ADT. Such milestone payments, if any, will be paid to the Company upon initiation of the clinical trial and completion of specific clinical development milestones throughout the course of the clinical trial, as outlined in the Amended Ipsen Collaboration Agreement. Although Ipsen has committed to fund up to €42,000 for a second pivotal Phase III clinical trial of toremifene 80 mg, if the projected cost of such second pivotal Phase III clinical trial of toremifene 80 mg exceeds €42,000, the Company is required to pay the excess amount. However, there is an established threshold of clinical trial costs in excess of €42,000 at which the Company or Ipsen may determine not to initiate the trial, in which event, Ipsen would not be obligated to provide any additional funding for the trial. In addition, if the FDA does not consider the proposed protocol for a second pivotal Phase III clinical trial to be sufficient to satisfy the deficiencies set forth in the Complete Response Letter and imposes additional requirements for a second clinical trial that the Company and Ipsen believe to be too burdensome and costly, the Company or Ipsen may determine not to pursue a second clinical trial for toremifene 80 mg required by the FDA for marketing approval of the product candidate. Accordingly, the Company may never receive any of the €42,000 in clinical development milestones under the Amended Ipsen Collaboration Agreement.

In exchange for Ipsen's commitment to fund a second toremifene 80 mg ADT Phase III clinical trial, the Company granted Ipsen certain additional rights, including an expansion of the territory in which Ipsen has the right to develop and commercialize toremifene beyond the European Territory to include Australia and certain countries in North Africa, the Middle East and Asia (excluding Japan), (collectively, the "Ipsen Territory"). In addition, Ipsen received the right to co-promote the Company's toremifene 80 mg product candidate for the ADT indication in the United States or, at Ipsen's election in lieu of co-promotion, the right to receive a double digit royalty on net sales of the Company's toremifene 80 mg product candidate for the ADT indication in the United States which declines as net sales increase beyond an established base. Additionally, Ipsen was released of the obligation to pay certain potential milestone payments totaling €18,000 related to the European approval of toremifene 80 mg and pricing approvals and received a reduction in the royalty payable to the Company on aggregate net sales of the Company's toremifene 80 mg product candidate for the ADT indication. Ipsen also received the right of first negotiation, subject to certain conditions, with respect to development, marketing, sale and distribution in the Ipsen Territory of GTx-758.

GTx, Inc.
NOTES TO THE CONDENSED FINANCIAL STATEMENTS
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Ipsen has agreed to be responsible for and to pay all clinical development, regulatory and launch activities to commercialize toremifene in the Ipsen Territory for both the high grade PIN indication and ADT indication. The Company will remain similarly responsible for all development and regulatory activities outside of the Ipsen Territory. However, in addition to the €42,000 committed by Ipsen to fund a second pivotal Phase III clinical trial for toremifene 80 mg, Ipsen has agreed to pay a portion of the Company's toremifene 20 mg development costs in the United States, if certain conditions are met. Under the Amended Ipsen Collaboration Agreement, Ipsen must elect to retain its rights to commercialize toremifene and other products containing toremifene for the high grade PIN indication. Depending on when Ipsen exercises this election, Ipsen may be required to pay an additional license fee as well as a premium on its share of the development and clinical trial expenses incurred by the Company in the United States since January 1, 2006, on account of toremifene for high grade PIN. If Ipsen does not exercise its election, Ipsen will not be obligated to pay the Company for a portion of the development and clinical trial expenses incurred by the Company in the United States since January 1, 2006, on account of toremifene for the high grade PIN indication. The Company and Ipsen are reviewing all data from the Phase III clinical trial to better understand the trial results and the ability of toremifene 20 mg to reduce cancer among high risk men, but the Company does not currently expect to conduct additional clinical trials evaluating toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN or to submit a NDA to the FDA for this indication.

If Ipsen exercises its election for toremifene 20 mg, the Company is entitled to receive from Ipsen up to an aggregate of €20,000 in milestone payments, depending on the successful development and launch of toremifene 20 mg in certain countries of the Ipsen Territory, subject to certain conditions. However, in lieu of Ipsen paying up to €20,000 in aggregate milestone payments and its share of development and clinical trial expenses for the high grade PIN indication, Ipsen may elect to receive a reduction in the royalty payable by the Company on net sales of the Company's toremifene 80 mg product candidate for the ADT indication in the United States which Ipsen is entitled to receive under the Amended Ipsen Collaboration Agreement. If Ipsen does not exercise its election for toremifene 20 mg, all of Ipsen's rights to toremifene 20 mg will revert to the Company.

Ipsen has agreed to pay the Company a royalty equal to a graduating percentage of aggregate net sales in the Ipsen Territory of the Company's toremifene 20 mg product candidate and a fixed percentage (12%) of aggregate net sales in the Ipsen Territory of the Company's toremifene 80 mg product candidate for the ADT indication. The Company will remain responsible for paying upstream royalties on toremifene to both Orion and UTRF for toremifene 20 mg and to Orion only for toremifene 80 mg. Ipsen will purchase the bulk drug product supply directly from Orion and is responsible for the packaging and labeling of the final product. With respect to the development and commercialization of toremifene-based products, the term of the Amended Ipsen Collaboration Agreement will continue until the parties are no longer developing and commercializing toremifene-based products. Ipsen may terminate the Amended Ipsen Collaboration Agreement for the Company's uncured breach, upon the Company's bankruptcy, with 12 months prior written notice for any reason and with 30 days prior written notice as a result of legitimate and documented safety concerns, or in the event that either the UTRF license for the chemoprevention of prostate cancer or the license and supply agreement with Orion terminates early.

Under the original Ipsen Collaboration Agreement, the Company recorded deferred revenue of $29,330 related to the Ipsen upfront license fee and expense reimbursement which is being amortized into revenue on a straight-line basis over an estimated ten year development period for toremifene in the Ipsen Territory. The estimated development period was extended from six years to ten years during the quarter ended June 30, 2010 due to the Company's increased obligation period associated with conducting a second toremifene 80 mg ADT Phase III clinical trial. The Company recognized as collaboration revenue $336 and $1,464 for the three months ended June 30, 2010 and 2009, respectively, and $1,258 and $2,927 for the six months ended June 30, 2010 and 2009, respectively, from the amortization of the Ipsen deferred revenue.

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

Merck & Co., Inc. Collaboration and License Agreement

In December 2007, GTx and Merck entered into a global exclusive license and collaboration agreement (the "Merck Collaboration Agreement") governing the Company's and Merck's joint research, development and commercialization of SARM compounds and related SARM products for all potential indications of interest. In March 2010, the Company reacquired full rights to its SARM program, including ostarine™, following the termination by the Company and Merck of the Merck Collaboration Agreement.

Under the Merck Collaboration Agreement, the Company granted Merck an exclusive worldwide license under its SARM-related patents and know-how. The Company conducted preclinical research of SARM compounds and products, and Merck was primarily responsible under the terms of the agreement for conducting and funding development and commercialization of products developed under the Merck Collaboration Agreement. Merck paid the Company an upfront licensing fee of $40,000 and purchased approximately $30,000 of the Company's common stock. In addition, Merck agreed to pay the Company $15,000 in guaranteed cost reimbursements for research and development activities in equal annual installments over a three year period beginning on the first anniversary of the effective date of the Merck Collaboration Agreement. The Company received $5,000 from Merck in both December 2008 and December 2009 as the first and second annual payments of cost reimbursements for research and development activities.

The Company deferred the recognition of the upfront licensing fee of $40,000 and the $10,800 in equity premium received that represented the difference between the purchase price and the closing price of the Company's common stock on the date the stock was purchased by Merck. These payments were being recognized as collaboration revenue over the period of the Company's performance obligation, which the Company estimated to be ten years. The $5,000 of cost reimbursements received in both December 2008 and December 2009 were being recognized as collaboration revenue over the remaining period of the Company's performance obligation. In March 2010, the Company reacquired full rights to the Company's SARM program following the termination by the Company and Merck of the Merck Collaboration Agreement. Merck remains obligated to pay the Company the final $5,000 payment for research and development activities cost reimbursement due under the terms of the Merck Collaboration Agreement in December 2010 for which the Company has no further performance obligations. In the first quarter of 2010, the Company recognized as collaboration revenue all of the remaining $49,856 unamortized revenue that was deferred as of December 31, 2009, as well as the final $5,000 research and development activities cost reimbursement. The Company recognized as collaboration revenue $1,409 and $2,818 for the three and six months ended June 30, 2009, respectively, from the amortization of the Merck deferred revenue.

University of Tennessee Research Foundation License Agreements

The Company and UTRF are parties to a consolidated, amended and restated license agreement (the "SARM License Agreement") pursuant to which the Company was granted exclusive worldwide rights in all existing SARM technologies owned or controlled by UTRF, including all improvements thereto, and exclusive rights to future SARM technology that may be developed by certain scientists at the University of Tennessee or subsequently licensed to UTRF under certain existing inter-institutional agreements with The Ohio State University. Additionally, the Company and UTRF have entered into an amended and restated license agreement (the "SERM License Agreement") pursuant to which the Company was granted exclusive worldwide rights to UTRF's method of use patents relating to SERMs, including toremifene for chemoprevention of prostate cancer as well as future related SERM technologies that may be developed by certain scientists at the University of Tennessee. Under the SARM License Agreement and the SERM License Agreement, the Company is obligated to pay UTRF annual license maintenance fees and royalties on sublicense revenues and net sales of products.

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

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

Forward-Looking Information

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

- the anticipated progress of our research, development and clinical programs, including whether current and future clinical trials will achieve similar results to clinical trials that we have successfully concluded;
- the timing, scope and anticipated completion of current and future clinical trials;
- the timing of regulatory submissions and the timing, scope and anticipated outcome of related regulatory actions;
- potential future licensing fees, milestone payments and royalty payments, including any milestone payments or royalty payments that we may receive under our collaborative arrangement with Ipsen Biopharm Limited, or Ipsen;
- our and Ipsen's ability to obtain and maintain regulatory approvals of our product candidates and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our and Ipsen's ability to market, commercialize and achieve market acceptance for our product candidates or products that we may develop;
- our ability to generate additional product candidates for clinical testing;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; and
- our estimates regarding the sufficiency of our cash resources.

In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would" and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events, are based on assumptions and are subject to risks, uncertainties and other important factors. 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 risks, uncertainties and other important factors, 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 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

Business Overview

We are a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules that selectively target hormone pathways for the treatment and prevention of cancer, the treatment of side effects of anticancer therapy, cancer supportive care, and other serious medical conditions.

Business Highlights

We are developing toremifene 80 mg, a selective estrogen receptor modulator, or SERM, for the reduction of fractures and treatment of other estrogen deficiency side effects of androgen deprivation therapy, or ADT, in men with prostate cancer. We commenced a pivotal Phase III clinical trial evaluating toremifene 80 mg for this indication in November 2003. In the first quarter of 2008, we announced that the Phase III clinical trial results for toremifene 80 mg to reduce fractures and treat other estrogen deficiency side effects of ADT in men with prostate cancer showed that toremifene 80 mg reduced new morphometric vertebral fractures, met other key endpoints of bone mineral density, or BMD, lipid profiles and gynecomastia, and also showed that toremifene 80 mg demonstrated a reduction in hot flashes in a subset of patients. In December 2008, we submitted a New Drug Application, or NDA, for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT to the U.S. Food and Drug Administration, or FDA. In October 2009, we received a Complete Response Letter from the FDA regarding our NDA for toremifene 80 mg notifying us that the FDA would not approve our NDA in its present form as a result of certain clinical deficiencies identified in the Complete Response Letter. The FDA identified two deficiencies in the Complete Response Letter and recommended that the following information be provided to the FDA to address these clinical deficiencies: (i) results of a second adequate and well-controlled Phase III clinical trial demonstrating the safety and efficacy of toremifene 80 mg to reduce fractures in men with prostate cancer on ADT and (ii) results from an adequate and well-controlled clinical trial demonstrating that toremifene 80 mg treatment to reduce fractures in men with prostate cancer on ADT does not have a detrimental effect on either time-to-disease progression or overall survival. We met with the FDA in December 2009 to better understand our options for addressing the points made by the FDA in the Complete Response Letter. In April 2010, we submitted a proposed protocol for a second pivotal Phase III clinical trial evaluating toremifene 80 mg to reduce fractures in men with prostate cancer on ADT, which we refer to as TREAT 2 (Toremifene for Reduction of fractures and other Estrogen deficiency side effects in men on Androgen deprivation Therapy), to address in a single clinical trial the deficiencies identified by the FDA in the Complete Response Letter. In July 2010, we met with the FDA and are continuing to work with the FDA to finalize the protocol for a second pivotal Phase III clinical trial. If we and the FDA agree on a protocol for a second pivotal Phase III clinical trial sufficient to address each of the deficiencies identified in the FDA's Complete Response Letter, and we and Ipsen approve any projected costs of such trial which may be in excess of the threshold established under our amended license and collaboration agreement, we plan to initiate a second pivotal Phase III clinical trial in the first quarter of 2011.

We also have been developing toremifene 20 mg for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia, or high grade PIN. In May 2010, we announced that toremifene 20 mg failed to meet the primary efficacy endpoint in a recently completed Phase III clinical trial evaluating toremifene 20 mg for this indication. In the Phase III clinical trial, toremifene 20 mg treatment compared to placebo resulted in a reduction in prostate cancer incidence, but the results were not statistically significant. We are reviewing all data from the Phase III clinical trial to better understand the trial results and the ability of toremifene 20 mg to reduce cancer among high risk men, but we do not currently expect to conduct additional clinical trials evaluating toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN or to submit a NDA to the FDA for this indication.

In September 2006, we licensed to Ipsen exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States, which we collectively refer to as the European Territory, to develop and commercialize toremifene in all indications which we have licensed from Orion Corporation, or Orion, which include all indications in humans except the treatment and prevention of breast cancer outside of the United States. In March 2010, we amended our collaboration and license agreement with Ipsen, or the Amended Ipsen Collaboration Agreement, primarily to expand our collaboration for the development and commercialization of toremifene 80 mg to reduce fractures in men with prostate cancer and to fund a second pivotal Phase III clinical trial of toremifene 80 mg. Under the Amended Ipsen Collaboration Agreement, Ipsen agreed to pay us up to €42.0 million in clinical development milestones for the purpose of conducting a second pivotal Phase III clinical trial evaluating toremifene 80 mg to reduce fractures in men with prostate cancer on ADT. Such milestone payments, if any, will be paid to us upon initiation of the clinical trial and completion of specific clinical development milestones throughout the course of the clinical trial as outlined in the Amended Ipsen Collaboration Agreement. Although Ipsen has committed to fund up to €42.0 million for a second pivotal Phase III clinical trial of toremifene 80 mg, if the projected cost of such second pivotal Phase III clinical trial of toremifene 80 mg exceeds €42.0 million, we are required to pay the excess amount. However, there is an established threshold of clinical trial costs in excess of €42.0 million at which we or Ipsen may determine not to initiate the trial, in which event, Ipsen would not be obligated to provide any additional funding for the trial. In addition, if the FDA does not consider the proposed protocol for a second pivotal Phase III clinical trial to be sufficient to satisfy the deficiencies set forth in the Complete Response Letter and imposes additional requirements for a second clinical trial that we and Ipsen believe to be too burdensome and costly, we or Ipsen may determine not to pursue a second clinical trial for toremifene 80 mg and to cease further development of the product candidate.

In exchange for Ipsen's commitment to fund a second Phase III clinical trial of toremifene 80 mg, we granted Ipsen certain additional rights, including an expansion of the territory in which Ipsen has the right to develop and commercialize toremifene beyond the European Territory to include Australia and certain countries in North Africa, the Middle East and Asia (excluding Japan), which we collectively refer to as the Ipsen Territory. In addition, Ipsen received the right to co-promote our toremifene 80 mg product candidate for the ADT indication in the United States or, at Ipsen's election in lieu of co-promotion, the right to receive a double digit royalty on net sales of our toremifene 80 mg product candidate for the ADT indication in the United States, which declines as net sales increase beyond an established base. Additionally, Ipsen was released of the obligation to pay certain potential milestone payments totaling €18.0 million related to the European approval of toremifene 80 mg and pricing approvals and received a reduction in the royalty payable to us on aggregate net sales of our toremifene 80 mg product candidate for the ADT indication. Ipsen also received the right of first negotiation, subject to certain conditions, with respect to development, marketing, sale and distribution in the Ipsen Territory of GTx-758.

We are also entitled to receive from Ipsen up to an aggregate of €20.0 million in milestone payments, depending on the successful development and launch of toremifene 20 mg in certain countries of the Ipsen Territory, subject to certain conditions. Depending on when Ipsen exercises this election, Ipsen may be required to pay an additional license fee as well as a premium on its share of the development and clinical trial expenses incurred by us in the United States since January 1, 2006, on account of toremifene for high grade PIN. We and Ipsen are reviewing all data from the Phase III clinical trial to better understand the trial results and the ability of toremifene 20 mg to reduce cancer among high risk men, but we do not currently expect to conduct additional clinical trials evaluating toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN or to submit a NDA to the FDA for this indication. Ipsen retains its election rights for toremifene 20 mg to treat high risk men with high grade PIN. However, we do not currently anticipate Ipsen will exercise its election rights. Nevertheless, if Ipsen elects to retain its rights to toremifene 20 mg, it may exercise its right under the Amended Ipsen Collaboration Agreement to be released from its obligation to pay up to €20.0 million in aggregate milestone payments and its share of development and clinical trial expenses for the high grade PIN indication in exchange for a reduction in the royalty payable by us on net sales of our toremifene 80 mg product candidate for the ADT indication in the United States. Ipsen has agreed to pay us a royalty equal to a graduating percentage of aggregate net sales of products sold in the Ipsen Territory containing toremifene 20 mg and a fixed percentage (12%) of aggregate net sales of products sold in the Ipsen Territory containing toremifene 80 mg.

Additionally, we are developing selective androgen receptor modulators, or SARMs, a new class of drugs with the potential to treat cancer cachexia (cancer induced muscle loss), chronic sarcopenia, which is the loss of skeletal muscle mass resulting in reduced physical strength and ability to perform activities of daily living, and other musculoskeletal wasting or muscle loss conditions. In December 2006, we announced that ostarine™ met its primary endpoint in a Phase II proof of concept, double blind, randomized, placebo controlled clinical trial in 60 elderly men and 60 postmenopausal women. In October 2008, we announced that ostarine™ met its primary endpoint in a Phase II clinical trial evaluating absolute change in total lean body mass (muscle) compared to placebo. In March 2010, we reacquired full rights to our SARM program, including ostarine™, following the termination by us and Merck & Co., Inc., or Merck, of our exclusive license and collaboration agreement for SARM compounds and related SARM products, which was entered into in December 2007. Merck remains obligated to pay us the final $5.0 million cost reimbursement payment for research and development activities in December 2010. We are pursuing a partnership for the development of SARMs, which includes ostarine™, our lead SARM, for the treatment of cancer cachexia. We do not anticipate significant development progress on ostarine™, or our SARM program in general, including the initiation of any additional clinical trials, unless and until we enter into one or more new collaborations with third parties or otherwise obtain additional funding.

We are also developing GTx-758 which is a selective estrogen receptor, or ER, alpha agonist for the first line treatment of advanced prostate cancer. In preclinical animal models, GTx-758 has demonstrated the potential to reduce testosterone concentrations in blood to castrate levels, increase BMD, and prevent hot flashes. In 2009, we completed two Phase I clinical trials, a single ascending dose clinical trial and a multiple ascending dose clinical trial, evaluating GTx-758 in healthy male volunteers. GTx-758 was well tolerated in both trials. In February 2010, we initiated a Phase II proof of concept clinical trial evaluating the ability of GTx-758 to reduce testosterone to castrate levels in 70 healthy male volunteers. We expect results of this clinical trial in the third quarter of 2010.

We market FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of metastatic breast cancer in postmenopausal women in the United States. We are increasing our promotional efforts in an attempt to increase commercial sales of FARESTON®. FARESTON® has efficacy, safety and pharmacokinetic properties which we believe makes it an appropriate treatment option for certain postmenopausal women with metastatic breast cancer. The active pharmaceutical ingredient in FARESTON® is the same as in our toremifene 80 mg and toremifene 20 mg product candidates.

Financial Highlights

Our net income for the six months ended June 30, 2010 was $31.4 million. Our net income included the recognition of the remaining $49.9 million of unamortized revenue from our exclusive license and collaboration agreement with Merck and the final payment from Merck of $5.0 million of cost reimbursement for research and development activities that will be received from Merck in December 2010. Our net income also included FARESTON® net product sales of $1.4 million for the six months ended June 30, 2010.

We have financed our operations and internal growth primarily through public offerings and private placements of our common stock, as well as payments from our current and former collaborations. As a result of the recognition of $49.9 million in deferred revenue and the final payment from Merck of $5.0 million of cost reimbursement, we expect to report net income for the year ending December 31, 2010. However, while recognition of this revenue is expected to result in net income for 2010, we expect to incur significant operating losses in 2011 and for the foreseeable future and we do not expect to obtain FDA or any other regulatory approvals to market any of our product candidates in the near future, if at all. In addition, significant additional clinical development will be required in order to potentially obtain FDA approval of toremifene 80 mg, including a second pivotal Phase III clinical trial of toremifene 80 mg.

At June 30, 2010, we had cash, cash equivalents and short-term investments of $28.4 million, compared to $49.0 million at December 31, 2009. We estimate that our current cash and cash equivalent balances, short-term investments, interest income, product revenue from the sale of FARESTON®, and the final payment from Merck of $5.0 million of cost reimbursement will be sufficient to meet our projected operating requirements through the next twelve months. We have based this estimate on our current business plan and assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. In addition, this estimate does not include any costs related to any additional clinical development of our SARM program, nor does it include any additional costs that we may be required to bear to continue the development of toremifene 80 mg if the funding from Ipsen is not sufficient to pay all clinical trial costs of a second pivotal Phase III clinical trial of toremifene 80 mg. Before undertaking any of these additional activities and requirements, we will need to raise additional funds and/or receive commitments from partners to pay for some or all of these additional costs. With the exception of payments that we may receive under our collaboration with Ipsen, we do not currently have any commitments for future external funding.

The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act were signed into law in March of this year, but certain provisions applied retroactively as of January 1, 2010. The legislation, among other things: increased drug rebates under Medicaid; applied those rebates to Medicaid managed care enrollees for the first time; and expanded 340B discounted drug pricing to more categories of providers. In particular, as a result of the new legislation, minimum percentage Medicaid drug rebates on FARESTON® increased from 15.1% to 23.1% of our average manufacturer price. We do not expect these changes to have a significant impact on our statement of operations for the year ending December 31, 2010.

Research and Development

Since our inception in 1997, we have been focused on drug discovery and development programs. Research and development expenses include, but are not limited to, 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 activities, quality assurance activities and license fees.

We expect that future research and development expenditures will be focused on the following:

- activities relating to our efforts to obtain regulatory approvals of toremifene 80 mg to reduce fractures and treat other estrogen deficiency side effects of ADT in men with prostate cancer, including potentially a second pivotal Phase III clinical trial of toremifene 80 mg;
- our ongoing research and development efforts for ostarine™ and other SARMs;
- the continued clinical development of GTx-758; and
- the continued preclinical development of other product candidates.

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

Product Candidates

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

Program	Product Candidate/ Proposed Indication	Development Phase	Status
SERM	**Toremifene 80 mg** To reduce fractures in men with prostate cancer on ADT	Completed pivotal Phase III clinical trial	Received a Complete Response Letter from the FDA regarding the NDA in October 2009; met with the FDA in July 2010 and plan to continue working with the FDA to finalize the protocol for a second pivotal Phase III clinical trial (TREAT 2).
	Toremifene 20 mg Prevention of prostate cancer in high risk men with high grade PIN	Completed pivotal Phase III clinical trial	Clinical trial results reported in May 2010; toremifene 20 mg failed to meet the primary efficacy endpoint in the Phase III clinical trial; no additional clinical trials of toremifene 20 mg for this indication are expected.
SARM	**Ostarine™** Treatment of cancer cachexia	Phase II clinical trial	Phase II clinical trial completed in September 2008.
	Ostarine™ Treatment of chronic sarcopenia	Phase II clinical trial	Phase II clinical trial completed in December 2006.
Selective ER alpha agonist	**GTx-758** Treatment of advanced prostate cancer	Phase II clinical trial	Results expected in the third quarter of 2010.

Sales and Marketing

We market FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of metastatic breast cancer in postmenopausal women in the United States. We are increasing our promotional efforts in an attempt to increase commercial sales of FARESTON®. FARESTON® has efficacy, safety, and pharmacokinetic properties which we believe makes it an appropriate treatment option for certain postmenopausal women with metastatic breast cancer. In order to commercialize any future products, we must broaden our sales and marketing infrastructure or collaborate with third parties with sales and marketing experience and personnel. We have partnered with Ipsen to commercialize toremifene 80 mg and toremifene 20 mg in the Ipsen Territory if approved for commercial sale. We are continuing to seek partners to market toremifene 80 mg in Japan and other markets outside of the United States and the Ipsen Territory.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries and other related costs for personnel serving executive, finance, legal, human resources, information technology, investor relations and marketing functions. General and administrative costs include facility costs, insurance costs, and professional fees for legal, accounting, public relations, and marketing services, and FARESTON® selling and distribution expenses. We expect our general and administrative expenses for fiscal year 2010 to be less than fiscal year 2009 since fiscal year 2009 general and administrative expenses included spending on sales and marketing, medical education and other supporting activities in anticipation of regulatory approval of our toremifene product candidates that we will not incur in 2010, as well as the December 2009 reduction in our workforce.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial statements. 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 condensed financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments related to revenue recognition, income taxes, intangible assets, long-term service contracts and other contingencies. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our financial statements appearing in our Annual Report on Form 10-K for the year ended December 31, 2009 filed with the SEC, we believe that the following accounting policies are most critical to aid you in fully understanding and evaluating our reported financial results.

Revenue Recognition

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

Collaboration revenue consists of non-refundable upfront payments, license fees, reimbursements for research and development activities, and milestone payments associated with our collaboration and license agreements and is based on the performance requirements of the specific agreements. We analyze any of our agreements with multiple element arrangements to determine whether the deliverables under the agreement, including license and performance obligations such as joint steering committee participation and research and development activities, can be separated or whether all of the deliverables must be accounted for as a single unit of accounting. For arrangements for which we are not able to identify evidence of fair value for the undelivered elements, we will recognize any consideration for a single unit of accounting in the same manner as the revenue is recognized for the final deliverable, which is ratable over the performance period. The performance period is estimated at the inception of the agreement and is reevaluated at each reporting period. Cost reimbursements for research activities are recognized as collaboration revenue if amounts are determinable and collection of the related receivable is reasonably assured. Revenues from milestone payments for which we have no continuing performance obligations are recognized upon achievement of the performance milestone, as defined in the related agreement, provided the milestone is substantive and a culmination of the earnings process has occurred. Performance obligations typically consist of significant milestones in the development life cycle of the related product candidates and technology, such as initiation of clinical trials, achievement of specified clinical trial endpoints, filing for approval with regulatory agencies and approvals by regulatory agencies.

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 continually monitor these factors for indications of appropriate revisions. We have estimated the performance obligation period to be ten years for the development of toremifene under our collaboration agreement with Ipsen which is based upon the estimated development period for toremifene 80 mg. We estimated the performance obligation period to be ten years for our collaboration agreement with Merck. However, due to the termination of our license and collaboration agreement with Merck in March 2010, we recognized as collaboration revenue in the first quarter of 2010 all of the remaining $49.9 million of unamortized revenue that was deferred as of December 31, 2009, as well as the final payment of $5.0 million for cost reimbursement for research and development activities that we will receive from Merck in December 2010 as we have no further performance obligations.

We recognize revenue from product sales of FARESTON® less deductions for estimated sales discounts and sales returns. We recognize revenue from product sales when persuasive evidence of an arrangement exists, title passes, the price is fixed or determinable, and collectability is reasonably assured. We account for rebates to certain governmental agencies as a reduction of product sales. We allow customers to return product within a specified time period prior to and subsequent to the product's labeled expiration date. As a result, we estimate an accrual for product returns, which is recorded as a reduction of product sales. We consider historical product return trend information that we continue to update each period. We estimate the number of months of product on hand and the amount of product which is expected to exceed its expiration date and be returned by the customer by receiving information from our three largest wholesale customers about the levels of FARESTON® inventory held by these customers. These three largest wholesale customers accounted for 96% of our product sales of FARESTON® for the six months ended June 30, 2010. Based on this information and other factors, we estimate an accrual for product returns. At June 30, 2010 and December 31, 2009, our accrual for product returns was $797,000 and $494,000, respectively. In the second quarter of 2010, we increased the price of FARESTON®. While we do not expect a material increase in the volume of product returns in future periods as a result of the price increase, the price increase resulted in an increase in the product returns accrual since certain product returns are accepted at or near the current sales price of FARESTON®.

Research and Development Expenses

Research and development expenses include, but are not limited to, our expenses for personnel, supplies, and facilities associated with research activities, screening and identification of product candidates, formulation and synthesis activities, manufacturing, preclinical studies, toxicology studies, clinical trials, regulatory affairs, quality assurance activities and license fees. We expense these costs in the period in which they are incurred. We estimate our liabilities for research and development expenses in order to match the recognition of expenses to the period in which the actual services are received. As such, accrued liabilities related to third party research and development activities are recognized based upon our estimate of services received and degree of completion of the services in accordance with the specific third party contract.

Research and development expenses for the three and six months ended June 30, 2010 included an impairment charge of $1.7 million related to unamortized portions of capitalized license fees paid to Orion and the University of Tennessee Research Foundation related to our toremifene 20 mg program.

Share-Based Compensation

We have stock option and equity incentive plans that provide for the purchase of our common stock by certain of our employees and non-employee directors. We recognize compensation expense for our share-based payments based on the fair value of the awards on the grant date and recognize the expense over the period during which an employee or non-employee director is required to provide service in exchange for the award.

The determination of the fair value of share-based payment awards on the date of grant include the expected life of the award, the expected stock price volatility over the expected life of the awards, expected dividend yield, and risk-free interest rate. We estimate the expected life of options by calculating the average of the vesting term and contractual term of the options. We estimate the expected stock price volatility based on the historical volatility of our common stock. The risk-free interest rate is determined using U.S. Treasury rates where the term is consistent with the expected life of the stock options. Expected dividend yield is not considered as we have not made any dividend payments and have no plans of doing so in the foreseeable future. The amount of share-based compensation expense recognized is reduced ratably over the vesting period by an estimate of the percentage of options granted that are expected to be forfeited or canceled before becoming fully vested. 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 June 30, 2010 was $1.1 million, of which $454,000 and $625,000 were recorded in the condensed statement of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the three months ended June 30, 2009 was $1.1 million, of which $389,000 and $675,000 were recorded in the condensed statement of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the six months ended June 30, 2010 was $2.8 million, of which $1.3 million and $1.5 million were recorded in the condensed statement of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the six months ended June 30, 2009 was $2.1 million, of which $769,000 and $1.4 million were recorded in the condensed statement of operations as research and development expenses and general and administrative expenses, respectively. Included in share-based compensation expense for the three months ended June 30, 2010 and 2009 was share-based compensation expense related to deferred compensation arrangements for our non-employee directors of $46,000 and $39,000, respectively, and $96,000 and $84,000 for the six months ended June 30, 2010 and 2009, respectively. At June 30, 2010, the total compensation cost related to non-vested awards not yet recognized was approximately $13.2 million with a weighted average expense recognition period of 2.09 years.

Recent Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2009-13, *Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements (a consensus of the FASB Emerging Issues Task Force)* (“ASU No. 2009-13”). ASU No. 2009-13 amends revenue recognition guidance related to multiple deliverable arrangements to provide new guidance concerning the determination of whether an arrangement involving multiple deliverables contains more than one unit of accounting and the manner in which arrangement consideration should be allocated to such deliverables. The amended guidance is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010 and may be applied prospectively or retroactively. We do not expect the adoption of ASU No. 2009-13 to have a material impact on our financial position or results of operations.

In April 2010, the FASB issued Accounting Standards Update No. 2010-17, *Revenue Recognition (Topic 605): Milestone Method of Revenue Recognition (a consensus of the FASB Emerging Issues Task Force)* (“ASU No. 2010-17”). ASU No. 2010-17 allows an entity to make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. Additionally, ASU No. 2010-17 provides guidance in identifying milestones and determining whether the milestones are substantive. The amended guidance is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010 and may be applied prospectively or retroactively. We do not expect the adoption of ASU No. 2010-17 to have a material impact on our financial position or results of operations.

Results of Operations

Three Months Ended June 30, 2010 and 2009

Revenues. Revenues for the three months ended June 30, 2010 were $935,000, as compared to $3.8 million for the same period of 2009. Revenues included net sales of FARESTON® marketed for the treatment of metastatic breast cancer in postmenopausal women, collaboration revenue from Ipsen for the three months ended June 30, 2010 and collaboration revenue from Ipsen and Merck for the three months ended June 30, 2009. During the three months ended June 30, 2010 and 2009, FARESTON® net product sales were $599,000 and $949,000, respectively, while cost of product sales were $134,000 and $431,000, respectively. FARESTON® net product sales for the three months ended June 30, 2010 decreased from the same period in the prior year due to a decrease in sales volume and an increase in the provision for product returns due to an increase in the price of FARESTON® in the second quarter of 2010. While we do not expect a material increase in the volume of product returns in future periods as a result of the price increase, the price increase resulted in an increase in the product returns accrual since certain product returns are accepted at or near the current sales price of FARESTON®. These decreases were partially offset by an increase in the sales price of FARESTON® during the second quarter of 2010. Cost of product sales decreased from the same period in the prior year due to the lower sales volume as well as a reduction in the royalty payable to Orion on our net sales of FARESTON®. Collaboration revenue was $336,000 for the three months ended June 30, 2010 and $2.9 million for the three months ended June 30, 2009. Collaboration revenue for the three months ended June 30, 2010 consisted solely of the amortization of deferred revenue from Ipsen. Collaboration revenue for the three months ended June 30, 2009 consisted of $1.5 million and $1.4 million from the amortization of deferred revenue from Ipsen and Merck, respectively. The collaboration revenue recognized from Ipsen for the three months ended June 30, 2010 decreased from the same period of the prior year as we extended the estimated development period to ten years due to our increased obligation period associated with a second toremifene 80 mg Phase III clinical trial.

Research and Development Expenses. Research and development expenses increased 22% to $9.5 million for the three months ended June 30, 2010 from $7.7 million for the three months ended June 30, 2009. Research and development expenses for the three months ended June 30, 2010 included an impairment charge of $1.7 million related to the our toremifene 20 mg intangible assets. This amount is included in “Toremifene 20 mg” in the table below. Research and development for past periods is not indicative of spending in future periods. The following table identifies the research and development expenses for each of our clinical product candidates, as well as research and development expenses pertaining to our other research and development efforts, for both of the periods presented.

Program	Product Candidate/ Proposed Indication	Three Months Ended June 30, 2010	Three Months Ended June 30, 2009	Increase/ (Decrease)
		(in thousands)		
SERM	**Toremifene 80 mg** To reduce fractures in men with prostate cancer on ADT	$ 1,260	$ 654	$ 606
	Toremifene 20 mg Prevention of prostate cancer in high risk men with high grade PIN	2,831	1,472	1,359
SARM	**Ostarine™** Treatment of cancer cachexia	818	230	588
Selective ER alpha agonist	**GTx-758** Treatment of advanced prostate cancer	2,507	2,314	193
Other research and development		2,061	3,076	(1,015)
Total research and development expenses		$ 9,477	$ 7,746	$ 1,731

General and Administrative Expenses. General and administrative expenses decreased during the three months ended June 30, 2010 to $4.3 million from $7.0 million for the three months ended June 30, 2009. This decrease was primarily due to decreased personnel related expenses of $1.3 million resulting from the reduction in our workforce in December 2009, reduced marketing expenses of $777,000, and reduced medical affairs expenses of $182,000, in each case, as a result of our not receiving regulatory approval of our toremifene 80 mg product candidate.

Six Months Ended June 30, 2010 and 2009

Revenues. Revenues for the six month periods ended June 30, 2010 and 2009 were $57.5 million and $7.5 million, respectively and included net sales of FARESTON® and collaboration revenue from Ipsen and Merck. In the first six months of 2010 and 2009, FARESTON® net product sales were $1.4 million and $1.7 million, respectively, while cost of product sales were $285,000 and $779,000, respectively. FARESTON® net product sales for the six months ended June 30, 2010 decreased from the same period in the prior year primarily as a result of an increase in the provision for product returns due to an increase in sales price in the second quarter of 2010. This decrease was partially offset by an increase in both sales volume and the price of FARESTON®. Cost of product sales decreased from the same period in the prior year due to a reduction in the royalty payable to Orion on our net sales of FARESTON®. Collaboration revenue was $56.1 million for the six months ended June 30, 2010 and consisted of $1.3 million from Ipsen and $54.9 million from Merck. As a result of the termination of our license and collaboration agreement with Merck in March 2010, we recognized as collaboration revenue the remaining $49.9 million of unamortized deferred revenue in the first quarter of 2010, as well as the final payment of $5.0 million of cost reimbursement that will be received from Merck in December 2010. Collaboration revenue was $5.7 million for the six months ended June 30, 2009 and consisted of $2.9 million and $2.8 million from the amortization of deferred revenue from Ipsen and Merck, respectively.

Research and Development Expenses. Research and development expenses increased by 7% to $17.1 million for the six months ended June 30, 2010 from $16.1 million for the six months ended June 30, 2009. Research and development expenses for the six months ended June 30, 2010 included an impairment charge of $1.7 million related to the our toremifene 20 mg intangible assets. This amount is included in “Toremifene 20 mg” in the table below. The following table identifies the research and development expenses for each of our clinical product candidates, as well as research and development expenses pertaining to our other research and development efforts, for both of the periods presented.

Program	Product Candidate/ Proposed Indication	Six Months Ended June 30, 2010	Six Months Ended June 30, 2009	Increase/ (Decrease)
		(in thousands)		
SERM	**Toremifene 80 mg** To reduce fractures in men with prostate cancer on ADT	$ 2,220	$ 1,191	$ 1,029
	Toremifene 20 mg Prevention of prostate cancer in high risk men with high grade PIN	4,450	3,592	858
SARM	**Ostarine™** Treatment of cancer cachexia	1,485	538	947
Selective ER alpha agonist	**GTx-758** Treatment of advanced prostate cancer	4,830	4,479	351
Other research and development		4,142	6,258	(2,116)
Total research and development expenses		$ 17,127	$ 16,058	$ 1,069

General and Administrative Expenses. General and administrative expenses decreased during the six months ended June 30, 2010 to $8.8 million from $13.5 million for the six months ended June 30, 2009. This decrease was primarily due to decreased personnel related expenses of $2.2 million resulting from the reduction in our workforce in December 2009, reduced marketing expenses of $1.7 million, and reduced medical affairs expenses of $374,000, in each case, as a result of our not receiving regulatory approval of our toremifene 80 mg product candidate.

Liquidity and Capital Resources

At June 30, 2010, we had cash, cash equivalents and short-term investments of $28.4 million, compared to $49.0 million at December 31, 2009. Net cash used in operating activities was $20.5 million and $27.9 million for the six months ended June 30, 2010 and 2009, respectively, and resulted primarily from funding our operations for the periods.

Net cash provided by investing activities was $366,000 for the six months ended June 30, 2010 and resulted from the maturities of short-term investments of $7.4 million, offset by the purchase of short-term investments of $6.9 million and the purchase of information technology equipment and research and development equipment of approximately $85,000. For the six month period of 2009, net cash used in investing activities of $248,000 was for the purchase of information technology equipment, software, and research and development equipment.

Net cash used in financing activities was $46,000 for six months ended June 30, 2010 and was related to payments on capital lease and financed equipment obligations. For the six months ended June 30, 2009, net cash provided by financing activities was $114,000 and was provided primarily from proceeds from the exercises of employee stock options.

We estimate that our current cash and cash equivalent balances, short-term investments, interest income, product revenue from the sale of FARESTON®, and the final payment from Merck of $5.0 million of cost reimbursement will be sufficient to meet our projected operating requirements through the next twelve months. We have based this estimate on our current business plan and assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. In addition, this estimate does not include any costs related to any additional clinical development of our SARM program, nor does it include any additional costs that we may be required to bear to continue the development of toremifene 80 mg if the funding from Ipsen is not sufficient to pay all clinical trial costs of a second pivotal Phase III clinical trial of toremifene 80 mg. Before undertaking any of these additional activities and requirements, we will need to raise additional funds and/or receive commitments from partners to pay for some or all of these additional costs. In addition, we may never receive any of the €42.0 million in toremifene 80 mg clinical development milestone payments under our collaboration agreement with Ipsen, particularly if the FDA does not consider the proposed protocol for a second pivotal Phase III clinical trial of toremifene 80 mg to be sufficient to satisfy the deficiencies set forth in the Complete Response Letter.

Our estimate of the period of time through which our financial resources will be adequate to support our projected operating requirements is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed under Part II, Item 1A “Risk Factors” section of this Quarterly Report on Form 10-Q. Because of the numerous risks and uncertainties associated with the development and potential commercialization of our product candidates and other research and development activities, including risks and uncertainties that could impact the rate of progress of our development and commercialization 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, other research and development activities, and commercialization activities. Our future funding requirements will depend on many factors, including:

- matters related to our collaborative arrangement with Ipsen, including a determination as to whether and to what extent we and Ipsen determine to continue the development of toremifene and any additional costs that we may be required to bear with respect to any such continued development, including with respect to a second pivotal Phase III clinical trial of toremifene 80 mg;
- the scope, rate of progress and cost of our, Ipsen’s and/or any potential future collaborators’ clinical trials and other research and development activities;

- future clinical trial results;
- the terms and timing of any future collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory filings and/or approvals to commercialize our product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- potential future licensing fees, milestone payments and royalty payments, including any milestone payments that we may receive under our collaborative arrangement with Ipsen;
- the cost and timing of establishing medical education, sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we, Ipsen, and/or any potential future collaborators 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 cost of defending any other litigation claims; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Until we can generate a sufficient amount of product revenue, we expect to finance future cash needs through public or private equity offerings, debt financings or collaboration and licensing arrangements, as well as through interest income earned on the investment of our cash balances and short-term investments and revenues from the sale of FARESTON®. With the exception of payments that we may receive under our collaboration with Ipsen, we do not currently have any commitments for future external funding. In December 2009, we announced a reduction of approximately 26% of our workforce in order to reduce our operating expenses in connection with the receipt of the Complete Response Letter regarding our NDA for toremifene 80 mg and the associated delay in the potential regulatory approval of toremifene 80 mg. If we are unable to raise additional funds in the near term, we may need to further reduce our expenditures, perhaps significantly, to preserve our cash. The cost-cutting measures we have taken and may take in the future may not be sufficient to enable us to meet our cash requirements, and they may negatively affect our business and growth prospects. 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. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. To the extent that we raise additional funds through collaboration and licensing arrangements, such as our arrangement with Ipsen, it may be necessary to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. Our ability to raise additional funds and the terms upon which we are able to raise such funds may be adversely impacted by the uncertainty regarding our ability to gain FDA approval of toremifene 80 mg, the results in our Phase III clinical trial of toremifene 20 mg, the termination of our license and collaboration agreement with Merck, and/or current economic conditions, including the effects of the disruptions to and continuing volatility in the credit and financial markets in the United States and worldwide. As a result of these and other factors, we cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available when we need them, we may be required to further delay, reduce the scope of or eliminate one or more of our research or development programs, including our SARM and toremifene programs, conduct additional workforce or other expense reductions, or obtain funds through collaborations with others that are on unfavorable terms or that may require us to relinquish rights to some of our technologies or product candidates that we would otherwise seek to develop on our own.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the six months ended June 30, 2010, there were no material changes to our market risk disclosures as set forth in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2009.

ITEM 4. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities and Exchange Act of 1934, as amended (the "Exchange Act") that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosures.

We have carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of the end of the period covered by this report. Based on the evaluation of these disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective.

There were no changes in our internal control over financial reporting during the second quarter of 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

ITEM 1A. RISK FACTORS

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

We have marked with an asterisk (*) those risks described below that reflect substantive changes from the risks described under Part I, Item 1A "Risk Factors" included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 15, 2010.

Risks Related to Our Financial Results and Need for Additional Financing

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

We have a limited operating history. As of June 30, 2010, we had an accumulated deficit of $336.8 million, of which $96.3 million related to non-cash dividends and adjustments to the preferred stock redemption value. Net income was $31.4 million for the six months ended June 30, 2010. However, we have incurred losses in each year since our inception in 1997, including net losses of $46.3 million and $51.8 million in 2009 and 2008, respectively. Due to the termination of our collaboration with Merck & Co., Inc., or Merck, and the associated recognition in the first quarter of 2010 of $49.9 million in deferred revenue and the final payment to be received from Merck later this year of $5.0 million of cost reimbursement for research and development activities, we expect to report net income for the year ending December 31, 2010. However, while recognition of this revenue is expected to result in net income for 2010, we expect to incur significant operating losses in 2011 and for the foreseeable future. In addition, we do not expect to obtain FDA or any other regulatory approvals to market any of our product candidates in the near future, if at all. These losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

In October 2009, we received a Complete Response Letter from the U.S. Food and Drug Administration, or FDA, regarding our New Drug Application, or NDA, for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT notifying us that the FDA would not approve our NDA in its present form as a result of certain clinical deficiencies identified in the Complete Response Letter. As a result, FDA approval of toremifene 80 mg, if it occurs, will be substantially delayed. In addition, significant additional clinical development will be required in order to potentially obtain FDA approval of toremifene 80 mg, including a second pivotal Phase III clinical trial of toremifene 80 mg. We recently expanded our collaboration with Ipsen Biopharm Limited, or Ipsen, pursuant to which Ipsen committed, subject to certain conditions, up to €42.0 million to fund a second pivotal Phase III clinical trial of toremifene 80 mg in exchange for certain additional rights we granted to Ipsen as well as a reduction or, in some cases, an elimination of Ipsen's potential future milestone and royalty obligations to us under our original agreement with Ipsen. If the projected cost of such second pivotal Phase III clinical trial exceeds €42.0 million, we are required to pay the excess amount. However, there is an established threshold of clinical trial costs in excess of €42.0 million at which we or Ipsen may determine not to initiate the trial, in which event, Ipsen would not be obligated to provide any additional funding for the trial. In addition, if the FDA does not consider the proposed protocol for a second pivotal Phase III clinical trial to be sufficient to satisfy the deficiencies set forth in the Complete Response Letter and imposes additional requirements for a second clinical trial that we and Ipsen believe to be too burdensome and costly, we or Ipsen may determine not to pursue a second clinical trial for toremifene 80 mg and either of us may determine to cease further development of the product candidate. Moreover, in May 2010, we announced that toremifene 20 mg failed to meet its primary efficacy endpoint in our Phase III clinical trial of toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia, or high grade PIN, and due to the results in the trial, we and Ipsen (or either of us individually) may determine to cease further development of toremifene 20 mg for the high grade PIN indication. Any determination to further delay or eliminate our toremifene development program could have a material adverse effect on our business and growth prospects.

Because of the numerous risks and uncertainties associated with developing and commercializing 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 primarily through public offerings and private placement of our common stock, as well as payments from our current and former collaborators, including Merck and Ipsen. In March 2010, we and Merck agreed to terminate our collaboration and, as a result, we will not receive any milestone payments or royalties for the development or sale of selective androgen receptor modulators, or SARMs, from Merck. We do not anticipate significant development progress on ostarine™, or our SARM program in general, including the initiation of any additional clinical trials, unless and until we enter into one or more new collaborations with third parties or otherwise obtain additional funding. FARESTON® is currently our only commercial product and, until such time that we receive regulatory approval to market any of our product candidates, if ever, we expect that FARESTON® will account for all of our product revenue. For the six months ended June 30, 2010, we recognized $1.4 million in net revenues from the sale of FARESTON®. If we, Ipsen, and/or any potential future collaborators are unable to develop and commercialize any of our product candidates, if development is further delayed or eliminated, or if sales revenue from any product candidate that receives marketing approval is insufficient, we may never become profitable and we will not be successful.

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

We will need to raise substantial additional capital in the near term to:

- fund our operations and conduct 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 and cash equivalent balances, short-term investments, interest income, product revenue from the sale of FARESTON®, and the final payment from Merck of $5.0 million of cost reimbursement will be sufficient to meet our projected operating requirements through the next twelve months. We have based this estimate on our current business plan and assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. In addition, this estimate does not include any costs related to additional clinical development of our SARM program, nor does it include any additional costs that we may be required to bear to continue the development of toremifene 80 mg if the funding from Ipsen is not sufficient to pay all clinical trial costs of a second pivotal Phase III clinical trial of toremifene 80 mg. Before undertaking any of these additional activities and requirements, we will need to raise additional funds and/or receive commitments from partners to pay for some or all of these additional costs. In addition, we may never receive any of the €42.0 million in toremifene 80 mg clinical development milestone payments under our collaboration agreement with Ipsen, particularly if the FDA does not consider the proposed protocol for a second pivotal Phase III clinical trial of toremifene 80 mg to be sufficient to satisfy the deficiencies set forth in the Complete Response Letter. Our future funding requirements will depend on many factors, including:

- matters related to our collaborative arrangement with Ipsen, including a determination as to whether and to what extent we and Ipsen determine to continue the development of toremifene and any additional costs that we may be required to bear with respect to any such continued development, including with respect to a second pivotal Phase III clinical trial of toremifene 80 mg;
- the scope, rate of progress and cost of our, Ipsen's and/or any potential future collaborators' clinical trials and other research and development activities;
- future clinical trial results;
- the terms and timing of any future collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory filings and/or approvals to commercialize our product candidates and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- potential future licensing fees, milestone payments and royalty payments, including any milestone payments that we may receive under our collaborative arrangement with Ipsen;
- the cost and timing of establishing medical education, sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we, Ipsen, and/or any potential future collaborators 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 cost of defending any other litigation claims; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Until we can generate a sufficient amount of product revenue, we expect to finance future cash needs through public or private equity offerings, debt financings or collaboration and licensing arrangements, as well as through interest income earned on the investment of our cash balances and short-term investments, and revenues from the sale of FARESTON®. With the exception of payments that we may receive under our collaboration with Ipsen, we do not currently have any commitments for future external funding. In December 2009, we announced a reduction of approximately 26% of our workforce in order to reduce our operating expenses in connection with the receipt of the Complete Response Letter regarding our NDA for toremifene 80 mg and the associated delay in the potential regulatory approval of toremifene 80 mg. If we are unable to raise additional funds in the near term, we may need to further reduce our expenditures, perhaps significantly, to preserve our cash. The cost-cutting measures we have taken and may take in the future may not be sufficient to enable us to meet our cash requirements, and they may negatively affect our business and growth prospects.

To the extent we raise additional funds by issuing equity securities, our stockholders may experience dilution, and 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. To the extent we raise additional funds through collaboration and licensing arrangements, such as our arrangement with Ipsen, it may be necessary to relinquish rights to some of our technologies or product candidates, or grant licenses on terms that are not favorable to us. Our ability to raise additional funds and the terms upon which we are able to raise such funds may be adversely impacted by the uncertainty regarding our ability to gain FDA approval of toremifene 80 mg, the results in our Phase III clinical trial of toremifene 20 mg, the termination of our license and collaboration agreement with Merck, and/or current economic conditions, including the effects of the disruptions to and continuing volatility in the credit and financial markets in the United States and worldwide. As a result of these and other factors, we cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available when we need them, we may be required to further delay, reduce the scope of or eliminate one or more of our research or development programs, including our SARM and toremifene programs, conduct additional workforce or other expense reductions, or 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.

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 if our or our collaborators' 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.

In clinical studies, the efficacy and/or safety results from the trial may be insufficient to support the submission or approval of a NDA with the FDA. For example, we received a Complete Response Letter in October 2009 from the FDA regarding our NDA for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT, notifying us that the FDA would not approve our NDA in its present form as a result of certain clinical deficiencies identified in the Complete Response Letter, which deficiencies may only be addressed by conducting an additional pivotal Phase III clinical trial of toremifene 80 mg. In April 2010, we submitted a proposed protocol for a second pivotal Phase III clinical trial evaluating toremifene 80 mg to reduce fractures in men with prostate cancer on ADT to address in a single clinical trial the deficiencies identified by the FDA in the Complete Response Letter; however, if the FDA does not consider the proposed protocol for a second pivotal Phase III clinical trial to be sufficient to satisfy the deficiencies set forth in the Complete Response Letter and imposes additional requirements for a second clinical trial that we and Ipsen believe to be too burdensome and costly, we and Ipsen may determine not to pursue a second clinical trial for toremifene 80 mg and either of us may determine to cease further development of the product candidate. In addition, in May 2010, we announced that toremifene 20 mg failed to meet its primary efficacy endpoint in our Phase III clinical trial of toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN. As a result, we will not be able to seek marketing approval for toremifene 20 mg in the timeframe we anticipated or at all, and we and Ipsen (or either of us individually) may determine to cease further development of this product candidate.

We, Ipsen, or any potential future collaborators may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent our or our collaborators' ability to commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us, Ipsen, or any potential future collaborators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- preclinical or clinical trials may produce negative or inconclusive results, which may require us, Ipsen, or any potential future collaborators to conduct additional preclinical or clinical testing or to abandon projects that we expect to be promising;
- registration or enrollment in clinical trials may be slower than we currently anticipate, resulting in significant delays;
- we, Ipsen, or any potential future collaborators may suspend or terminate 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, Ipsen, or any potential future collaborators 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.

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

Although the results from our Phase III clinical trial for toremifene 80 mg to reduce fractures and treat other estrogen deficiency side effects of ADT in men with prostate cancer showed that the drug was well tolerated and had a generally favorable safety profile, more subjects experienced a venous thromboembolic event, or VTE, in the toremifene 80 mg treatment group, 17 (2.6%) compared to 7 (1.1%) in the placebo group. Even though the majority of VTEs recorded in the clinical trial occurred in men who were at high risk for a VTE (including: age greater than 80 years, history of VTEs, recent surgical procedure or immobilization) and data from the clinical trial showed that the number of men without any of these independent risk factors for VTEs in whom a VTE occurred during the clinical trial was 5 in the toremifene 80 mg treatment group versus 3 in the placebo group, the FDA will consider the overall safety profile from the clinical trial when making its determination whether to grant marketing approval and to require potential warnings in the label if approval is granted. In our Phase III clinical trial of toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, the data has shown that the drug was generally well tolerated with similar safety profile. Although not statistically significant, there was a higher number of subjects in the toremifene 20 mg treatment group that experienced a VTE, 7 (0.9%) versus 4 (0.5%) in the placebo group.

As part of our effort to complete the requirements for the submission of applications for regulatory approval to commercialize toremifene 80 mg and 20 mg, we have conducted a number of studies of toremifene in addition to our clinical trials, including a Thorough QT study (toremifene 80 mg and toremifene 20 mg), a bioequivalence study (toremifene 80 mg), a series of drug-drug interaction studies (toremifene 80 mg and toremifene 20 mg), and a semen quality study (toremifene 20 mg) to assess the effect of toremifene. The results of the Thorough QT study of 250 healthy male volunteers, with 5 parallel cohorts receiving 20 mg, 80 mg or 300 mg doses of toremifene, moxifloxacin, or placebo, showed that toremifene prolonged the QT interval in a dose dependent manner. The mean change in QTcB (a measurement of QT interval corrected by Bazett's formula) from baseline relative to placebo for toremifene 20 mg was 5.79 milliseconds, for toremifene 80 mg, it was 22.43 milliseconds, and for moxifloxacin, it was 8.83 milliseconds. Since we market FARESTON® in the United States under a license agreement with Orion Corporation, or Orion, we notified the FDA of the Thorough QT study results and have proposed modifications to the FARESTON® label in the United States. FDA action on the proposed label changes is pending. Separately, Orion recommended label changes to the European Medicines Agency, or EMEA. In January 2009, the EMEA recommended that the FARESTON® label within the European Union reflect that toremifene should not be given to patients at risk of prolonged QT intervals or other certain heart problems. The results of these completed studies have been included as a part of the NDA submission to the FDA for our toremifene 80 mg product candidate to reduce fractures in men with prostate cancer on ADT and will be used to update the label for FARESTON®. The study results could lead to the inclusion of restrictions, limitations and/or warnings in the label of FARESTON® or an approved toremifene product candidate, which may adversely affect the marketability of the product or limit the patients to whom the product is prescribed.

In addition, in our Phase II clinical trial for ostarine™ for the treatment of cancer cachexia (cancer induced muscle loss), we observed mild elevations of hepatic enzymes in a few patients, and in our preclinical studies for ostarine™, only at the highest doses, we observed expected selective effects on the reproductive and other target organs in the male population consistent with the stimulating and inhibiting effects on the androgen receptor which is located in these organs.

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

- we, Ipsen, or any potential future collaborators may be required to conduct additional preclinical or clinical trials, make changes in labeling of any such approved products, reformulate any such products, or implement changes to or obtain new approvals of our contractors' manufacturing facilities;
- regulatory authorities may be unwilling to approve our product candidates or may withdraw approval of our products;
- we may experience a significant drop in the sales of the affected products;
- our reputation in the marketplace may suffer; and
- we may become the target of lawsuits, including class action suits.

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

Risks Related to Our Dependence on Third Parties

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

In September 2006, we entered into a collaboration agreement with Ipsen for the development and commercialization of toremifene, which collaboration was amended in March 2010 to, among other things, expand Ipsen's licensed territory for the development and commercializing of toremifene product candidates. Pursuant to the collaboration agreement, as recently amended, Ipsen committed up to €42.0 million to fund a second pivotal Phase III clinical trial of toremifene 80 mg in exchange for certain additional rights we granted to Ipsen, including an expansion of its licensed territory, as well as a reduction in or, in some cases, an elimination of Ipsen's potential future milestone and royalty obligations to us under our original agreement with Ipsen. The loss of Ipsen as a collaborator in the development or commercialization of toremifene, any dispute over the terms of our collaboration with Ipsen, or any other adverse developments in our relationship with Ipsen could materially harm our business and would substantially increase our need for additional capital. For example, if we were to lose Ipsen as a collaborator, we may not be able to obtain sufficient additional funding to complete the development of toremifene 80 mg. In addition, Ipsen is obligated to initiate and conduct appropriate clinical studies as required by the appropriate regulatory authorities in order to obtain marketing approvals of toremifene in its licensed territory. Any failure on the part of Ipsen to initiate these studies could delay the commercialization of toremifene in its licensed territory. In addition, the receipt of the Complete Response Letter from the FDA in October 2009 has delayed Ipsen's plans to seek marketing approval of toremifene 80 mg in its licensed territory. Moreover, if we and Ipsen (or either of us individually) determines that clinical development of toremifene 80 mg and/or toremifene 20 mg should be further delayed or discontinued, our potential future milestone payments and potential future revenues from the commercialization of toremifene would be reduced or eliminated.

We may not be successful in entering into additional collaborative arrangements with other third parties, and even if we do enter into collaborative arrangements with other parties, such arrangements may not be successful. If we fail to enter into additional collaborative arrangements on favorable terms, it could delay or impair our ability to develop and commercialize our other product candidates and could increase our costs of development and commercialization.

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

- we are not able to control either the amount and timing of resources that Ipsen devotes to toremifene;
- we may not be able to control the amount and timing of resources that our potential future collaborators may devote to our product candidates;
- Ipsen or any potential future collaborations may experience financial difficulties or changes in business focus;
- we may be required to relinquish important rights such as marketing and distribution rights;
- under certain circumstances, Ipsen may not be required to commercialize toremifene in its licensed territory if Ipsen determines that it is not commercially reasonable for it to do so;
- pricing reimbursement constraints in Europe, which is part of Ipsen's licensed territory, may diminish the prospects of our receiving royalty payments from Ipsen on aggregate net sales of toremifene in some or all of the countries in Europe;
- 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 the 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;
- under certain circumstances, a collaborator could move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, such as our former collaboration with Merck, which would delay the development and may increase the cost of developing our product candidates.

We may not realize the anticipated benefits from our collaborative arrangement with Ipsen, and may not receive the anticipated benefits from any future collaboration arrangements that we might establish.*

We may not receive any future milestone payments provided for under our collaborative arrangement with Ipsen if our agreement with Ipsen is terminated, if certain clinical development and regulatory milestones under our agreement with Ipsen are not achieved or if Ipsen fails to develop and commercialize toremifene in its licensed territory. In addition, although Ipsen has committed, subject to certain conditions, up to €42.0 million to fund a second pivotal Phase III clinical trial of toremifene 80 mg to address the deficiencies identified by the FDA in the Complete Response Letter we received in October 2009, if the projected cost of such second pivotal Phase III clinical trial of toremifene 80 mg exceeds €42.0 million, we are required to pay the excess amount. However, there is an established threshold of clinical trial costs in excess of €42.0 million at which we or Ipsen may determine not to initiate the trial, in which event, Ipsen would not be obligated to provide any additional funding for the trial. In addition, if the FDA does not consider the proposed protocol for a second pivotal Phase III clinical trial to be sufficient to satisfy

the deficiencies set forth in the Complete Response Letter and imposes additional requirements for a second clinical trial that we and Ipsen believe to be too burdensome and costly, we or Ipsen may determine not to pursue a second clinical trial for toremifene 80 mg and either of us may determine to cease further development of the product candidate. In addition, in May 2010, we announced that toremifene 20 mg failed to meet its primary efficacy endpoint in our Phase III clinical trial of toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, and, as a result, we and Ipsen (or either of us individually) may determine to cease further development of the product candidate for the high grade PIN indication. In connection with a determination to cease further development of toremifene 80 mg and/or toremifene 20 mg, Ipsen may elect to terminate our collaboration. Even if required regulatory approvals to market toremifene are obtained, it is possible that Ipsen will not successfully market and sell any toremifene products in which case we would not receive royalties to the extent that we currently anticipate. Furthermore, our royalty rates under our collaboration and license agreement with Ipsen are subject to a possible reduction if a generic version of toremifene achieves specified sales levels in a major country within its licensed territory. Ipsen also may be entitled to offset a portion of any royalties due to us if Ipsen licenses patent rights from a third party that would otherwise be infringed by Ipsen's use, manufacture, sale or import of toremifene compounds. Moreover, we have agreed to grant Ipsen co-promotion rights in the United States with respect to toremifene 80 mg for the ADT indication, which may, if toremifene 80 mg receives regulatory approval and is commercialized, reduce the amount of product revenue that we would have otherwise received had we commercialized toremifene 80 mg in the United States solely ourselves.

Under our agreement with Ipsen, we and Ipsen have agreed that neither party will seek to commercialize, promote, market or sell certain products within its licensed territory for an agreed period of time subsequent to the time of the first commercial launch of toremifene within its licensed territory. We and Ipsen have also agreed to grant to the other a right of first negotiation with respect to the development, marketing, sale and distribution of any new SERM-based products for the field of the prevention and treatment of prostate cancer or related side effects, or any other indication the parties agree on. We have also agreed to grant to Ipsen a right of first negotiation, subject to certain conditions, with respect to the development, marketing, sale and distribution of GTx-758 in Ipsen's licensed territory. However, there can be no assurance that we will be able to reach an agreement with Ipsen on reasonable terms, or at all, for any new SERM-based products or GTx-758, as applicable.

Ipsen may terminate the license and collaboration agreement, as amended, for our uncured breach, upon our bankruptcy, with 12 months prior written notice for any reason and with 30 days prior written notice as a result of legitimate and documented safety concerns, or in the event that either the UTRF license for chemoprevention of prostate cancer or the license and supply agreement with Orion terminates early. If our agreement with Ipsen is terminated, the anticipated future benefits to us from this agreement would be eliminated and the development and commercialization of toremifene in Ipsen's licensed territory would be delayed and could be abandoned. In any such or similar events, we may not realize the anticipated benefits from our collaborative arrangement with Ipsen.

Besides Ipsen, we have in the past established and intend to continue to establish collaborations with third parties to develop and commercialize some of our current and future product candidates, and these collaborations may not be successful or we may otherwise not realize the anticipated benefits from these collaborations. For example, in March 2010, following Merck's determination to discontinue internal development of ostarine™, we and Merck mutually agreed to terminate our collaboration and, as a result, we will not receive any milestone payments or royalties for the development or sale of SARMs from Merck. In the future, we may not be able to locate third-party collaborators to develop and market our product candidates, and we may lack the capital and resources necessary to develop our product candidates alone.

If third parties do not manufacture our product candidates in sufficient quantities, in the required timeframe, 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, if any, 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 in a finished tablet form at specified prices under a license and supply agreement. Similarly, Ipsen has agreed to purchase from Orion toremifene tablets for clinical testing and commercial sale in its licensed territory under an amended supply agreement with Orion. As such, both we and Ipsen rely on Orion as the single source supplier of toremifene.

Orion may terminate its supply obligations at its election at any time as a result of our failure to obtain regulatory approval of one of our toremifene product candidates in the United States prior to December 31, 2009. If Orion elects to terminate its obligation to manufacture and supply us and Ipsen with toremifene, any arrangements we make for an alternative supply would have to be made with a qualified alternative supplier with appropriate FDA approval in order for us to obtain our supply requirements for toremifene. In addition, although Orion's composition of matter patents have expired, and as such, neither we nor Ipsen would be prevented from manufacturing toremifene within the United States or European Territory, there is no obligation on the part of Orion to transfer its manufacturing technology to us or Ipsen or to assist us or Ipsen in developing manufacturing capabilities to meet our respective supply needs. We and Ipsen have mutually agreed to cooperate in the manufacture of toremifene in the event that Orion elects to terminate its obligation to manufacture and supply us and Ipsen with toremifene. Although we and Ipsen have agreed to cooperate with each other in the event either of our supply rights are terminated by Orion for any reason, a disruption in the supply of toremifene could delay the development of and impair our and Ipsen's ability to commercialize toremifene. In addition, in the event of such a termination by Orion, Ipsen could elect to exercise its right to terminate our collaboration agreement on limited notice to us.

We also rely on Orion to cooperate with us in the filing and maintenance of regulatory filings with respect to the manufacture of toremifene, and Orion may terminate its obligation to assist us in obtaining and maintaining regulatory approval of toremifene at its election at any time. 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 further delay or prevent regulatory approval of toremifene.

Historically, we have relied on third party vendors for the manufacture of ostarine™ drug substance. However, Merck assumed primary manufacturing responsibilities for ostarine™ under our exclusive license and collaboration agreement with Merck, which agreement was terminated in March 2010. In connection with the termination of the agreement with Merck, Merck agreed to return to us all remaining inventory of ostarine™ drug substance. If this supply of ostarine™ becomes unusable or if we are unsuccessful in identifying a contract manufacturer or negotiating a manufacturing agreement on a timely basis for our ostarine™ or other SARM product candidates supply needs, we could experience a further delay in conducting any additional clinical trials of ostarine™ or other SARM product candidates. 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 the relationship with Orion for toremifene, or to do so at an acceptable cost, or other suppliers fail to meet our requirements for ostarine™ or other SARM product candidates for any reason, we would be required to obtain alternate suppliers. Any inability to obtain alternate suppliers, including an inability to obtain approval from the FDA of an alternate supplier, would delay or prevent the clinical development and commercialization of these product candidates.

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

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

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party because of factors beyond our control;
- the possible termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us;
- drug product supplies not meeting the requisite requirements for clinical trial use; and
- the possible exercise by Orion of its right to terminate its obligation to supply us with toremifene, which it may do at its election at any time.

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, Ipsen and/or our potential future collaborators may develop may compete with other product candidates and products for access to manufacturing facilities. For example, the active pharmaceutical ingredient in our toremifene 80 mg and toremifene 20 mg product candidates is also the active pharmaceutical ingredient in FARESTON®. Further, Orion has agreed to supply toremifene tablets to Ipsen for clinical trials and commercial supply in its licensed territory. Orion also manufactures toremifene for third parties for sale outside the United States for the treatment of metastatic breast cancer in postmenopausal women.

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

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

Risks Related to Our Intellectual Property

If we lose our licenses from the University of Tennessee Research Foundation, or UTRF, we may be unable to continue a substantial part of our business.*

We have licensed intellectual property rights and technology from UTRF used in a substantial part of our business. These license agreements may be terminated by UTRF if we are in breach of our obligations under, or fail to perform any terms of, the agreement and fail to cure that breach. If any of these agreements were terminated, then we may lose our rights to utilize the technology and intellectual property covered by that agreement to market, distribute and sell our licensed products, which may prevent us from continuing a substantial part of our business and may result in a serious adverse effect on our financial condition, results of operations and any prospects for growth. Additionally, the termination of our UTRF license for chemoprevention of prostate cancer could lead to a termination of our license and collaboration agreement with Ipsen, which would result in a loss of any potential milestone or royalty payments from Ipsen related to the high grade PIN indication and could impact the rights and benefits we are to receive from Ipsen on account of the ADT indication.

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 result in issued patents or result in patents with narrow or unenforceable claims, or if we are prevented from asserting that the claims of an issued patent cover a product of a third party, we may be subject to competition from third parties with products with the same active pharmaceutical ingredients as our product candidates.*

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

Our rights to certain patent applications relating to SARM compounds that we have licensed from UTRF are subject to the terms of UTRF's inter-institutional agreements with The Ohio State University, or OSU, and our rights to future related improvements in some instances are subject to UTRF's exercise of exclusive options under its agreements with OSU for such improvements. In addition, under the terms of some of our agreements with diagnostic companies to which we provided clinical samples from our clinical trials of toremifene 20 mg, we will not obtain any intellectual property rights in any of their developments, including any test developed to detect high grade PIN or prostate cancer.

Even if our product candidates and the methods for treating patients for prescribed indications using these product candidates are covered by valid and enforceable patents and have claims with sufficient scope and support in the specification, the patents will provide protection only for a limited amount of time. For example, the patent that we have licensed from Orion covering the composition of matter of toremifene has expired in the United States and abroad. As a result, we will need to rely primarily on the protection afforded by method of use patents relating to the use of toremifene for the relevant prescribed indications that have been issued or may be issued from our owned or licensed patent applications. Also, within its licensed territories, Ipsen may need to rely primarily on the protection afforded by marketing and data exclusivity for the toremifene products that may be sold within the respective territory. To date, many of our applications for method of use patents filed for toremifene outside of the United States are still pending and have not yielded issued patents. Loss of marketing and data exclusivity for any toremifene products that may be commercialized within the territories licensed to Ipsen could adversely affect Ipsen's ability to successfully commercialize these products.

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 non-infringing 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 sales of toremifene 80 mg and toremifene 20 mg tablets if approved for commercial sale, and could lead to pricing pressure if such products become available at competitive prices and in dosages that are appropriate for the indications for which we and Ipsen may continue to develop toremifene.*

In all countries in which we hold or have licensed rights to patents or patent applications related to toremifene, the composition of matter patents we license from Orion have expired. As a result, we will need to rely primarily on the protection afforded by method of use patents. Our method of use patents may not protect toremifene from the risk of off-label sale or use of other toremifene products in place of toremifene 80 mg and toremifene 20 mg tablets if approved for commercial sale. 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 other toremifene products may adversely affect our or Ipsen's ability to generate revenue from the sale of toremifene 80 mg and 20 mg tablets if we continue their development and they are approved for commercial sale.

Even in the event that patents are issued from our pending method of use patent applications, 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 method of use patents issuing from pending patent applications, even though these other toremifene products would not have been approved for those uses, and in most cases, the physician would not be liable for contributing to the infringement of our patents or potential 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 toremifene for the indications for which we and Ipsen may continue to develop 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 toremifene in the countries outside of the United States where these applications are currently pending, we would not have as extensive patent coverage to prevent competitors from marketing and selling generic versions of toremifene at doses and in formulations equivalent to toremifene 80 mg and toremifene 20 mg tablets for the indications covered by our pending method of use patent applications. Also, regulatory authorities may not recognize marketing and data exclusivity for toremifene in the territory we licensed to Ipsen under our collaboration for the treatment of prostate cancer and estrogen deficiency side effects resulting from ADT. If generic versions of toremifene are able to be sold in countries within the territory we licensed to Ipsen for the indications for which Ipsen could potentially market toremifene, the royalties to be paid to us by Ipsen will be reduced if the total generic sales exceed a certain threshold for a certain period of time.

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 toremifene for human uses outside the United States.

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

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

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, development, and manufacture and process synthesis 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, synthesis, commercialization, formulation or use of our product candidates. In addition, the production, manufacture, synthesis, 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, Ipsen and/or any potential future collaborators 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 that it does not infringe, which may not be possible or could require substantial funds and time.

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

Risks Related to Regulatory Approval of Our Product Candidates

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

Our product candidates and the activities associated with their development and commercialization are subject to comprehensive regulation by the FDA, 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 or any collaborator from commercializing the product candidate. We have not received regulatory approval to market any of our product candidates in any jurisdiction, and we do not expect to obtain FDA or any other regulatory approvals to market any of our product candidates in the near future, if at all. In addition, we will not receive a substantial majority of the milestone payments provided under our collaboration and license agreement with Ipsen for our toremifene 20 mg product candidate or any royalty payments associated with either our toremifene 80 mg or toremifene 20 mg product candidates if we and/or Ipsen determine to discontinue the development of toremifene or, if such development continues, if Ipsen is unable to obtain the necessary regulatory approvals to commercialize toremifene within its licensed territory. The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved.

Changes in the regulatory approval policy during the development period, changes in or the enactment of additional regulations or statutes, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. For example, the FDA announced in 2008 that, due to staffing and resource limitations, it has given its managers discretion to miss certain timing goals for completing reviews of NDAs set forth under the Prescription Drug User Fee Act, or PDUFA. Although the FDA has since publicly expressed a recommitment to meeting PDUFA deadlines, it remains unclear whether and to what extent the FDA will adhere to PDUFA deadlines in the future. If the FDA were to miss a PDUFA timing goal for one of our product candidates, the development and commercialization of the product candidate could be delayed. In addition, the Food and Drug Administration Amendments Act of 2007, or the FDA Amendments Act, which was enacted in September 2007, expands the FDA's authority to regulate drugs throughout the product life cycle, including enhanced authority to require post-approval studies and clinical trials. Other proposals have been made to impose additional requirements on drug approvals, further expand post-approval requirements and restrict sales and promotional activities. This new legislation, and the additional proposals if enacted, may make it more difficult or burdensome for us or our potential future collaborators to obtain approval of our product candidates. 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 approval may also impose risk evaluation mitigation strategies, or REMS, on a product if the FDA believes there is a reason to monitor the safety of the drug in the market place. REMS may include requirements for additional training for health care professionals, safety communication efforts and limits on channels of distribution, among other things. The sponsor would be required to evaluate and monitor the various REMS activities and adjust them if need be. 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, in October 2009, we received a Complete Response Letter from the FDA regarding our NDA for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT notifying us that the FDA would not approve our NDA in its present form as a result of certain clinical deficiencies identified in the Complete Response Letter. As a result, FDA approval of toremifene 80 mg, if it occurs, will be substantially delayed. In addition, we completed our Phase III clinical trial of toremifene 80 mg to reduce fractures and treat other estrogen deficiency side effects of ADT in men with prostate cancer under a Special Protocol Assessment, or SPA, with the FDA. A SPA is designed to facilitate the FDA's review and approval of drug products by allowing the FDA to evaluate the proposed design and size of clinical trials that are intended to form the primary basis for determining a drug product's efficacy and safety. If agreement is reached with the FDA, a SPA documents the terms and conditions under which the design of the subject trial will be adequate for submission of the efficacy and human safety portion of a NDA. However, there are circumstances under which we may not receive the benefits of a SPA, notably if the FDA subsequently identifies a substantial scientific issue essential to determining the product's safety or efficacy, and we may be required to conduct significant additional development in order to obtain regulatory approval notwithstanding a SPA with the FDA. For example, even though our Phase III clinical trial of toremifene 80 mg to reduce fractures in men with prostate cancer on ADT was completed under a SPA, we were unable to obtain approval of our NDA for toremifene 80 mg that we submitted in December 2008. 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 submit an application to 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, including toremifene 80 mg in the near future, if at all. In October 2009, we received a Complete Response Letter from the FDA regarding our NDA for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT identifying two deficiencies in our application and requesting that clinical trials be conducted to address the deficiencies. Furthermore, it is not anticipated that Ipsen will receive the appropriate regulatory approvals to market toremifene within its licensed territory any sooner than we will achieve regulatory approval in the United States, and it likely will be thereafter. The inability to obtain FDA approval or approval from comparable authorities in other countries for our product candidates would prevent us, Ipsen, or any potential future collaborators from commercializing these product candidates in the United States or other countries. See the section entitled "Business — Government Regulation" of our Annual Report on Form 10-K, filed with the SEC on March 15, 2010, for additional information regarding risks associated with marketing approval, as well as risks related to post-approval requirements.

Risks Related to Commercialization

The commercial success of any products that we, Ipsen, and/or any potential future collaborators may develop, including any toremifene products, will depend upon the market and the degree of market acceptance among physicians, patients, healthcare payors and the medical community.*

Any products that we, Ipsen, and/or any potential future collaborators 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 or receive royalties to the extent we currently anticipate, 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:

- efficacy and safety results in clinical trials;
- the prevalence and severity of any side effects;

- potential advantages over alternative treatments;
- whether the products we commercialize remain a preferred course of treatment;
- 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.

As part of our effort to complete the requirements for the submission of applications for regulatory approval to commercialize toremifene 80 mg and toremifene 20 mg, we have conducted a number of studies of toremifene in addition to our clinical trials, including a Thorough QT study (toremifene 80 mg and toremifene 20 mg), a bioequivalence study (toremifene 80 mg), a series of drug-drug interaction studies (toremifene 80 mg and toremifene 20 mg), and a semen quality study (toremifene 20 mg) to assess the effect of toremifene. The results of the Thorough QT study of 250 healthy male volunteers, with 5 parallel cohorts receiving 20 mg, 80 mg or 300 mg doses of toremifene, moxifloxacin, or placebo, showed that toremifene prolonged the QT interval in a dose dependent manner. The mean change in QTcB (a measurement of QT interval corrected by Bazett's formula) from baseline relative to placebo for toremifene 20 mg was 5.79 milliseconds, for toremifene 80 mg, it was 22.43 milliseconds, and for moxifloxacin, it was 8.83 milliseconds. Since we market FARESTON® in the United States under a license agreement with Orion, we notified the FDA of the Thorough QT study results and have proposed modifications to the FARESTON® label in the United States. FDA action on the proposed label changes is pending. Separately, Orion recommended label changes to the European Medicines Agency, or EMEA. In January 2009, the EMEA recommended that the FARESTON® label within the European Union reflect that toremifene should not be given to patients at risk of prolonged QT intervals or other certain heart problems. The results of these completed studies were included as a part of the NDA submission to the FDA for our toremifene 80 mg product candidate to reduce fractures in men with prostate cancer on ADT and will be used to update the label for FARESTON®. The study results could lead to the inclusion of restrictions, limitations and/or warnings in the label of FARESTON® or an approved toremifene product candidate, which may adversely affect the marketability of the product or limit the patients to whom the product is prescribed.

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

FARESTON® is currently our only marketed product. FARESTON® is indicated for the treatment of metastatic breast cancer in postmenopausal women. FARESTON® competes against tamoxifen, fulvestrant, and several aromatase inhibitors, including anastrozole, letrozole, and exemestane, for hormonal treatment of breast cancer. Sales of pharmaceuticals for breast cancer in the SERM class have declined in recent years as aromatase inhibitors have gained market share and we believe this trend will continue. Further, the branded competitors have greater resources and generic competitors are preferred by insurers. Continued sales of FARESTON® also could be impacted by many other factors. The occurrence of one or more of the following risks may cause sales of FARESTON® to decline more than we currently anticipate:

- the loss of the availability of Orion's website to market FARESTON®, which is an important source of advertising;
- the loss of one or more of our three largest wholesale drug distributors, which together accounted for approximately 96% of our product sales of FARESTON® for the six months ended June 30, 2010;
- any restrictions, limitations, and/or warnings added to the FARESTON® label as a result of our studies of toremifene, including a Thorough QT study and drug interaction studies, or otherwise;
- 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 introduction of generic toremifene products that compete with FARESTON® for the treatment of breast cancer; and
- the loss of Orion, upon which we rely as a single source, as our supplier of FARESTON®.

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

We have a limited number of people in the Company to undertake the sales, marketing and distribution of pharmaceutical products. There are risks involved in expanding our own sales and marketing capabilities, as well as entering into arrangements with third parties to perform these services. We would be relying on Ipsen to market and distribute our toremifene product candidates if their development continues and they are approved for commercial sale through Ipsen's established sales and marketing network within its licensed territory. If our collaboration and license agreement with Ipsen is terminated for any reason, our ability to sell any of our toremifene product candidates that may be approved for commercial sale in Ipsen's licensed territory would be adversely affected, and we may be unable to develop or engage an effective sales force to successfully market and sell such toremifene product candidates in Ipsen's licensed territory. Currently, we do not have a partner outside of Ipsen's licensed territory and our success in regions other than Ipsen's licensed territory may be dependent on our ability to find suitable partners in other regions of the world. 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, Ipsen, and/or any potential future collaborators are unable to obtain reimbursement or experience a reduction in reimbursement from third-party payors for products we sell, our revenues and prospects for profitability will suffer.*

Sales of products developed by us, Ipsen, and/or any potential future collaborators are dependent on the availability and extent of reimbursement from third-party payors. Changes in the reimbursement policies of these third-party payors that reduce reimbursements for FARESTON® and any other products that we, Ipsen and/or any potential future collaborators may develop and sell could negatively impact our future operating and financial results.

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 established comprehensive Medicare coverage and reimbursement of prescription drugs under Medicare Part D. The prescription drug program established by this legislation may have the effect of reducing the prices that we, Ipsen, or any potential future collaborators are able to charge for products we, Ipsen, and/or any potential future collaborators develop and sell through the program. This 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, Ipsen, and/or any potential future collaborators may develop or to lower the amount that they pay. State Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization for use of drugs where supplemental rebates are not provided.

In March 2010, the United States Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act. This health care reform legislation will increase the number of individuals who receive health insurance coverage and will close a gap in drug coverage under Medicare Part D as established in 2003. However, the newly-enacted legislation also implements cost containment measures that could adversely affect our revenues. These measures include increased drug rebates under Medicaid starting in 2010 for brand name prescription drugs, such as FARESTON®, and extension of these rebates to Medicaid managed care, which would reduce the amount of net reimbursement received for FARESTON® or any other products that we, Ipsen, and/or any potential future collaborators may develop and sell. Also effective for 2010, the legislation extends 340B discounted pricing on outpatient drugs to children's hospitals, critical access hospitals, and rural health centers, which extension reduces the amount of reimbursement received for drugs purchased by these new 340B-covered entities.

Additional provisions of the health care reform legislation, which become effective in 2011, may negatively affect our revenues and prospects for profitability in the future. Along with other pharmaceutical manufacturers and importers of brand name prescription drugs, we will be assessed a fee based on our proportionate share of sales of brand name prescription drugs to certain government programs, including Medicare and Medicaid. As part of the health care reform legislation's provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the "donut hole"), we will also be required to provide a 50% discount on brand name prescription drugs, including FARESTON®, sold to beneficiaries who fall within the donut hole.

In the aftermath of the 2010 health care reform legislation, private health insurers and managed care plans are likely to continue challenging the prices charged for medical products and services, and many of these third-party payors may 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, Ipsen, and/or any potential future collaborators may develop or sell. These cost-control initiatives could decrease the price we might establish for products that we, Ipsen, or any potential future collaborators may develop or sell, which would result in lower product revenues or royalties payable to us.

Similar cost containment initiatives exist in countries outside of the United States, particularly in the countries of the European Union, where the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to twelve months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we, Ipsen, or any potential future collaborators may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our, Ipsen's or a potential future collaborators' commercialization efforts. 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, Ipsen, and/or any potential future collaborators may develop or sell. Cost-control initiatives could decrease the price we might establish for products that we, Ipsen, or any potential future collaborators may develop or sell, which would result in lower product revenues or royalties payable to us.

Another development that could affect the pricing of drugs would be 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 from countries where the drugs are sold at a lower price than in the United States. Provisions allowing for the direct reimportation of drugs under certain circumstances were not included in the 2010 health care reform legislation, but could be revisited in the future. If legislation or regulations were passed allowing the reimportation of drugs, they could decrease the price we, Ipsen, or any potential future collaborators receive for any products that we, Ipsen, and/or any potential future collaborators may develop, negatively affecting our revenues and prospects for profitability.

Health care reform measures could hinder or prevent our product candidates' commercial success.*

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting health care reform, as evidenced by the recent enactment in the United States of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act. It is likely that federal and state legislatures within the United States and foreign governments will continue to consider changes to existing health care legislation. These changes adopted by governments may adversely impact our business by lowering the price of health care products in the United States and elsewhere.

We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations or existing laws, regulations or decisions, related to health care availability, method of delivery or payment for health care products and services, or sales, marketing and pricing practices could negatively impact our business, operations and financial condition.

If product liability lawsuits are brought against us, we may 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 our commercial sale of FARESTON® and the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any product that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

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

We have product liability insurance that covers our clinical trials and commercial products up to a $25 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, Ipsen, and/or any potential future collaborators may develop, our commercial opportunity will be reduced or eliminated.*

We face competition from commercial pharmaceutical and biotechnology enterprises, 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, Ipsen, and/or any potential future collaborators 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 any ability to commercialize our product candidates.

Various products are currently marketed or used off-label for some of the diseases and conditions that we are targeting in our pipeline, and a number of companies are or may be developing new treatments. These product uses, as well as promotional efforts by competitors and/or clinical trial results of competitive products, could significantly diminish any ability to market and sell any products that we, Ipsen, and/or any potential future collaborators may develop. For example, although there are no products that have been approved by the FDA to reduce fractures or treat estrogen deficiency related side effects of ADT, we are aware of a number of drugs, including drugs marketed by Eli Lilly & Co. (Evista®), Merck (Fosamax®), Sanofi-Aventis and Warner Chilcott (Actonel®), Pfizer Inc. (Effexor®), Boehringer Ingelheim (Catapres®), Novartis (Zometa®) and generic megestrol acetate, that are prescribed to treat single side effects of ADT; that external beam radiation and tamoxifen are used to treat breast pain and enlargement, or gynecomastia. Prolia™ (denosumab), a monoclonal antibody developed by Amgen, is approved in the United States, Europe and Australia for the treatment of osteoporosis in postmenopausal women and additionally in Europe for the treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures, and is under regulatory review for cancer specific indications including prostate cancer. Testosterone and other anabolic agents are used to treat involuntary weight loss in patients who have acute muscle loss. There are other SARM product candidates in development that may compete with our product candidates. Pfizer Inc., Eli Lilly & Co., and Amgen have myostatin inhibitors in development that may compete with ostarine™ if approved for commercial sale. In addition, Cytokinetics, Inc. is developing a troponin activator with a muscle specific mechanism in a Phase I study. Moreover, there are other categories of drugs in development, including ghrelin receptor agonists and growth hormone secretagogues that may have some muscle activity. Other appetite stimulants such as megestrol acetate and dronabinol are also used off-label for cancer cachexia. Competition could result in reduced sales and pricing pressure on our product candidates, if approved, which in turn would reduce our ability to generate revenue and have a negative impact on our results of operations.

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

Risks Related to Employees and Growth

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

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

In December 2009, we announced a reduction of approximately 26% of our workforce in order to reduce our operating expenses in connection with the receipt of the Complete Response Letter regarding our NDA for toremifene 80 mg and the associated delay in the potential regulatory approval of toremifene 80 mg. This and any future workforce reductions may negatively affect our ability to retain or attract talented employees.

We will need to hire additional employees in order to commercialize our product candidates in the future. 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 commercialize our product candidates in the future, we will need to expand the number of our managerial, operational, financial and other employees and the competition for qualified personnel in the biotechnology field is intense.

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

Risks Related to Our Common Stock

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

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

- the results of our discussions with the FDA regarding the actions necessary to address the deficiencies identified by the FDA in the Complete Response Letter we received in October 2009 regarding our NDA for toremifene 80 mg, and any related announcements by us and/or Ipsen with respect to the same;
- announcements by us and/or Ipsen with respect to the continued development of toremifene, including any announcements that either we or Ipsen have determined to discontinue the development of toremifene 80 mg or toremifene 20 mg or both;
- adverse results or delays in our clinical trials;

- the timing of achievement of, or failure to achieve, our, Ipsen's and any potential future collaborators' 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, including regulatory actions requiring or leading to restrictions, limitations and/or warnings in the label of FARESTON® or an approved toremifene product candidate;
- the commercial success of any product approved by the FDA or its foreign counterparts;
- developments with respect to our collaboration with Ipsen, including any determination by Ipsen to terminate the collaboration;
- introductions or announcements of technological innovations or new products by us, Ipsen, potential future collaborators, or our competitors, and the timing of these introductions or announcements;
- market conditions for equity investments in general, or the biotechnology or pharmaceutical industries in particular;
- the terms and timing of any future collaborative, licensing or other arrangements that we may establish;
- regulatory developments in the United States and foreign countries;
- changes in the structure or reimbursement policies of health care payment systems;
- any intellectual property infringement lawsuit involving us;
- actual or anticipated fluctuations in our results of operations;
- 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. Recently, the financial markets have faced almost unprecedented turmoil, resulting in a decline in investor confidence and concerns about the proper functioning of the securities markets, which decline in general investor confidence has resulted in depressed stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. 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 executive officers, directors and largest stockholders have the ability to control all matters submitted to stockholders for approval.*

As of June 30, 2010, our executive officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 66.0% of our outstanding common stock, and our executive officers and directors alone beneficially owned approximately 48.9% of our outstanding common stock. As a result, these stockholders, acting together, may or will have the ability 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.

If there are substantial sales of our common stock, the market price of our common stock could drop substantially, even if our business is doing well.*

For the 12-month period ended June 30, 2010, the average daily trading volume of our common stock on the NASDAQ Global Market was 406,412 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 June 30, 2010, we had 36,420,901 shares of common stock outstanding.

Moreover, J.R. Hyde, III, and Oracle Investment Management, Inc., two of our largest stockholders, and their affiliates, have rights, subject to some conditions, to require us to file registration statements covering the approximately 10.8 million shares of common stock they hold in the aggregate which are subject to registration rights or to include these shares in registration statements that we may file for ourselves or other stockholders. If any of these large stockholders were to sell large blocks of shares in a short period of time, the market price of our common stock could drop substantially.

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: August 9, 2010

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

Date: August 9, 2010

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

EXHIBIT INDEX

Number	Description
3.1	Restated Certificate of Incorporation of GTx, Inc.(1)
3.2	Amended and Restated Bylaws of GTx, Inc.(2)
4.1	Reference is made to Exhibits 3.1 and 3.2
4.2	Specimen of Common Stock Certificate(3)
4.3	Amended and Restated Registration Rights Agreement between Registrant and Oracle Partners, L.P. dated August 7, 2003(3)
4.4	Amended and Restated Registration Rights Agreement between Registrant and J. R. Hyde, III dated August 7, 2003(3)
4.5	Consent, Waiver and Amendment between the Registrant and Oracle Partners, L.P., Oracle Investment Management, Inc. and Oracle Institutional Partners, L.P. dated November 29, 2007(4)
4.6	Consent, Waiver and Amendment between Registrant and J. R. Hyde, III and Pittco Associates, L.P. dated December 3, 2007(4)
12.1*	Statement of Computation of Deficiency of Earnings Available to Cover Fixed Charges
31.1*	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a)
31.2*	Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a)
32.1*	Certification of Chief Executive Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350) (5)
32.2*	Certification of Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350) (5)

* Filed herewith.

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

(2) Filed as the like numbered Exhibit to the Registrant's Current Report on Form 8-K (File No. 000-50549), filed with the SEC on July 26, 2007, 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), initially filed with the SEC on October 15, 2003, as amended, and incorporated herein by reference.

(4) Filed as the like numbered Exhibit to the Registrant's registration statement on Form S-3 (File No. 333-148321), filed with the SEC on December 26, 2007, and incorporated herein by reference.

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

Exhibit 12.1

GTx, Inc.
Computation of Ratio (Deficiency) of Earnings Available to Cover Fixed Charges

	Six Months Ended June 30, 2010	Year Ended December 31, 2009	2008	2007	2006	2005
Income (loss):						
Pretax income (loss) from continuing operations (1)	$ 31,398	$ (46,494)	$ (51,780)	$ (40,359)	$ (35,510)	$ (36,839)
Fixed charges (from below)	62	104	89	35	32	32
Total income (loss)	31,460	(46,390)	(51,691)	(40,324)	(35,478)	(36,807)
Fixed charges:						
Interest expense	6	—	—	—	—	—
Estimated interest portion of rent expenses	56	104	89	35	32	32
Total fixed charges	62	104	89	35	32	32
Coverage deficiency	$ —	$ (46,494)	$ (51,780)	$ (40,359)	$ (35,510)	$ (36,839)
Ratio of earnings to fixed charges	507.4	—	—	—	—	—

(1) Pretax income from continuing operations for the six months ended June 30, 2010 includes the recognition as collaboration revenue of all of the remaining $49.9 million of unamortized revenue that was deferred as of December 31, 2009 related to the Company's global exclusive license and collaboration agreement (the "Collaboration Agreement") with Merck & Co., Inc. ("Merck"), as well as the final payment of $5.0 million of research and development cost reimbursement that will be received under the Collaboration Agreement from Merck in December 2010, the accelerated recognition of which resulted from the termination of the Collaboration Agreement in March 2010.

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: August 9, 2010

/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: August 9, 2010

/s/ Mark E. Mosteller

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

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U. S. C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of GTx, Inc. (the "Company") on Form 10-Q for the three months ended June 30, 2010, 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, to the best of my knowledge:

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: August 9, 2010

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

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

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U. S. C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of GTx, Inc. (the "Company") on Form 10-Q for the three months ended June 30, 2010, 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, to the best of my knowledge:

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: August 9, 2010

/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.