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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 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 ☑ 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	Smaller reporting company o
		(Do not check if a smaller reporting company)	

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

As of August 3, 2011, 62,759,411 shares of the registrant's Common Stock were outstanding.

GTx, INC.
FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2011
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PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2011 (unaudited)	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 82,421	$ 58,181
Short-term investments	8,535	450
Accounts receivable, net	904	683
Inventory	143	171
Prepaid expenses and other current assets	1,077	875
Total current assets	93,080	60,360
Property and equipment, net	1,526	2,040
Intangible and other assets, net	221	1,850
Total assets	$ 94,827	$ 64,250
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,139	$ 848
Accrued expenses and other current liabilities	3,765	3,112
Deferred revenue — current portion	—	1,345
Total current liabilities	4,904	5,305
Deferred revenue, less current portion	—	6,721
Other long-term liabilities	217	497
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value: 120,000,000 and 60,000,000 shares authorized at June 30, 2011 and December 31, 2010, respectively; 62,756,411 and 51,719,187 shares issued and outstanding at June 30, 2011 and December 31, 2010, respectively	63	52
Additional paid-in capital	455,791	404,555
Accumulated deficit	(366,148)	(352,880)
Total stockholders' equity	89,706	51,727
Total liabilities and stockholders' equity	$ 94,827	$ 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 June 30,		Six Months Ended June 30,	
	2011	**2010**	**2011**	**2010**
Revenues:				
Product sales, net	$ 1,645	$ 599	$ 2,874	$ 1,398
Collaboration revenue	—	336	8,066	56,114
Total revenues	1,645	935	10,940	57,512
Costs and expenses:				
Cost of product sales	264	134	469	285
Research and development expenses	7,591	9,477	14,894	17,127
General and administrative expenses	4,470	4,325	9,154	8,834
Total costs and expenses	12,325	13,936	24,517	26,246
(Loss) income from operations	(10,680)	(13,001)	(13,577)	31,266
Other income, net	7	60	309	132
Net (loss) income	$ (10,673)	$ (12,941)	$ (13,268)	$ 31,398
Net (loss) income per share:				
Basic and diluted	$ (0.21)	$ (0.36)	$ (0.26)	$ 0.86
Weighted average shares used in computing net (loss) income per share:				
Basic and diluted	51,968,667	36,420,901	51,844,616	36,420,901

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

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

	Six Months Ended June 30,	
	2011	**2010**
Cash flows from operating activities:		
Net (loss) income	$ (13,268)	$ 31,398
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation and amortization	586	849
Share-based compensation	2,097	2,697
Directors' deferred compensation	96	96
Deferred revenue amortization	(8,066)	(51,114)
Impairment of intangible assets	1,598	1,687
Changes in assets and liabilities:		
Accounts receivable, net	(221)	37
Inventory	28	(8)
Prepaid expenses and other assets	(203)	(5,217)
Accounts payable	291	(417)
Accrued expenses and other liabilities	415	(557)
Net cash used in operating activities	(16,647)	(20,549)
Cash flows from investing activities:		
Purchase of property and equipment	(40)	(85)
Purchase of short-term investments, held to maturity	(8,085)	(6,939)
Proceeds from maturities of short-term investments, held to maturity	—	7,390
Net cash (used in) provided by investing activities	(8,125)	366
Cash flows from financing activities:		
Proceeds from issuance of common stock	49,012	—
Payments on capital lease and financed equipment obligations	(42)	(46)
Proceeds from exercise of employee stock options	42	—
Net cash provided by (used in) financing activities	49,012	(46)
Net increase (decrease) in cash and cash equivalents	24,240	(20,229)
Cash and cash equivalents, beginning of period	58,181	40,219
Cash and cash equivalents, end of period	$ 82,421	$ 19,990

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). The Company plans to initiate two pivotal Phase III clinical trials evaluating Ostarine™ for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer in the third quarter of 2011.

Additionally, the Company is developing Capesaris™ (GTx-758), an oral nonsteriodal selective estrogen receptor alpha agonist. The Company is developing Capesaris™ for first line and second line hormonal treatment of advanced prostate cancer. For first line hormonal therapy, the Company initiated in June 2011, a Phase IIb open label clinical trial to determine the dose of Capesaris™ required to maintain medical castration in 156 men with advanced prostate cancer. The Company also plans to initiate this year a Phase II open label clinical trial in 104 men to determine the loading dose of Capesaris™ required to achieve medical castration in 90% of men with advanced prostate cancer by day 28. For second line hormonal therapy, the Company plans to initiate this year a Phase II clinical trial evaluating Capesaris™ in men on androgen deprivation therapy ("ADT") that have developed castration resistant prostate cancer.

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. The Company previously determined to discontinue its toremifene 80 mg and toremifene 20 mg development programs.

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 and six months ended June 30, 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)
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Revenue Recognition

The Company recognizes revenue from product sales of FARESTON® less deductions for estimated sales discounts and sales returns. Revenue from product sales is recognized when persuasive evidence of an arrangement exists, title passes, the price is fixed or determinable, and collectability is reasonably assured. The Company accounts for rebates to certain governmental agencies as a reduction of product sales. The Company allows customers to return product within a specified time period prior to and subsequent to the product's labeled expiration date. The Company estimates an accrual for product returns, which is recorded as a reduction of product sales, based on factors which include historical product returns and estimated product in the distribution channel which is expected to exceed its expiration date. At June 30, 2011 and December 31, 2010, the Company's accrual for product returns was $998 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. Due to the termination of the Company's license and collaboration agreement with Ipsen Biopharm Limited ("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.

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 June 30, 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.

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.

GTx, Inc.
NOTES TO THE CONDENSED FINANCIAL STATEMENTS
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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 six months ended June 30, 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 June 30, 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.

Reduction in Force

In June 2011, the Company implemented a reduction in its workforce in connection with its decision to discontinue development and commercialization of its toremifene 80 mg and toremifene 20 mg product candidates. The reduction in force was effective immediately and represented approximately 15% of the Company's total workforce, including three non-executive officers of the Company. As a result of the workforce reduction, the Company incurred severance related cash expenses of approximately $681, of which $633 was included in general and administrative expenses and $48 was included in research and development expenses for the three and six months ended June 30, 2011. As of June 30, 2011, $283 of these expenses were recorded in accrued expenses and other current liabilities and were paid during the third quarter of 2011. Additionally, the Company incurred a one-time, non-cash share-based compensation charge of $481 related to the amendment of certain stock option provisions for the affected non-executive officers, which was included in general and administrative expenses for the three and six months ended June 30, 2011. This charge was offset by the reversal of $704 of previously recognized share-based compensation expense for non-vested stock options that were cancelled in conjunction with the total workforce reduction. Of this amount, $646 was included in general and administrative expenses and $58 was included in research and development expenses for the three and six months ended June 30, 2011.

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

The Company has evaluated all events or transactions that occurred after June 30, 2011 up through the date the condensed financial statements were issued. There were no material recognizable or nonrecognizable subsequent events during the period evaluated.

2. Share-Based Compensation

Share-based payments include stock option grants under the Company's stock option and equity incentive plans and deferred compensation arrangements for the Company's non-employee directors. The Company recognizes compensation expense for its share-based payments based on the fair value of the awards over the period during which an employee or non-employee director is required to provide service in exchange for the award. The Company's share-based compensation plans are described more fully in Note 3 to the Company's financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2010.

The following table summarizes share-based compensation expense included within the condensed statements of operations for the three and six months ended June 30, 2011 and 2010:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Research and development expenses	$ 398	$ 454	$ 907	$ 1,300
General and administrative expenses	545	625	1,286	1,493
Total share-based compensation	$ 943	$ 1,079	$ 2,193	$ 2,793

Share-based compensation expense recorded as general and administrative expense for the three months ended June 30, 2011 and 2010 included share-based compensation expense related to deferred compensation arrangements for the Company's non-employee directors of $45 and $46, respectively. Share-based compensation expense related to deferred compensation arrangements for the Company's non-employee directors of $96 was included in share-based compensation expense recorded as general and administrative expenses for both the six months ended June 30, 2011 and 2010. Additionally, as part of the June 2011 workforce reduction, the Company modified certain stock options of three terminated non-executive officers to accelerate the vesting of certain outstanding non-vested stock options and to extend the post-termination exercise period of their vested stock options. As a result of these modifications, the Company incurred a one-time share-based compensation charge of $481, which was included in general and administrative expenses for the three and six months ended June 30, 2011. This charge was offset by the reversal of $704 of previously recognized share-based compensation expense for non-vested stock options that were canceled in conjunction with the total workforce reduction. Of this amount, $646 was included in general and administrative expenses and $58 was included in research and development expenses for the three and six months ended June 30, 2011.

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.

GTx, Inc.
NOTES TO THE CONDENSED FINANCIAL STATEMENTS
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The fair value of options granted was estimated using the following assumptions for the periods presented:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Expected price volatility	64.3%	64.2%	64.9%	64.6%
Risk-free interest rate	2.6%	3.3%	2.5%	3.4%
Weighted average expected life in years	6.0 years	6.0 years	6.5 years	6.5 years

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

	Number of Shares	Weighted Average Exercise Price Per Share
Options outstanding at December 31, 2010	4,430,495	$ 10.91
Options granted	1,392,500	2.81
Options forfeited or expired	(659,496)	8.44
Options exercised	(10,000)	4.20
Options outstanding at June 30, 2011	5,153,499	9.06

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

Basic and diluted net (loss) income per share attributable to common stockholders is calculated based on the weighted average number of common shares outstanding during the period. Diluted net (loss) income 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 5,530,288 and 4,536,821 for the three months ended June 30, 2011 and 2010, respectively, and 5,629,411 and 4,526,796 for the six months ended June 30, 2011 and 2010, respectively, were excluded from the calculations of diluted net (loss) income per share as inclusion of the options would have had an anti-dilutive effect on the net (loss) income per share for the periods.

4. Common Stock

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.

On June 28, 2011, the Company completed an underwritten public offering of 10,000,000 shares of its common stock at a price to the public of $4.75 per share. The Company also granted the underwriters a 30-day option to purchase up to an additional 1,500,000 shares of common stock to cover over-allotments, if any. The underwriters exercised this option and purchased an additional 1,023,000 shares of the Company's common stock on June 28, 2011 at a price of $4.75 per share. Net cash proceeds from the public offering were approximately $49,000 after deducting the underwriting discount and offering expenses.

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

5. 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, and certain improvements thereto, and exclusive rights to certain 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 previously 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.

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"). During the first quarter of 2011, the Company recognized as collaboration revenue all of the remaining $8,066 unamortized revenue that was deferred as of December 31, 2010. This amount is included in collaboration revenue in the condensed statement of operations for the six months ended June 30, 2011. The Company recognized as collaboration revenue $336 and $1,258 for the three months and six months ended June 30, 2010, respectively, from the amortization of the Ipsen deferred revenue.

Merck & Co., Inc. Collaboration and License Agreement

In December 2007, GTx and Merck & Co., Inc. ("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.

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

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 paid the Company $15,000 in cost reimbursements for research and development activities in equal annual installments over a three year period.

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. These amounts are included in collaboration revenue in the condensed statement of operations for the six months ended June 30, 2010.

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 our ongoing and planned clinical trials will achieve similar results to clinical trials that we have previously concluded;
- the timing, scope and anticipated initiation, enrollment and completion of our ongoing and planned clinical trials and any other 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;
- our 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). Our current SARM product candidate, Ostarine™ (GTx-024), has to date been evaluated in eight clinical trials enrolling approximately 600 subjects, including in a Phase Ib and two Phase II efficacy studies.

We have concluded End of Phase II meetings with the U.S. Food and Drug Administration, or FDA, regarding our planned Phase III clinical development of Ostarine™ for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer, or NSCLC. Based upon feedback from the FDA, we plan to initiate the POWER1 and POWER2 (Prevention and treatment Of muscle Wasting in cancER) pivotal Phase III clinical trials evaluating Ostarine™ in this indication in the third quarter of 2011. Each of the placebo-controlled, double-blind pivotal Phase III clinical trials is designed to enroll 300 patients with Stage III or IV NSCLC who are initiating first line chemotherapy. Subjects will be randomized to either placebo or Ostarine™ 3 mg. Each of the planned clinical trials will evaluate as co-primary endpoints the effect of Ostarine™ on total lean body mass (muscle) assessed by dual x-ray absorptiometry and on physical function assessed by the Stair Climb Test at three months. Durability of effect will be assessed at five months as a secondary endpoint in each of the planned clinical trials. We intend to continue our pursuit of a strategic partnership or collaboration for the development and commercialization of SARMs, including Ostarine™.

We are also developing Capesaris™ (GTx-758), an oral nonsteroidal selective estrogen receptor, or ER, alpha agonist. We are initially developing Capesaris™ for first line hormonal treatment of advanced prostate cancer. In 2009, we completed two Phase I clinical trials, a single ascending dose clinical trial and a multiple ascending dose clinical trial, evaluating Capesaris™ in healthy male volunteers. Capesaris™ was well tolerated in both trials. 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 medical castration levels, increased serum sex hormone binding globulin, or SHBG, and reduced serum free testosterone, the form of testosterone which is available to prostate cancer cells for growth. Medical castration (levels of serum total testosterone less than 50ng/dL) was achieved in the 1000 mg and 1500 mg treatment groups. Capesaris™ was well tolerated and no serious adverse events were reported in the trial. In May 2011, we completed a Phase I clinical trial of Capesaris™ using a tablet formulation in older healthy male volunteers. In this trial, reductions in testosterone to medical castration levels, increases in SHBG and decreases in free testosterone were observed at doses from 1000 mg to 2000 mg given orally each day. Capesaris™ was generally well tolerated in this trial, however, one subject experienced a blood clot in his leg and was discontinued from the study. We have met with the FDA and confirmed that the primary endpoint for approval of Capesaris™ for first line hormonal treatment of advanced prostate cancer is maintaining medical castration levels of serum testosterone (less than 50ng/dL) from day 28 to day 364. Based on this FDA feedback, we have designed Phase IIb and Phase II clinical trials to assess the dose necessary to achieve and maintain medical castration. In June 2011, we initiated a Phase IIb open label clinical trial to determine the maintenance dose of Capesaris™ in 156 men with advanced prostate cancer. This Phase IIb clinical trial is evaluating oral daily doses of Capesaris™ in 1000 mg and 2000 mg treatment groups compared to a group treated with Lupron Depot® (leuprolide acetate for depot suspension). Primary efficacy results from the Phase IIb clinical trial are expected by year end 2011. We plan to initiate this year a Phase II loading dose clinical trial evaluating Capesaris™ 1500 mg twice daily and 3000 mg once daily in 104 men with advanced prostate cancer (52 subjects per study arm). The objective of this study is to determine the optimal dose of Capesaris ™ to achieve medical castration in at least 90% of men by day 28. We expect data from this study by year end 2011. We also plan to evaluate Capesaris™ as second line hormonal therapy in men with advanced prostate cancer. We plan to initiate this year a 25 patient Phase II clinical trial to evaluate Capesaris™ in men on androgen deprivation therapy who have developed castration resistant prostate cancer. We are currently seeking a strategic partnership or collaboration for the development and commercialization of Capesaris™ for the treatment of advanced prostate cancer.

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. Following the reacquisition of our toremifene program, we evaluated the business case for toremifene 80 mg and determined to discontinue our toremifene 80 mg development program. Additionally, we previously determined to discontinue our toremifene 20 mg development program which was being developed for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia.

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 six months ended June 30, 2011 was $13.3 million. Our net loss included the recognition of the remaining $8.1 million of deferred revenue following the termination of our license and collaboration agreement with Ipsen and FARESTON® net product sales of $2.9 million. Additionally, research and development expenses for the six months ended June 30, 2011 included an impairment charge of $1.6 million related to our toremifene 80 mg intangible asset. In June 2011, we implemented a reduction in our workforce in connection with our decision to discontinue development and commercialization of the toremifene 80 mg and toremifene 20 mg product candidates. As a result of the workforce reduction, we incurred severance related cash expenses of approximately $681,000. We expect to incur significant net losses in 2011 and for the foreseeable future as we continue our clinical development and research and development activities.

At June 30, 2011, we had cash, cash equivalents and short-term investments of $91.0 million, compared to $58.6 million at December 31, 2010. On June 28, 2011 we completed an underwritten public offering of 11,023,000 shares of our common stock at a price to the public of $4.75 per share. Net cash proceeds from the public offering were approximately $49.0 million, after deducting the underwriting discount and offering expenses.

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 into the first half of 2013. 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. In any event, to complete the development of and seek regulatory approval for Ostarine™ and Capesaris™, we will need to obtain substantial additional funding.

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 the POWER1 and POWER2 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 hormonal treatment of advanced prostate cancer	Selective ER alpha agonist	Phase IIb	Initiated a Phase IIb clinical trial in June 2011 in men with advanced prostate cancer. Plan to initiate an additional Phase II clinical trial this year.
Capesaris™ Second line hormonal treatment of advanced prostate cancer	Selective ER alpha agonist	Phase II	Plan to initiate a Phase II clinical trial this year in men who have developed castration resistant prostate cancer.

Sales and Marketing

We market and sell FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of advanced metastatic breast cancer in postmenopausal women, in the United States. Effective June 1, 2011, we no longer utilize a sales force for FARESTON® promotional efforts, which has the potential to result in a decline in sales volume in future periods. In order to commercialize any future products, we will need to develop our sales and marketing capabilities or establish and maintain agreements with third parties to market and sell our product candidates.

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 less than fiscal year 2010 due primarily to the June 2011 reduction in our workforce.

Critical Accounting Policies and Significant Judgments and Estimates

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

While our significant accounting policies are more fully described in Note 2 to our financial statements appearing in our Annual Report on Form 10-K for the year ended December 31, 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. This amount is included in collaboration revenue in the condensed statement of operations for the six months ended June 30, 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 in December 2010 due to the termination of our license and collaboration agreement with Merck. These amounts are included in collaboration revenue in the condensed statement of operations for the six months ended June 30, 2010.

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 six months ended June 30, 2011. Based on this information and other factors, we estimate an accrual for product returns. At June 30, 2011 and December 31, 2010, our accrual for product returns was $998,000 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 six months ended June 30, 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. Further, research and development expenses for the six months ended June 30, 2010 included an impairment charge of $1.7 million related to the unamortized portion of capitalized license fees paid to Orion Corporation and the University of Tennessee Research Foundation related to our toremifene 20 mg program.

Share-Based Compensation

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

The determination of the fair value of share-based payment awards on the date of grant include the expected life of the award, the expected stock price volatility over the expected life of the awards, expected dividend yield, and risk-free interest rate. We estimate the expected life of options by calculating the average of the vesting term and contractual term of the options. We estimate the expected stock price volatility based on the historical volatility of our common stock. The risk-free interest rate is determined using U.S. Treasury rates where the term is consistent with the expected life of the stock options. Expected dividend yield is not considered as we have not made any dividend payments and have no plans of doing so in the foreseeable future. The amount of share-based compensation expense recognized is reduced ratably over the vesting period by an estimate of the percentage of options granted that are expected to be forfeited or canceled before becoming fully vested. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate.

Total share-based compensation expense for the three months ended June 30, 2011 was $943,000, of which $398,000 and $545,000 were recorded in the condensed statement of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the three months ended June 30, 2010 was $1.1 million, of which $454,000 and $625,000 were recorded in the condensed statement of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the six months ended June 30, 2011 was $2.2 million, of which $907,000 and $1.3 million were recorded in the condensed statement of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the six months ended June 30, 2010 was $2.8 million, of which $1.3 million and $1.5 million were recorded in the condensed statement of operations as research and development expenses and general and administrative expenses, respectively. Included in share-based compensation expense for the three months ended June 30, 2011 and 2010 was share-based compensation expense related to deferred compensation arrangements for our non-employee directors of $45,000 and $46,000, respectively, and $96,000 for both of the six months ended June 30, 2011 and 2010. At June 30, 2011, the total compensation cost related to non-vested awards not yet recognized was approximately $8.4 million with a weighted average expense recognition period of 3.2 years.

Results of Operations

Three Months Ended June 30, 2011 and 2010

Revenues. Revenues for the three months ended June 30, 2011 were $1.6 million as compared to $935,000 for the same period of 2010. Revenues for the three months ended June 30, 2011 consisted of net product sales of FARESTON® marketed for the treatment of advanced metastatic breast cancer in postmenopausal women while revenues for the same period of 2010 included net sales of FARESTON® and collaboration revenue from our former collaboration with Ipsen. During the three months ended June 30, 2011 and 2010, FARESTON® net product sales were $1.6 million and $599,000, respectively, while cost of product sales were $264,000 and $134,000, respectively. FARESTON® net product sales for the three months ended June 30, 2011 increased from the same period in the prior year due primarily to an increase in sales volume and, to a lesser extent, an increase in sales price of FARESTON®. Collaboration revenue for the three months ended June 30, 2010 was $336,000.

Research and Development Expenses. Research and development expenses decreased 20% to $7.6 million for the three months ended June 30, 2011 from $9.5 million for the three months ended June 30, 2010. The decrease in "Other research and development" during the three months ended June 30, 2011 compared to the three months ended June 30, 2010, as shown in the following table, was due to the discontinuance of the toremifene 80 mg and toremifene 20 mg development programs during 2011 and due to the recognition of an impairment charge of $1.7 million related to our toremifene 20 mg intangible asset during the three months ended June 30, 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 June 30, 2011	Three Months Ended June 30, 2010	Increase/ Decrease
		(in thousands)		
Ostarine™				
Prevention and treatment of muscle wasting in patients with non-small cell lung cancer	**SARM**	$ 2,460	$ 818	$ 1,642
Capesaris™				
First line hormonal treatment of advanced prostate cancer	**Selective ER alpha agonist**	3,335	2,507	828
Other research and development		1,796	6,152	(4,356)
Total research and development expenses		$ 7,591	$ 9,477	$ (1,886)

General and Administrative Expenses. General and administrative expenses increased during the three months ended June 30, 2011 to $4.5 million from $4.3 million for the three months ended June 30, 2010. This increase was primarily due to severance related expenses of the workforce reduction that occurred in June 2011 partially offset by reduced marketing and insurance expenses.

Six Months Ended June 30, 2011 and 2010

Revenues. Revenues for the six month periods ended June 30, 2011 and 2010 were $10.9 million and $57.5 million, respectively and included net product sales of FARESTON® and collaboration revenue. In the first six months of 2011 and 2010, FARESTON® net product sales were $2.9 million and $1.4 million, respectively, while cost of product sales were $469,000 and $285,000, respectively. FARESTON® net product sales for the six months ended June 30, 2011 increased from the same period in the prior year due to an increase in the price of FARESTON®, as well as an increase in sales volume. Collaboration revenue was $8.1 million for the six months ended June 30, 2011. 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 in the three months ended March 31, 2011. Collaboration revenue was $56.1 million for the six months ended June 30, 2010 and consisted of $1.3 million from Ipsen and $54.9 million from Merck. As a result of the termination of our license and collaboration agreement with Merck in March 2010, we recognized as collaboration revenue the remaining $49.9 million of unamortized deferred revenue in the first quarter of 2010, as well as the final payment of $5.0 million of cost reimbursement that was received from Merck in December 2010.

Research and Development Expenses. Research and development expenses decreased by 13% to $14.9 million for the six months ended June 30, 2011 from $17.1 million for the six months ended June 30, 2010. The decrease in "Other research and development" during the six months ended June 30, 2011 compared to the six months ended June 30, 2010, as shown in the following table, was due primarily to the discontinuance of the toremifene 80 mg and toremifene 20 mg development programs during 2011. 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.

Product Candidate/ Proposed Indication	Program	Six Months Ended June 30, 2011	Six Months Ended June 30, 2010	Increase/ Decrease
		(in thousands)		
Ostarine™				
Prevention and treatment of muscle wasting in patients with non-small cell lung cancer	**SARM**	$ 3,476	$ 1,485	$ 1,991
Capesaris™				
First line hormonal treatment of advanced prostate cancer	**Selective ER alpha agonist**	5,648	4,830	818
Other research and development		5,770	10,812	(5,042)
Total research and development expenses		$ 14,894	$ 17,127	$ (2,233)

General and Administrative Expenses. General and administrative expenses increased during the six months ended June 30, 2011 to $9.2 million from $8.8 million for the six months ended June 30, 2010. This increase was primarily due to severance related expenses of the workforce reduction that occurred in June 2011 partially offset by reduced occupancy and insurance expenses.

Liquidity and Capital Resources

At June 30, 2011, we had cash, cash equivalents and short-term investments of $91.0 million, compared to $58.6 million at December 31, 2010. On June 28, 2011 we completed an underwritten public offering of 11,023,000 shares of our common stock at a price to the public of $4.75 per share. Net cash proceeds from the public offering were approximately $49.0 million, after deducting the underwriting discount and offering expenses.

Net cash used in operating activities was $16.6 million and $20.5 million for the six months ended June 30, 2011 and 2010, respectively, and resulted primarily from funding our operations for the periods.

Net cash used in investing activities was $8.1 million for the six months ended June 30, 2011 and was primarily for the purchase of short-term investments. Net cash provided by investing activities was $366,000 for the six months ended June 30, 2010 and resulted from the maturities of short-term investments of $7.4 million, offset by the purchase of short-term investments of $6.9 million and the purchase of information technology equipment and research and development equipment of approximately $85,000.

Net cash provided by financing activities was $49.0 million for the six months ended June 30, 2011 and reflects proceeds from our underwritten public offering of common stock in June 2011 and proceeds from the exercise of employee stock options. These proceeds were reduced by payments on our capital lease and financed equipment obligations. Net cash used in financing activities of $46,000 for the six months ended June 30, 2010 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 into the first half of 2013. 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. In any event, to complete the development of and seek regulatory approval for Ostarine™ and Capesaris™, we will need to obtain substantial additional funding.

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 ongoing and planned clinical trials of Ostarine™ and Capesaris™;
- the terms and timing of any potential future collaborative, licensing and other arrangements that we may establish;
- the amount and timing of any licensing fees, milestone payments and royalty payments from potential future collaborators, if any;
- 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 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 June 2011 and December 2009, we announced workforce reductions of approximately 15% and 26%, respectively, in order to reduce our operating expenses relating to our discontinued toremifene development programs. If we are unable to raise additional funds when needed, 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 financial condition, the outcomes of our ongoing and 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 six months ended June 30, 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 second 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 for 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 June 30, 2011, we had an accumulated deficit of $366.1 million. Due to the recognition of the remaining $49.9 million of unamortized revenue following 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 six months ended June 30, 2011 was $13.3 million. We expect to incur significant net 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.

We have discontinued our toremifene 80 mg and toremifene 20 mg development programs, and 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, Ostarine™ (GTx-024) and Capesaris™ (GTx-758), are in various stages of clinical development, and significant additional clinical development and financial resources will be required to obtain necessary regulatory approvals for each of these product candidates 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 product candidates 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 six months ended June 30, 2011, we recognized $2.9 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 capital 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;
- seek regulatory approval for our product candidates; 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 into the first half of 2013. 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. In any event, to complete the development of and seek regulatory approval for Ostarine™ and Capesaris™, we will need to obtain substantial additional funding. 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 ongoing and planned clinical trials of Ostarine™ and Capesaris™;
- the terms and timing of any potential future collaborative, licensing and other arrangements that we may establish;
- the amount and timing of any licensing fees, milestone payments and royalty payments from potential future collaborators, if any;
- 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 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 June 2011 and December 2009, we announced workforce reductions of approximately 15% and 26%, respectively, in order to reduce our operating expenses relating to our discontinued toremifene development programs. If we are unable to raise additional funds when needed, 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 financial condition, the outcomes of our ongoing and 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 programs.

Significant delays in clinical testing could materially impact our product development costs. We do not know whether planned clinical trials will begin on time, or whether ongoing or planned clinical trials will need to be restructured or will be completed on schedule, if at all. We or any potential future collaborators may experience numerous unforeseen and/or adverse 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, or we may experience substantial delays in obtaining these authorizations;
- 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 anticipate, resulting in significant delays or study terminations;
- 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 also been observed in subjects treated with Ostarine™.

Capesaris™ is a new chemical entity that is selective for estrogen receptor alpha. Similar to other estrogenic therapies, there may be an increased risk of venous thromboembolic events, or blood clots, and increases in liver enzymes with Capesaris™ treatment. Although to date Capesaris™ has been generally well tolerated in clinical trials that we have conducted, one subject receiving Capesaris™ in one of our recent studies experienced a blood clot in his leg and was discontinued from the study. It is possible that blood clots, increases in liver enzymes and other adverse effects may be observed in future Capesaris™ clinical studies.

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 the collaboration discussions we are pursuing 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 Biopharm Limited, or 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 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 any 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 any 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™, Ostarine™ or any future 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 or products.*

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

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party because of factors beyond our control;
- the possible termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us; and
- drug product supplies not meeting the requisite requirements for clinical trial use.

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.

We have agreed to purchase exclusively 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 to us at its election at any time. If Orion elects to terminate its obligation to manufacture and supply us with FARESTON® 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 FARESTON® 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 FARESTON® tablets are terminated by Orion for any reason, a disruption in the supply could impair our ability to continue to commercialize FARESTON®.

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. While we have met with the FDA to discuss the development programs and endpoints for Ostarine™ and Capesaris™, there can be no assurance that the FDA will ultimately determine that data from our current and planned trials will be sufficient for approval of either of these product candidates.

In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent regulatory approval of a product candidate. 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 potential 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. Although we continue to market and sell FARESTON®, we no longer utilize a sales force for promotional efforts. Additionally, continued sales may 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 six months ended June 30, 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; and
- the loss of Orion, upon which we rely as a single source, as our supplier of FARESTON®.

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

We have 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 legislation also implements cost containment measures that could adversely affect our revenues. These measures include increased drug rebates under Medicaid 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.

The health care reform legislation has been subject to judicial challenge. While some courts have upheld the law, other courts have concluded that the individual mandate component of the law is unconstitutional. One of those courts determined that the individual mandate component could not be severed from the law and therefore concluded that the entire law was void. All of the rulings on the merits are being appealed. There is no certainty regarding the final outcome of the litigation or the impact of the outcome on the pricing and potential profitability of any products that we and/or any potential future collaborators may develop.

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 enactment in the United States of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act in 2010. 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 Ostarine™ and any future SARM product candidates, if approved for commercial sale, including SARMs in development from Ligand Pharmaceuticals Inc., Galapagos NV, 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, growth hormone, secretagogues and other agents, that may have some muscle building activity. Helsinn Group is developing anamorelin, a ghrelin receptor agonist, in Phase III clinical trials for treatment of cancer cachexia in patients with non-small cell lung cancer. Appetite stimulants such as megestrol acetate and dronabinol are used off-label for the treatment of weight loss and the treatment of loss of appetite in patients with cancer.

We are developing Capesaris™ for first line hormonal 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. We also announced a reduction of approximately 15% of our workforce in June 2011 in connection with our decision to discontinue the development of toremifene 80 mg and toremifene 20 mg. These 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, enrollment or completion of our ongoing and 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;

- additional 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;
- hedging or arbitrage trading activity that may develop regarding our common stock;
- 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 June 30, 2011, our executive officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 59.3% of our outstanding common stock, and our executive officers and directors alone beneficially owned approximately 38.7% of our outstanding common stock. As a result, these stockholders, acting together, may or will have the ability to control all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders.

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

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

- a classified Board of Directors;

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

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

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

For the 12-month period ended June 30, 2011, the average daily trading volume of our common stock on The NASDAQ Global Market was 210,178 shares. As a result, future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the then-prevailing market price of our common stock. As of June 30, 2011, we had 62,756,411 shares of common stock outstanding.

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

ITEM 6. EXHIBITS

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

SIGNATURES

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

GTx, Inc.

Date: August 9, 2011

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

Date: August 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)
10.59*	Memorandum of Understanding Concerning the Lease Agreement between The University of Tennessee Research Foundation and the Registrant as Amended July 20, 2009
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) (6)
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) (6)
101.INS*	XBRL Instance Document(7)
101.SCH*	XBRL Taxonomy Extension Schema Document(7)
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document(7)
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document(7)
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document(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) 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.

(7) Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

Exhibit 10.59

Memorandum of Understanding
Concerning the Lease Agreement between
The University of Tennessee Research Foundation and GTx, Inc.
As Amended July 20, 2009

RECITALS

WHEREAS, The University of Tennessee Research Foundation (the "SUBLESSOR") and The University of Tennessee (the "LESSOR") have entered into a Lease dated March 7, 2001, which was subsequently amended by agreements dated April 1, 2005 and July 20, 2009 (the "Lease"); and

WHEREAS, the SUBLESSOR and GTx, Inc., a Delaware corporation (the "SUBLESSEE"), have entered into a Sublease dated October 1, 2009 with the consent of LESSOR (the "Sublease");

WHEREAS, the SUBLESSOR and SUBLESSEE desire to reduce the portion of the premises leased to the SUBLESSEE and the Rent to be paid by SUBLESSEE to SUBLESSOR, as hereinafter described;

NOW THEREFORE, in consideration of the foregoing and other good and valuable consideration set forth herein, the parties agree as follows:

1. The leased premises described in the Sublease shall be reduced as of the Effective Date from 71,754 square feet to 41,628 square feet as described below and shown on the Floor Plans attached to and incorporated within this Memorandum as Exhibit A:

CURRENT AND PROPOSED ALLOCATION OF SPACE

	Current Areas		Proposed New Areas	
Floor	SUBLESSOR	LESSOR	SUBLESSOR	LESSOR
Basement	5,238		4,732	0
1st floor	12,563	3,625	8,210	10,010
2nd floor	23,326	5,771	22,708	6,210
3rd floor	30,626		5,978	23,302
Totals	**71,754**	**9,396**	**41,628**	**39,522**
	88%	**12%**	**51%**	**49%**

2. Pursuant to Section 2 of the Sublease, as of the Effective Date, the Rent SUBLESSEE will continue to pay to SUBLESSOR for the reduced leased premises will be based on that portion of the "actual cost of operations" (as defined in the Sublease) for the Premises commensurate with the amount of space leased by SUBLESSEE. With the reduction of the leased premises, as of the Effective Date, SUBLESSEE will pay as Rent to SUBLESSOR 50% of the actual cost of operations of the Premises (which includes the building located on the Premises).

3. This MOU is to become effective on May 1, 2011 (the "Effective Date") and will continue in effect through the end of the current Sublease term on December 31, 2012. If SUBLESSEE determines to exercise any option to extend the Sublease, this MOU will continue in effect for up to an additional five (5) months through April 30, 2013.

4. This MOU can be canceled with 90 days advance written notice and acceptance by all parties., in which event the lease premises will automatically return to the entire leased premises described in the Sublease.

5. All parties agree to respect the privacy and confidentiality of intellectual property of each other as provided by Tennessee and federal law.

IN WITNESS WHEREOF, the SUBLESSEE and the SUBLESSEE have executed this Sublease in duplicate on the date written below.

THE UNIVERSITY OF TENNESSEE RESEARCH FOUNDATION (SUBLESSOR)

By: /s/ Richard Magid
Richard Magid
Vice President

Date: 14 April 2011

GTx, Inc. (SUBLESSEE)

By: /s/ Henry P. Doggrell
Henry P. Doggrell
Vice President, General Counsel

Date: April 13, 2011

THE UNIVERSITY OF TENNESSEE (LESSOR)

By: /s/ Chares M. Peccolo
Charles M. Peccolo
Treasurer

Date: April 19, 2011

Exhibit A

Floor Plans

EXHIBIT 31.1

CHIEF EXECUTIVE OFFICER CERTIFICATION

I, Mitchell S. Steiner, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 9, 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: August 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 June 30, 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: August 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 June 30, 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: August 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.