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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2011

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 May 3, 2011, 51,719,187 shares of the registrant's Common Stock were outstanding.

GTx, INC.
FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2011
INDEX

PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2011 (unaudited)	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 42,790	$ 58,181
Short-term investments	6,575	450
Accounts receivable, net	680	683
Inventory	164	171
Prepaid expenses and other current assets	1,666	875
Total current assets	51,875	60,360
Property and equipment, net	1,764	2,040
Intangible and other assets, net	223	1,850
Total assets	$ 53,862	$ 64,250
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 658	$ 848
Accrued expenses and other current liabilities	2,576	3,112
Deferred revenue — current portion	—	1,345
Total current liabilities	3,234	5,305
Deferred revenue, less current portion	—	6,721
Other long-term liabilities	246	497
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value: 60,000,000 shares authorized; 51,719,187 shares issued and outstanding at March 31, 2011 and December 31, 2010	52	52
Additional paid-in capital	405,805	404,555
Accumulated deficit	(355,475)	(352,880)
Total stockholders' equity	50,382	51,727
Total liabilities and stockholders' equity	$ 53,862	$ 64,250

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

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

	Three Months Ended March 31,	
	2011	**2010**
Revenues:		
Product sales, net	$ 1,229	$ 799
Collaboration revenue	8,066	55,778
Total revenues	9,295	56,577
Costs and expenses:		
Cost of product sales	205	151
Research and development expenses	7,303	7,650
General and administrative expenses	4,684	4,509
Total costs and expenses	12,192	12,310
(Loss) income from operations	(2,897)	44,267
Other income, net	302	72
Net (loss) income	$ (2,595)	$ 44,339
Net (loss) income per share:		
Basic and diluted	$ (0.05)	$ 1.22
Weighted average shares used in computing net (loss) income per share:		
Basic and diluted	51,719,187	36,420,901

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

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

	Three Months Ended March 31,	
	2011	**2010**
Cash flows from operating activities:		
Net (loss) income	$ (2,595)	$ 44,339
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation and amortization	318	438
Share-based compensation	1,199	1,664
Directors' deferred compensation	51	50
Deferred revenue amortization	(8,066)	(50,778)
Impairment of intangible asset	1,598	—
Foreign currency transaction (gain) loss	—	(61)
Changes in assets and liabilities:		
Accounts receivable, net	3	(113)
Inventory	7	50
Prepaid expenses and other current assets	(788)	(5,790)
Accounts payable	(190)	(442)
Accrued expenses and other long term liabilities	(766)	398
Net cash used in operating activities	(9,229)	(10,245)
Cash flows from investing activities:		
Purchase of property and equipment	(16)	(83)
Purchase of short-term investments, held to maturity	(6,125)	(3,959)
Proceeds from maturities of short-term investments, held to maturity	—	3,675
Net cash used in investing activities	(6,141)	(367)
Cash flows from financing activities:		
Payments on capital lease and financed equipment obligations	(21)	(26)
Net cash used in financing activities	(21)	(26)
Net decrease in cash and cash equivalents	(15,391)	(10,638)
Cash and cash equivalents, beginning of period	58,181	40,219
Cash and cash equivalents, end of period	$ 42,790	$ 29,581

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 of cancer, cancer supportive care, and other serious medical conditions.

The Company is developing selective androgen receptor modulators ("SARMs"), including Ostarine™ (GTx-024). SARMs are a new class of drugs with the potential to prevent and treat muscle wasting in patients with cancer and other musculoskeletal wasting or muscle loss conditions including chronic sarcopenia (age related muscle loss). Additionally, the Company is developing Capesaris™ (GTx-758), a selective estrogen receptor alpha agonist, for first line treatment of advanced prostate cancer.

In December 2008, the Company submitted a New Drug Application ("NDA") for toremifene 80 mg, a selective estrogen receptor modulator ("SERM"), to reduce fractures in men with prostate cancer on androgen deprivation therapy ("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, which deficiencies could only be addressed by conducting an additional pivotal Phase III clinical trial of toremifene 80 mg. In March 2011, the Company reacquired full rights to its toremifene program following the termination by the Company and Ipsen Biopharm Limited ("Ipsen") of the collaboration and license agreement, which was entered into by the Company and Ipsen in September 2006 and amended in March 2010. During the second quarter of 2011, the Company decided to discontinue its toremifene 80 mg development program.

The Company markets FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of advanced 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, 2010. Operating results for the three months ended March 31, 2011 are not necessarily indicative of the results that may be expected for the entire fiscal year ending December 31, 2011.

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.

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

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 March 31, 2011 and December 31, 2010, the Company's accrual for product returns was $869 and $802, 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 former collaboration and license agreements. Revenues from the Company's prior collaboration and license agreements were recognized based on the performance requirements of the specific agreements. The Company analyzed 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, could have been separated or whether all of the deliverables must have been accounted for as a single unit of accounting. Revenues from milestone payments for which the Company had no continuing performance obligations were recognized upon achievement of the performance milestone, as defined in the related agreement, provided the milestone was substantive and a culmination of the earnings process had occurred. Performance obligations typically consisted 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 Ipsen in March 2011, the Company recognized collaboration revenue of $8,066 in the first quarter of 2011 as the Company has no further performance obligations. Additionally, the Company recognized collaboration revenue of $54,856 in the first quarter of 2010 due to the termination of the Company's license and collaboration agreement with Merck & Co., Inc. ("Merck") in March 2010. See Note 4, *Collaboration and License Agreements*, for further discussion. As of March 31, 2011, the Company had no ongoing collaborations for the development and commercialization of its product candidates.

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 affairs activities, quality assurance activities and license 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 March 31, 2011 and December 31, 2010, short-term investments consisted of certificates of deposit with original maturities of greater than three months and less than one year. As the Company has the positive intent and ability to hold the certificates of deposit until maturity, these investments have been classified as held to maturity investments and are stated at cost, which approximates fair value.

GTx, Inc.
NOTES TO THE CONDENSED FINANCIAL STATEMENTS
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Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in facts and circumstances are present, both internally and externally, that may indicate impairment of long-lived assets held for use. 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.

Based upon the Company's decision to discontinue toremifene 80 mg development and after analyzing future cash flows and estimates of fair market value from a market participant perspective, the Company determined that its toremifene 80 mg intangible asset was impaired and recorded an impairment charge of $1,598 during the three months ended March 31, 2011. The impaired intangible asset consisted of the unamortized portion of capitalized license fees paid to Orion Corporation ("Orion") related to the Company's toremifene 80 mg program. This license fee was paid under the amended and restated license and supply agreement for the Company's exclusive license from Orion to develop and commercialize toremifene-based products.

The impairment charge was included in research and development expenses in the condensed statement of operations for the three months ended March 31, 2011.

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 March 31, 2011 and December 31, 2010, 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, 2010.

Other Income, net

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

Subsequent Events

The Company has evaluated all events or transactions that occurred after March 31, 2011 up through the date the condensed financial statements were issued.

During the second quarter of 2011, the Company decided to discontinue its toremifene 80 mg development program. Based upon this decision, the Company determined that the intangible asset relating to the Company's toremifene 80 mg program was impaired. This intangible asset consisted of the unamortized portion of capitalized license fees paid to Orion related to the Company's toremifene 80 mg program. The Company considered this a recognizable subsequent event and, therefore, recorded an impairment charge of $1,598 for the three months ended March 31, 2011.

On May 6, 2011, the Company filed a Certificate of Amendment to the Company's Restated Certificate of Incorporation with the Secretary of State of the State of Delaware to increase the number of authorized shares of the Company's common stock, par value $0.001 per share, from 60,000,000 shares to 120,000,000 shares. The foregoing amendment was approved by the Company's stockholders at the Company's 2011 Annual Meeting of Stockholders held on May 5, 2011.

There were no other material recognizable or nonrecognizable subsequent events during the period evaluated.

GTx, Inc.
NOTES TO THE CONDENSED FINANCIAL STATEMENTS
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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, 2010.

The following table summarizes share-based compensation expense included within the condensed statements of operations for the three months ended March 31, 2011 and 2010:

	Three Months Ended March 31,	
	2011	2010
Research and development expenses	$ 509	$ 846
General and administrative expenses	741	868
Total share-based compensation	$ 1,250	$ 1,714

Share-based compensation expense recorded in the condensed statements of operations as general and administrative expense for the three months ended March 31, 2011 and 2010 included share-based compensation expense related to deferred compensation arrangements for the Company's non-employee directors of $51 and $50, 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 March 31,	
	2011	2010
Expected price volatility	65.0%	64.6%
Risk-free interest rate	2.5%	3.4%
Weighted average expected life in years	6.5 years	6.5 years

GTx, Inc.
NOTES TO THE CONDENSED FINANCIAL STATEMENTS
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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, 2010	4,430,495	$ 10.91
Options granted	1,309,500	2.65
Options forfeited or expired	(20,965)	10.82
Options outstanding at March 31, 2011	5,719,030	9.02

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. Weighted average options outstanding to purchase shares of common stock of 5,729,635 and 4,559,646 for the three months ended March 31, 2011 and 2010, 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.

4. Collaboration and License Agreements

University of Tennessee Research Foundation License Agreements

The Company and the University of Tennessee Research Foundation ("UTRF") have entered into 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. Under the SARM License Agreement, the Company is obligated to pay UTRF annual license maintenance fees, low single-digit royalties on net sales of products and mid single-digit royalties on sublicense revenues.

Additionally, the Company and UTRF had 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. In light of the Company's decision to discontinue further clinical development of toremifene 20 mg, the Company exercised its right to terminate the SERM License Agreement with UTRF during the first quarter of 2011.

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.

GTx, Inc.
NOTES TO THE CONDENSED FINANCIAL STATEMENTS
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In accordance with the terms of the Ipsen Collaboration Agreement, Ipsen paid the Company €23,000 as a license fee and expense reimbursement. In February 2008, the Company earned a milestone of €1,000 (approximately $1,482) with the achievement of the primary endpoint in the Company's completed pivotal Phase III clinical trial evaluating toremifene 80 mg to reduce fractures in men with prostate cancer on ADT. This amount was recognized as collaboration revenue in the first quarter of 2008. Under the Ipsen Collaboration Agreement, the Company recorded deferred revenue of $29,330 related to the Ipsen upfront license fee and expense reimbursement which was being amortized into revenue on a straight-line basis over the estimated ten year development period for toremifene in the European Territory.

In March 2011, the Company reacquired full rights to its toremifene program following the termination by the Company and Ipsen of the collaboration and license agreement, as amended (the "Amended Ipsen Collaboration Agreement"). In exchange for reacquiring all of Ipsen's rights under the Amended Ipsen Collaboration Agreement, the Company agreed to pay Ipsen a low single digit royalty on net sales of toremifene 80 mg in the United States if approved for commercial sale. During the three months ended March 31, 2011, the Company recognized as collaboration revenue all of the remaining $8,066 unamortized revenue that was deferred as of December 31, 2010. The Company recognized as collaboration revenue $922 for the three months ended March 31, 2010 from the amortization of the Ipsen deferred revenue.

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 December 2008, 2009 and 2010 as the first, second and third 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. 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 due under the terms of the Merck Collaboration Agreement in December 2010 for which the Company had no further performance obligation.

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 any future clinical trials we conduct will achieve similar results to clinical trials that we have successfully concluded;
- the timing, scope and anticipated initiation and completion of any future clinical trials that we may conduct;
- the timing of regulatory submissions and the timing, scope and anticipated outcome of related regulatory actions;
- our ability to establish and maintain potential new collaborative arrangements for the development and commercialization of our product candidates;
- 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 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, expenses, capital requirements and needs for additional financing, and our ability to obtain additional financing.

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 and the documents that we incorporate by reference in and have filed as exhibits to this Quarterly Report on Form 10-Q, completely and with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update any forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, even if new information becomes available in the future.

Overview

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 of cancer, cancer supportive care, and other serious medical conditions.

Business Highlights

We are developing selective androgen receptor modulators, or SARMs, a new class of drugs with the potential to prevent and treat muscle wasting in patients with cancer, and other musculoskeletal wasting or muscle loss conditions, including chronic sarcopenia (age related muscle loss). We have held End of Phase II meetings with the U.S. Food and Drug Administration, or FDA, to discuss our proposed Phase III clinical development of Ostarine™ (GTx-024) for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer. Based upon feedback from the FDA, we expect to initiate two pivotal Phase III clinical trials for this indication in the third quarter of 2011. We also intend to continue our pursuit of a strategic partnership or collaboration for the development and commercialization of SARMs, which includes Ostarine™ for the prevention and treatment of muscle wasting in patients with cancer, as well as other indications.

Additionally, we are developing Capesaris™ (GTx-758), a selective estrogen receptor, or ER, alpha agonist for first line treatment of advanced prostate cancer. In September 2010, we announced that in a Phase II, open label, pharmacokinetic and pharmacodynamic clinical trial in young healthy male volunteers, Capesaris™ suppressed serum total testosterone to castrate levels, increased serum sex hormone binding globulin, and reduced serum free testosterone, the form of testosterone which is available to prostate cancer cells for growth. Capesaris™ was well tolerated and no serious adverse events were reported in the study. We have met with the FDA and confirmed that the primary endpoint acceptable for approval for this indication is the maintenance of castrate levels of serum testosterone (less than 50ng/dL) from day 28 to day 364. In the second quarter of 2011, we plan to initiate a Phase IIb open label clinical trial evaluating Capesaris™ compared to Lupron Depot® (leuprolide acetate for depot suspension), a luteinizing hormone releasing hormone, or LHRH, agonist for first line treatment in men with advanced prostate cancer. We are also currently seeking a strategic partnership or collaboration for the development and commercialization of Capesaris™ for the treatment of advanced prostate cancer.

In December 2008, we submitted a New Drug Application, or NDA, for toremifene 80 mg, a selective estrogen receptor modulator, or SERM, to reduce fractures in men with prostate cancer on androgen deprivation therapy, or ADT, to the 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, which deficiencies could only be addressed by conducting an additional pivotal Phase III clinical trial of toremifene 80 mg. In March 2011, we reacquired full rights to our toremifene program following the termination by us and Ipsen Biopharm Limited, or Ipsen, of our collaboration and license agreement, which was entered into by us and Ipsen in September 2006 and amended in March 2010. We have evaluated the business case for toremifene 80 mg and concluded that we will discontinue our toremifene 80 mg development program. This decision was due to the expense and time required to conduct a second Phase III clinical trial, which the FDA has now confirmed must be conducted prior to the FDA considering toremifene 80 mg for marketing approval.

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

Financial Highlights

Our net loss for the three months ended March 31, 2011 was $2.6 million. Our net loss included the recognition of the remaining $8.1 million of deferred revenue due to the termination of our license and collaboration agreement with Ipsen and FARESTON® net product sales of $1.2 million. Additionally, research and development expenses for the three months ended March 31, 2011 included an impairment charge of $1.6 million related to our toremifene 80 mg intangible asset. We expect to incur significant operating losses in 2011 and for the foreseeable future as we continue our clinical development and research and development activities.

At March 31, 2011, we had cash, cash equivalents and short-term investments of $49.4 million, compared to $58.6 million at December 31, 2010. We estimate that our current cash, cash equivalents, and short-term investments, together with interest income and product revenue from the sale of FARESTON®, will be sufficient to meet our projected operating requirements for at least the next twelve months. We have based this estimate on our current business plan and assumptions that may prove to be wrong. We could utilize our available capital resources sooner than we currently expect, and we could need additional funding sooner than currently anticipated. We believe that our current cash resources, together with interest income and product revenue from the sale of FARESTON®, will be sufficient to enable us to initiate in 2011 our planned pivotal Phase III clinical trials of Ostarine™ for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer and to initiate and complete our planned Phase IIb clinical trial to evaluate Capesaris™ for first line treatment of advanced prostate cancer. To complete the two Phase III clinical trials we expect to initiate in 2011 for Ostarine™, we will need to obtain additional funding. Further, to conduct any additional clinical trials for our product candidates, we will need to obtain additional funding through partnerships and/or collaborations or the sale of our securities.

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 our research and development expenses for fiscal year 2011 to increase from fiscal year 2010 and to be primarily focused on the following:

- the continued clinical development of Ostarine™;
- the continued clinical development of Capesaris™; and
- the continued preclinical development of other potential 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:

Product Candidate/ Proposed Indication	Program	Clinical Development Phase	Status
Ostarine™			
Prevention and treatment of muscle wasting in patients with non-small cell lung cancer	SARM	Phase III	Plan to initiate two pivotal Phase III clinical trials in the third quarter of 2011 for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer.
Capesaris™			
First line treatment of advanced prostate cancer	Selective ER alpha agonist	Phase IIb	Plan to initiate a Phase IIb clinical trial in the second quarter of 2011 for first line treatment in men with advanced prostate cancer.

Sales and Marketing

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

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 expenses also include facility costs, insurance costs, 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 2011 to be relatively consistent with fiscal year 2010.

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, 2010 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 former collaboration and license agreements and was based on the performance requirements of the specific agreements. We analyzed 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, could have been separated or whether all of the deliverables must have been accounted for as a single unit of accounting. Cost reimbursements for research activities were recognized as collaboration revenue if amounts were determinable and collection of the related receivable was reasonably assured. Revenues from milestone payments for which we had no continuing performance obligations were recognized upon achievement of the performance milestone, as defined in the related agreement, provided the milestone was substantive and a culmination of the earnings process had occurred. Performance obligations typically consisted 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 used all of these factors in initially estimating the economic useful lives of our performance obligations, and we also continually monitored these factors for indications of appropriate revisions. We estimated the performance obligation period to be ten years for the development of toremifene under our former collaboration agreement with Ipsen. However, due to the termination of our license and collaboration with Ipsen in March 2011, we recognized as collaboration revenue all of the remaining $8.1 million unamortized revenue that was deferred as of December 31, 2010 in the first quarter of 2011. Additionally, 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 received from Merck & Co., Inc., or Merck, in December 2010 due to the termination of our license and collaboration agreement with Merck.

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 94% of our product sales of FARESTON® for the three months ended March 31, 2011. Based on this information and other factors, we estimate an accrual for product returns. At March 31, 2011 and December 31, 2010, our accrual for product returns was $869,000 and $802,000, respectively.

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 activities, 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 months ended March 31, 2011 included an impairment charge of $1.6 million related to the unamortized portion of capitalized license fees paid to Orion Corporation related to our toremifene 80 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 March 31, 2011 was $1.3 million, of which $509,000 and $741,000 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 March 31, 2010 was $1.7 million, of which $846,000 and $868,000 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 March 31, 2011 and 2010 was share-based compensation expense related to deferred compensation arrangements for our non-employee directors of $51,000 and $50,000, respectively. At March 31, 2011, the total compensation cost related to non-vested awards not yet recognized was approximately $11.2 million with a weighted average expense recognition period of 3.4 years.

Results of Operations

Three Months Ended March 31, 2011 and 2010

Revenues. Revenues for the three months ended March 31, 2011 were $9.3 million, as compared to $56.6 million for the same period of 2010. Revenues included net sales of FARESTON® marketed for the treatment of advanced metastatic breast cancer in postmenopausal women and collaboration income from Ipsen and Merck. During the three months ended March 31, 2011 and 2010, FARESTON® net product sales were $1.2 million and $799,000, respectively, while cost of products sales were $205,000 and $151,000, respectively. FARESTON® net product sales for the three months ended March 31, 2011 increased from the same period in the prior year due primarily to an increase in the sales price of FARESTON®. Collaboration income was $8.1 million for the three months ended March 31, 2011, and $55.8 million for the three months ended March 31, 2010. As a result of the termination of our license and collaboration agreement with Ipsen in March 2011, we recognized as collaboration revenue all of the remaining $8.1 million of unamortized revenue that was deferred as of December 31, 2010. Collaboration revenue for the three months ended March 31, 2010 was $55.8 million due to the termination of the license and collaboration agreement with Merck and the subsequent recognition of 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 of research and development activities cost reimbursement. Collaboration revenue for the three months ended March 31, 2010 also included approximately $922,000 from the amortization of deferred revenue from Ipsen.

Research and Development Expenses. Research and development expenses decreased 5% to $7.3 million for the three months ended March 31, 2011 from $7.7 million for the three months ended March 31, 2010. Research and development expenses for the three months ended March 31, 2011 included an impairment charge of $1.6 million related to our toremifene 80 mg intangible asset. This amount is included in "Other research and development" in the table below. The decrease in "Other research and development" during the three months ended March 31, 2011 compared to the three months ended March 31, 2010 was due to the completion of the toremifene 20 mg Phase III clinical trial in early 2010. 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. Research and development expenses for past periods may not be indicative of future periods.

Product Candidate/ Proposed Indication	**Program**	**Three Months Ended March 31,**		**Increase/ Decrease**
		2011	**2010**	
		(in thousands)		
Ostarine™				
Prevention and treatment of muscle wasting in patients with non-small cell lung cancer	**SARM**	$ 1,016	$ 960	$ 56
Capesaris™				
First line treatment of advanced prostate cancer	**Selective ER alpha agonist**	2,314	1,619	695
Other research and development		3,973	5,071	(1,098)
Total research and development expenses		$ 7,303	$ 7,650	$ (347)

General and Administrative Expenses. General and administrative expenses increased during the three months ended March 31, 2011 to $4.7 million from $4.5 million for the three months ended March 31, 2010. This increase was primarily due to increased marketing expenses related to promotional efforts for FARESTON®.

Liquidity and Capital Resources

At March 31, 2011, we had cash, cash equivalents and short-term investments of $49.4 million, compared to $58.6 million at December 31, 2010. Net cash used in operating activities was $9.2 million and $10.2 million for the three months ended March 31, 2011 and 2010, respectively, and resulted primarily from funding our operations for the periods.

Net cash used in investing activities was $6.1 million and $367,000 for the three months ended March 31, 2011 and 2010, respectively. Net cash used in investing activities for the three months ended March 31, 2011 was primarily for the purchase of short-term investments of approximately $6.1 million. Net cash used in investing activities for the three months ended March 31, 2010 was primarily for the purchase of short-term investments of approximately $4.0 million and the purchase of information technology equipment and research and development equipment of approximately $83,000. This was reduced by the maturities of short-term investments of approximately $3.7 million.

Net cash used in financing activities was $21,000 and $26,000 for the three months ended March 31, 2011 and 2010, respectively, and was related to payments on capital lease and financed equipment obligations.

We estimate that our current cash, cash equivalents, and short-term investments, together with interest income and product revenue from the sale of FARESTON®, will be sufficient to meet our projected operating requirements for at least the next twelve months. We have based this estimate on our current business plan and assumptions that may prove to be wrong. We could utilize our available capital resources sooner than we currently expect, and we could need additional funding sooner than currently anticipated. We believe that our current cash resources, together with interest income and product revenue from the sale of FARESTON®, will be sufficient to enable us to initiate in 2011 our planned pivotal Phase III clinical trials of Ostarine™ for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer and to initiate and complete our planned Phase IIb clinical trial to evaluate Capesaris™ for first line treatment of advanced prostate cancer. To complete the two Phase III clinical trials we expect to initiate in 2011 for Ostarine™, we will need to obtain additional funding. Further, to conduct any additional clinical trials for our product candidates, we will need to obtain additional funding through partnerships and/or collaborations or the sale of our securities.

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 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 anticipated future clinical trials, other research and development activities, and potential commercialization activities. Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical trials and other research and development activities, including our currently-planned clinical trials of Ostarine™ and Capesaris™;
- the terms and timing of any potential future collaborative, licensing and other arrangements that we may establish;
- future clinical trial results;
- 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;
- the amount and timing of any licensing fees, milestone payments and royalty payments from potential future collaborators, if any;
- 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 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.

We do not currently have any commitments for future external funding and until we can generate a sufficient amount of product revenue, which we may never do, we expect to finance future cash needs through public or private equity offerings, debt financings or collaboration and licensing arrangements, or a combination of the above, 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®. 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. If we are unable to raise additional funds when we need them, we may need to further reduce our expenditures, perhaps significantly, to preserve our cash. Cost-cutting measures that we 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 potential future collaboration and licensing arrangements, 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 uncertain financial condition, the outcomes of our currently-planned clinical trials of Ostarine™ and Capesaris™ and/or current economic conditions, including the effects of disruptions to and 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 delay, reduce the scope of or eliminate one or more of our research or development programs, including our SARM and selective ER alpha agonist programs, or conduct additional workforce or other expense reductions, any of which could have a material adverse effect on our business.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the three months ended March 31, 2011, 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, 2010.

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

There were no changes in our internal control over financial reporting during the first quarter of 2011 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 8, 2011. In addition, the risks described under, and the captions entitled, "Off-label sale or use of third-party toremifene products could decrease sales of any toremifene product candidates that we continue to develop and that are approved for commercial sale, and could lead to pricing pressure if such products become available at competitive prices and in dosages that are appropriate or the indications for which we may continue to develop toremifene" and "Our license agreement with Orion excludes the use of toremifene in humans to treat breast cancer outside of the United States and may limit our ability to market toremifene for human uses outside the United States" included under Part 1, Item 1A "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 8, 2011 have been removed.

Risks Related to Our Financial Condition and Need for Additional Financing

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

As of March 31, 2011, we had an accumulated deficit of $355.5 million. Due to the recognition of the remaining $49.9 million of unamortized revenue due to the termination of an exclusive license and collaboration agreement for our SARM program, we reported net income of $15.3 million for the year ended December 31, 2010. However, we have incurred losses in each prior year since our inception in 1997, including net losses of $46.3 million and $51.8 million in 2009 and 2008, respectively. Our net loss for the three months ended March 31, 2011 was $2.6 million. We expect to incur significant operating losses in 2011 and for the foreseeable future as we continue our clinical development and research and development activities. These losses, among other things, 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 as a result of certain clinical deficiencies identified in the Complete Response Letter. Following the termination of our collaboration agreement with Ipsen Biopharm Limited, or Ipsen, in March 2011 and based on the FDA's decision to require that a second pivotal Phase III clinical trial be conducted prior to the FDA considering toremifene 80 mg for marketing approval, we have decided to discontinue our toremifene 80 mg development program. As we have previously decided to discontinue our toremifene 20 mg development program, we do not anticipate that we will receive any return on our investment in either of our toremifene 80 mg or toremifene 20 mg product candidates. Our current product candidates are in various stages of clinical development, and significant additional clinical development and financial resources will be required to obtain necessary regulatory approvals for them, including Ostarine™ (GTx-024) and Capesaris™ (GTx-758) and to develop these product candidates into commercially viable products. Accordingly, we do not expect to obtain FDA or any other regulatory approvals to market any of our product candidates in the near future, and it is possible these products will never gain regulatory approval.

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 former collaborators. Currently, we have no ongoing collaborations for the development and commercialization of our product candidates. 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 three months ended March 31, 2011, we recognized $1.2 million in net revenues from the sale of FARESTON®. If we 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 will need to raise substantial additional funding 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 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, cash equivalents, and short-term investments, together with interest income and product revenue from the sale of FARESTON®, will be sufficient to meet our projected operating requirements for at least the next twelve months. We have based this estimate on our current business plan and assumptions that may prove to be wrong. We could utilize our available capital resources sooner than we currently expect, and we could need additional funding sooner than currently anticipated. We believe that our current cash resources, together with interest income and product revenue from the sale of FARESTON®, will be sufficient to enable us to initiate in 2011 our planned pivotal Phase III clinical trials of Ostarine™ for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer and to initiate and complete our planned Phase IIb clinical trial to evaluate Capesaris™ for first line treatment of advanced prostate cancer. To complete the two Phase III clinical trials we expect to initiate in 2011 for Ostarine™, we will need to obtain additional funding. Further, to conduct any additional clinical trials for our product candidates, we will need to obtain substantial additional funding through partnerships and/or collaborations or the sale of our securities. Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical trials and other research and development activities, including our currently-planned clinical trials of Ostarine™ and Capesaris™;
- the terms and timing of any potential future collaborative, licensing and other arrangements that we may establish;
- future clinical trial results;
- 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;
- the amount and timing of any licensing fees, milestone payments and royalty payments from potential future collaborators, if any;
- 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 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.

We do not currently have any commitments for future external funding and until we can generate a sufficient amount of product revenue, which we may never do, we expect to finance future cash needs through public or private equity offerings, debt financings or collaboration and licensing arrangements, or a combination of the above, 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®. 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. If we are unable to raise additional funds when we need them, we may need to further reduce our expenditures, perhaps significantly, to preserve our cash. Cost-cutting measures that we 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 potential future collaboration and licensing arrangements, 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 uncertain financial condition, the outcomes of our currently-planned clinical trials of Ostarine™ and Capesaris™ and/or current economic conditions, including the effects of disruptions to and 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 delay, reduce the scope of or eliminate one or more of our research or development programs, including our SARM and selective ER alpha agonist programs, or conduct additional workforce or other expense reductions, any of which could have a material adverse effect on our business.

Risks Related to Development of Product Candidates

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

Significant additional research and development and financial resources will be required to obtain necessary regulatory approvals for our product candidates and to develop them into commercially viable products. Preclinical and clinical testing is expensive, can take many years to complete 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. If a product candidate fails at any stage of development, we will not have the anticipated revenues from that product candidate to fund our operations, and we will not receive any return on our investment in that product candidate. For example, we announced in May 2010 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, after we had incurred significant development costs. Even if the results of a clinical trial are positive, the efficacy and/or safety results from the trial may be insufficient to support the submission of a NDA to the FDA, or if submitted, the filing or approval of the NDA by 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 the NDA. We have since determined to discontinue our toremifene development program.

Significant delays in clinical testing could materially impact our product development costs. We do not know whether planned clinical trials will begin on time, will need to be restructured or will be completed on schedule, if at all. We 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 potential future collaborators' ability to commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us 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 or any potential future collaborators to conduct additional preclinical or clinical testing or to abandon projects that we expect to be promising;
- even if preclinical or clinical trial results are positive, the FDA or foreign regulatory authorities could nonetheless require us to conduct unanticipated additional clinical trials;
- registration or enrollment in clinical trials may be slower than we currently anticipate, resulting in significant delays or study termination;
- we 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 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 materially and adversely impact our business, financial condition and growth prospects.

If we 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 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.*

In our Phase II clinical trials for Ostarine™ for the treatment of muscle wasting in patients with cancer and healthy older males and postmenopausal females, we observed mild elevations of hepatic enzymes in a few patients in both the placebo and Ostarine™ treated groups. Reductions in high-density lipoproteins have been observed in subjects treated with Ostarine™. In our preclinical studies for Ostarine™ in which high exposures to drug were achieved, we observed expected effects on the reproductive and other target organs in animals consistent with stimulation and inhibition of the androgen receptor which is located in these organs.

Capesaris™ is a new chemical entity that is selective for estrogen receptor alpha. Although Capesaris™ has been well tolerated in clinical trials to date, adverse effects may occur in future clinical studies. Increase in the incidence of thromboembolic events, a known risk factor associated with approved non-selective estrogenic therapies, and increases in hepatic enzymes, a known risk factor associated with orally administered estrogenic therapies, will be monitored and may be observed in future clinical studies. In our preclinical animal studies with Capesaris™ in which high exposures to drug were achieved, we observed expected effects on reproductive and other target organs in animals consistent with stimulation or inhibition of the estrogen receptors which are located in these organs.

If the incidence of serious or other adverse events related to our product candidates 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 or any potential future collaborators may conduct in the future or after any of our product candidates are approved and marketed:

- we or any potential future collaborators may be required to conduct additional preclinical or clinical trials, make changes in the 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

If we do not establish collaborations for our product candidates or otherwise raise substantial additional capital, we will likely need to alter our development and any commercialization plans.*

Our strategy includes selectively partnering or collaborating with leading pharmaceutical and biotechnology companies to assist us in furthering development and potential commercialization of our product candidates. We face significant competition in seeking appropriate collaborators, and collaborations are complex and time consuming to negotiate and document. We may not be successful in entering into new collaborations with third parties on acceptable terms, or at all, including as a result of any collaboration discussions we pursue for Ostarine™ and Capesaris™. In addition, we are unable to predict when, if ever, we will enter into any additional collaborative arrangements because of the numerous risks and uncertainties associated with establishing such arrangements. If we are unable to negotiate new collaborations, we may have to curtail the development of a particular product candidate, reduce, delay, or terminate its development or one or more of our other development programs, delay its potential commercialization or reduce the scope of our sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we will need to raise substantial additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenues.

Any collaborative arrangements that we establish in the future may not be successful or we may otherwise not realize the anticipated benefits from these collaborations. In addition, any future collaboration 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.*

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 2011, we and Ipsen mutually agreed to terminate our collaboration and, as a result, we will not receive any additional milestone payments from Ipsen on account of our collaboration with Ipsen. As of the date of this report, we have no ongoing collaborations for the development and commercialization of our product candidates. 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.

Dependence on collaborative arrangements subjects us to a number of risks, including:

- we may not be able to control the amount and timing of resources that our potential future collaborators may devote to our product candidates;
- 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;
- 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, which could delay the development and may increase the cost of developing our product candidates.

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. 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 with toremifene 60 mg tablets, 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, we would not be prevented from manufacturing toremifene 60 mg tablets, there is no obligation on the part of Orion to transfer its manufacturing technology to us or to assist us in developing manufacturing capabilities to meet our supply needs. If our supply rights for 60 mg tablets are terminated by Orion for any reason, a disruption in the supply of toremifene 60 mg tablets could impair our ability to continue to commercialize FARESTON®.

We rely on third party vendors for the manufacture of Ostarine™ drug substance. If our supply of Ostarine™ becomes unusable or if the contract manufacturers that we are currently utilizing to meet our supply needs for Ostarine™ or our other future SARM product candidates prove incapable or unwilling to continue to meet our supply needs, we could experience a delay in conducting any additional clinical trials of Ostarine™ or other future SARM product candidates. In addition, we rely on third party contractors for the manufacture of Capesaris™ drug substance. 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 our relationship with Orion for toremifene, or to do so at an acceptable cost, or other suppliers fail to meet our requirements for Capesaris™, or Ostarine™ or our other future 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 60 mg tablets, 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 and/or our potential future collaborators may develop may compete with other product candidates and products for access to manufacturing facilities.

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 license 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. This license agreement 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 this agreement is 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, including Ostarine™, 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.

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, overbroad, or unenforceable claims, or claims that are not supported in regard to written description or enablement by the specification, 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 in the same class of products as our product candidates or 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, as well as the methods for treating patients in the product indications using these product candidates. We will be able to protect our product candidates and the methods for treating patients in the product indications using these product candidates from unauthorized use by third parties only to the extent that we or our exclusive licensors own or control such valid and enforceable patents or trade secrets.

Our rights to certain patents and 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.

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, disclosure and support in the specification, the patents will provide protection only for a limited amount of time. 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, or the written description or enablement 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 materially 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, lack sufficient written description or enablement, 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.

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 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 other amounts, 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.

Risks Related to Regulatory Approval of Our Product Candidates

If we 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 potential future 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. 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 FDAAA, 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 as a result of certain clinical deficiencies identified in the Complete Response Letter. We have since determined to discontinue our toremifene 80 mg development program. 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, in the near future, if at all. The inability to obtain FDA approval or approval from comparable authorities in other countries for our product candidates would prevent us or any potential future collaborators from commercializing these product candidates in the United States or other countries. See the section entitled "Business — Government Regulation" under Part 1, Item 1 of our Annual Report on Form 10-K, filed with the SEC on March 8, 2011, 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 and/or any potential future collaborators may develop will depend upon the market and the degree of market acceptance among physicians, patients, health care payors and the medical community.*

Any products that we 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.

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

FARESTON®is currently our only marketed product. FARESTON®is indicated for the treatment of advanced 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 competitors 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, including the boxed warning added to the label of FARESTON® in March 2011 to highlight that FARESTON® has been shown to prolong the QTc interval in a dose- and concentration-related manner and that prolongation of the QTc interval can result in a type of ventricular tachycardia called Torsades de pointes, which may result in syncope, or temporary loss of consciousness, seizure, and or death. A boxed warning is the strongest type of warning that the FDA can require for a drug product and warns prescribers that the drug carries a significant risk of serious or even life-threatening adverse effects. The occurrence of one or more of the following risks may cause sales of FARESTON® to decline:

- the loss of one or more of our three largest wholesale drug distributors, which together accounted for approximately 94% of our product sales of FARESTON® for the three months ended March 31, 2011;
- any further restrictions, limitations, and/or warnings added to the FARESTON® label;
- 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;
- the loss of Orion, upon which we rely as a single source, as our supplier of FARESTON®; and
- the loss of the availability of our website to market FARESTON®, which is an important source of advertising.

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 limited experience as a company in the sales, marketing and distribution of pharmaceutical products, and in any event have only limited company personnel to undertake such activities, and we therefore need 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 build our own sales and marketing capabilities and there are risks involved with entering into arrangements with third parties to perform these services, which could delay the commercialization of any of our product candidates if approved for commercial sale. 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 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 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 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 or any potential future collaborators are able to charge for products we 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 and/or any potential future collaborators may develop or to lower the amount that they pay.

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, each of which have reduced the amount of net reimbursement received for FARESTON® and would reduce the amount of net reimbursement for any other products that we and/or any potential future collaborators may develop and sell. The legislation also extended 340B discounted pricing on outpatient drugs to children’s hospitals, critical access hospitals, and rural health centers, which has reduced the amount of reimbursement received for drugs purchased by these new 340B-covered entities.

Additional provisions of the health care reform legislation may negatively affect our revenues and prospects for profitability in the future. Along with other pharmaceutical manufacturers and importers of brand name prescription drugs, starting in September 2011, 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, made in the preceding year if such sales exceed a defined threshold. 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”), as of January 1, 2011, we are required to provide a 50% discount on brand name prescription drugs, including FARESTON®, sold to beneficiaries who fall within the donut hole.

Economic pressure on state budgets may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for drugs. 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. 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 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 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 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 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 and/or any potential future collaborators may develop or sell. Cost-control initiatives could decrease the price we might establish for products that we 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 if the Secretary of Health and Human Services allowed 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. If the circumstances were met and the Secretary exercised the discretion to allow for the direct reimportation of drugs, it could decrease the price we or any potential future collaborators receive for any products that we 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 $20 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 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 and/or any potential future collaborators may develop. Competition could result in reduced sales and pricing pressure on our product candidates, if approved, which in turn would reduce our ability to generate meaningful revenue and have a negative impact on our results of operations. 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 and/or any potential future collaborators may develop.

With respect to our SARM program, there are other SARM product candidates in development that may compete with our SARM product candidates, if approved for commercial sale, including SARMs in development from Ligand Pharmaceuticals Inc., GlaxoSmithKline, and Merck & Co., Inc. 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 Phase II studies, with a focus on neurological muscle diseases (amyotrophic lateral sclerosis and myasthenia gravis). Moreover, there are other categories of drugs in development, including ghrelin receptor agonists and growth hormone secretagogues that may have some muscle building activity. Other appetite stimulants such as megestrol acetate and dronabinol are also used off-label for weight loss and loss of appetite in patients with cancer.

We are developing Capesaris™ for first line treatment of advanced prostate cancer. Currently, there are several products approved to reduce testosterone levels in men with advanced prostate cancer that may compete with Capesaris™ if approved for commercial sale, including those marketed by Abbott Laboratories (Lupron Depot®), Sanofi-Aventis (Eligard®), AstraZeneca (Zoladex®), Ferring Pharmaceuticals (Firmagon®), Endo Pharmaceuticals (Vantas®) and Watson Pharmaceuticals (Trelstar®).

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 $22.5 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 competition exists for qualified personnel in the biotechnology field.

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:

- delays in the initiation or completion of our currently-planned clinical trials of Ostarine™ and Capesaris™, or adverse results in any of our initiated clinical trials;
- our ability to enter into new collaborative arrangements with respect to our product candidates;
- the terms and timing of any future collaborative, licensing or other arrangements that we may establish;
- our ability to raise additional capital to carry through with our clinical development plans and current and future operations and the terms of any related financing arrangements;
- the timing of achievement of, or failure to achieve, our 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 or adverse events during 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 an approved product candidate;
- changes to the label for FARESTON® that further restrict how we market and sell FARESTON®;

- the commercial success of any product approved by the FDA or its foreign counterparts;
- introductions or announcements of technological innovations or new products by us, our 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;
- 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. The financial markets continue to face significant uncertainty, 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 March 31, 2011, our executive officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 70.1% of our outstanding common stock, and our executive officers and directors alone beneficially owned approximately 45.1% 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 March 31, 2011, the average daily trading volume of our common stock on the NASDAQ Global Market was 191,055 shares. As a result, future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the then-prevailing market price of our common stock. As of March 31, 2011, we had 51,719,187 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 5. OTHER INFORMATION

On March 11, 2011, we notified the University of Tennessee Research Foundation, or UTRF, of our election to terminate that certain Amended and Restated License Agreement, dated September 24, 2007, as amended, between us and UTRF, or the SERM License Agreement, which such termination will be effective on June 11, 2011 or such earlier date that we and UTRF may agree. Under the SERM License Agreement, we were 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 SERM License Agreement, we were obligated to pay UTRF annual license maintenance fees, low single digit royalties on net sales of any products and mid single-digit royalties on any sublicense revenues. The termination of the SERM License Agreement will not affect our existing license agreement with UTRF related to SARM technologies.

ITEM 6. EXHIBITS

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

GTx, Inc.

Date: May 9, 2011

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

Date: May 9, 2011

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	Certificate of Amendment of Restated Certificate of Incorporation of GTx, Inc.(2)
3.3	Amended and Restated Bylaws of GTx, Inc.(3)
4.1	Reference is made to Exhibits 3.1, 3.2 and 3.3
4.2	Specimen of Common Stock Certificate(4)
4.3	Amended and Restated Registration Rights Agreement between Registrant and Oracle Partners, L.P. dated August 7, 2003(4)
4.4	Amended and Restated Registration Rights Agreement between Registrant and J. R. Hyde, III dated August 7, 2003(4)
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(5)
4.6	Consent, Waiver and Amendment between Registrant and J. R. Hyde, III and Pittco Associates, L.P. dated December 3, 2007(5)
10.29*	2011 Compensation Information for Registrant's Executive Officers
10.50*	Non-Employee Director Compensation Policy of GTx, Inc., effective February 18, 2011
10.57	Second Amendment to Sublease and Parking Sublicense Agreements dated January 1, 2011 by and between the Registrant and ESS SUSA Holdings, LLC(6)
10.58*	Letter Agreement, dated February 25, 2011, between the Registrant and Ipsen Biopharm Limited
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) (7)
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) (7)

* 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 May 6, 2011, and incorporated herein by reference.

(3) Filed as Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 000-50549), filed with the SEC on July 26, 2007, and incorporated herein by reference.

(4) 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.

(5) 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.

(6) Filed as the like numbered Exhibit to the Registrant's Annual Report on Form 10-K (File No. 000-50549), filed with the SEC on March 8, 2011, and incorporated herein by reference.

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

Exhibit 10.29

2011 COMPENSATION INFORMATION FOR REGISTRANT'S EXECUTIVE OFFICERS

The table below provides information regarding (i) the base salary of each executive officer of GTx, Inc. (the "Company"), effective as of January 1, 2011 (except as noted), and (ii) the target cash bonus award for Fiscal 2011 for each of the Company's executive officers under the Company's Executive Bonus Compensation Plan, expressed as a percentage of applicable base salary:

Executive Officer	Title	2011 Annual Salary ($)	2011 Target Bonus (% of Salary)
Mitchell S. Steiner	Chief Executive Officer and Vice-Chairman of the Board of Directors	525,000	65
Marc S. Hanover	President and Chief Operating Officer	456,750	55
Ronald A. Morton, Jr.	Vice President, Chief Medical Officer	452,025(1)	30
James T. Dalton	Vice President, Chief Scientific Officer	400,000	30
Henry P. Doggrell	Vice President, General Counsel and Secretary	351,281(2)	30
Mark E. Mosteller	Vice President, Chief Financial Officer and Treasurer	298,083	30

(1) Dr. Morton will also be eligible for tax gross-up payments related to certain travel expenses paid by the Company during 2011 on his behalf.

(2) Effective as of February 21, 2011.

Non-Employee Director Compensation Policy of GTx, Inc.
Effective Date: 2/18/2011

I. Purpose

This Policy sets forth guidelines pertaining to compensation for non-employee Directors of the GTx, Inc. Board of Directors ("Board").

II. Scope

This Policy applies to all non-employee members of the Board and is not applicable to employee members of the Board. This Policy shall remain in effect until it is revised or rescinded by further action of the Board.

III. Policy Statements

The Board sets non-employee Directors' compensation at the recommendation of the Nominating and Corporate Governance Committee and the Compensation Committee. Compensation for non-employee Directors is comprised of a mix of cash and equity-based compensation.

Periodically, at the direction of the Nominating and Corporate Governance Committee, the Company provides information from independent consultants and/or data management sources relating to Board compensation paid by companies comparable to the Company within the biotech and pharmaceutical industries. The Nominating and Corporate Governance Committee uses this information in making its recommendations to the Compensation Committee regarding any modifications to Board compensation. The Compensation Committee considers the information and recommendations provided by the Nominating and Corporate Governance Committee and makes its recommendations to the Board. The Board then sets the Directors' compensation taking into account the recommendations from the Committees. Cash compensation payments and equity awards shall be paid or be made, as applicable, automatically and without further action of the Board, unless such non-employee Director declines to receive such compensation or awards by written notice to the Company.

A. Cash Compensation

Annual Retainer

Each non-employee Director shall be eligible to receive an annual retainer of $25,000, except the Chairman of the Audit Committee who shall receive an annual retainer of $35,000 for services on the Board. The annual retainer will be paid in quarterly installments, on or about the first day of each quarterly period.

Meeting Stipends

Each non-employee Director shall receive a stipend of $2,000 for every regularly scheduled (or special) meeting of the Board and its committees physically attended by such Director and a $750 stipend for each telephonic meeting in which the Director participated, payable after the end of each calendar quarter.

Expense Reimbursement

The Company shall reimburse a non-employee Director for all of his or her reasonable expenses incurred to attend meetings of the Board or its committees. Any travel expenses shall be reimbursed in accordance with the Company's standard travel policy. The travel expenses will be reimbursed within thirty (30) days after receipt by the Company of an invoice together with originals or copies of receipts showing the payment of such expenses.

B. Directors' Deferred Compensation

Each non-employee Director has the opportunity to defer all or a portion of his or her cash compensation under the Company's Directors' Deferred Compensation Plan. Deferrals can be made into a cash account, a stock unit account, or a combination of both. All distributions under the Directors' Deferred Compensation Plan will be made in the form of a single lump sum in cash (for amounts credited to cash accounts) or in shares of GTx common stock (for amounts credited to stock unit accounts), except that any fractional shares of GTx common stock will be distributed in cash valued at the then current fair market value of GTx common stock, all of which is more particularly set forth in the Directors' Deferred Compensation Plan.

C. Equity-Based Compensation

The Company's 2004 Non-Employee Directors' Stock Option Plan, as amended, provides for the automatic grant of initial and annual nonstatutory stock options to GTx's non-employee Directors who do not own more than ten percent of the combined voting power of GTx's then outstanding securities.

Initial Award

Pursuant to the 2004 Non-Employee Directors' Stock Option Plan, as amended, any individual who first becomes a non-employee Director automatically is granted an option to purchase shares of GTx common stock. The number of shares subject to each of these initial option grants is 15,000 shares, provided that the number of options may be increased or decreased by the Board in its sole discretion.

Annual Awards

Any individual who is serving as a non-employee Director on the day following an annual meeting of GTx's stockholders automatically will be granted an option to purchase shares of common stock on that date; provided, however, that if the individual has not been serving as a non-employee director for the entire period since the preceding annual meeting, the number of shares subject to such individual's annual grant will be reduced pro rata for each full month prior to the date of grant during which such individual did not serve as a non-employee Director. The number of shares subject to each annual option grant is 15,000 shares, provided that the number of options may be increased or decreased by the Board in its sole discretion.

Provisions Applicable to All Non-Employee Director Awards

The exercise price per share for the options granted under the 2004 Non-Employee Directors' Stock Option Plan, as amended, is not less than the fair market value of the Company's common stock on the date of grant. The options which are the subject of an initial grant and an annual grant will vest in a series of three successive equal annual installments measured from the date of grant, so that each initial grant of options and each annual grant will be fully vested three years after the date of grant.

In the event of specified corporate transactions, as defined in the 2004 Non-Employee Directors' Stock Option Plan, as amended, all outstanding options under the 2004 Non-Employee Directors' Stock Option Plan, as amended, may be assumed or substituted for by any surviving or acquiring entity. If the surviving or acquiring entity elects not to assume or substitute for such options, then (a) with respect to any such options that are held by optionees then performing services for GTx or its affiliates, the vesting and exercise of such options will be accelerated in full and such options will be terminated if not exercised prior to the effective date of the corporate transaction, and (b) all other outstanding options will terminate if not exercised prior to the effective date of the corporate transaction.

If a specified “change of control” transaction occurs, as defined in the 2004 Non-Employee Directors’ Stock Option Plan, as amended, then the vesting and exercise of the optionee’s options will be accelerated in full immediately prior to (and contingent upon) the effectiveness of the transaction. If an optionee is required to resign his or her position as a non-employee Director as a condition of the transaction, the vesting and exercise of the optionee’s options will be accelerated in full immediately prior to the effectiveness of such resignation.

IV. Related Documents / Information

A. Directors’ Deferred Compensation Plan

B. 2004 Non-Employee Directors’ Stock Option Plan (Amended)

C. *Finance Policy, Business Travel and Expense*

V. Policy Owner

For assistance with interpretation regarding this policy, or any questions relating to this policy, contact:
Henry P. Doggrell
VP, General Counsel
(901) 507-6916
hdoggrell@gtxinc.com

VI. Revision History

Original Policy — Effective 1/1/2009
(Adopted by the GTx, Inc. Compensation Committee of the Board of Directors on 11/4/2008)

VII. Approval

The signature below indicates that this policy has been approved by the Finance Department as of the approval date set forth below.

/s/ Henry P. Doggrell	February 28, 2011
Henry P. Doggrell	**Date**
Vice President, General Counsel	

Exhibit 10.58

25 February 2011

Dr. Mitchell S. Steiner
Chief Executive Officer
GTx, Inc.
175 Toyota Plaza, 7th Floor
Memphis, Tennessee 38103
U.S.A

By email-and UPS

Re: Mutually agreed termination of the Toremifene Collaboration and License Agreement dated 7 September 2006 as amended by First Amendment dated 22 March 2010

Dear Mitch:

We refer to the Collaboration and License Agreement dated 7 September 2006 (as amended, the "Agreement") between GTx, Inc. ("GTx") and Ipsen Limited (n/k/a Ipsen Biopharm Limited) ("Ipsen" and, together with GTx, the "Parties"), as amended by the First Amendment dated 22 March 2010 ("Amendment").

This Letter Agreement formalizes the mutually agreed decision made by Ipsen and GTx based on the discussions held in New York on 21 February 2011 among the Parties' representatives, specifically Dr. Mitchell Steiner, Marc Hanover, Henry Doggrell and David Levinson of GTx, and Stéphane Thiroloix, Sean McKercher, Vanessa Malier and Toshiki Enomoto of Ipsen as follows:

1. Subject to approval of Ipsen's board of directors which Ipsen shall notify to GTx on or before 1 March 2011 5:00 pm US EST, the Agreement and the Amendment are hereby terminated by mutual agreement of the Parties as of 1 March 2011, except as provided at Sections 2 to 6 below.

2. In consideration of Ipsen's agreement to terminate its rights and obligations in the Ipsen Territory except as provided herein, including its rights to Right of First Negotiation to GTx-758, GTx agrees to pay to Ipsen running royalty payments in US dollars on US Net Sales of the Licensed Product for the ADT Indication in the amount of 3% until the later to occur of (a) the last Valid Patent Claim to expire in the US or (b) if the expiry of a Valid Patent Claim occurs earlier than 30 November 2022 as a result of a third party claim which shall lead to generic market penetration in the US by more than 20% for a period of two (2) consecutive quarters, then at the end of that second quarter. The US Royalty Payment due to Ipsen on account of US Net Sales shall be payable by GTx to Ipsen within 60 days of the end of each Calendar Quarter for which royalty payments are owed, accompanied by a quarterly report providing in reasonable detail in quantity and value an accounting of the US Net Sales made during such Calendar Quarter. Furthermore, Article 11.4 of the Agreement (i.e., records and audit rights) shall apply *mutatis mutandis* to Ipsen's right to verify the accuracy of GTx's reports for the calculation of US Net Sales of the Licensed Product for the ADT Indication.

3. Except as provided herein, no party shall be entitled to receive any compensation whatsoever as a consequence of such mutual termination.

4. Except as provided herein, Ipsen and GTx shall be fully and entirely discharged from any and all of their respective obligations under the Agreement and the Amendment and shall have no liability relating thereto, except for all obligations set forth in Article XIII “Indemnification,” Article XIV “Dispute Resolution,” and Articles 15.4 through 15.13 which shall survive this mutual termination and remain binding upon Ipsen and GTx as applicable to this Letter Agreement until the expiry of the term mentioned at Section 2 above and Article VIII “Confidentiality”, which shall survive this mutual termination and remain binding upon Ipsen and GTx for the time-period mentioned in such provision, provided that, the Parties agree that notwithstanding the provisions of Section 8.4 of the Agreement, GTx shall not be required to provide to Ipsen for prior review and approval “any proposed scientific/technical publications or scientific presentations which relate to Toremifene and/or Licensed Product” as otherwise required under Section 8.4.

5. The Parties hereby agree that the Parties shall issue a press release relating to this mutual termination of the Agreement and the Amendment on 2 March 2011. Working draft of press releases concerning this mutual termination shall be provided to Ipsen or GTx by the originator of the release no later than 25 February 2011 5:00 pm US EST for the other party’s written approval, which shall not unreasonably be withheld or delayed, except to the extent required by applicable laws or stock exchange rules.

All capitalized terms used in this Letter Agreement without definition have the respective meanings provided in the Agreement and the Amendment.

Please confirm your agreement to this mutual termination by returning to us a countersigned copy of this letter.

This Letter Agreement takes effect as of the date first above written.

Yours sincerely,

/s/ Stéphane Thiroloix
Stéphane Thiroloix
Executive Vice President, Corporate Development

Acknowledged and agreed as of February 28, 2011

GTx, Inc.

/s/ Mitchell S. Steiner

Cc: GTx, Inc. (Vice President, General Counsel and Secretary)

EXHIBIT 31.1

CHIEF EXECUTIVE OFFICER CERTIFICATION

I, Mitchell S. Steiner, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of GTx, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: May 9, 2011

/s/ Mitchell S. Steiner

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

EXHIBIT 31.2

CHIEF FINANCIAL OFFICER CERTIFICATION

I, Mark E. Mosteller, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of GTx, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: May 9, 2011

/s/ Mark E. Mosteller

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

EXHIBIT 32.1

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

In connection with the Quarterly Report of GTx, Inc. (the "Company") on Form 10-Q for the three months ended March 31, 2011, 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: May 9, 2011

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

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

EXHIBIT 32.2

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

In connection with the Quarterly Report of GTx, Inc. (the "Company") on Form 10-Q for the three months ended March 31, 2011, 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: May 9, 2011

/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.