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 September 30, 2009

OR

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

For the transition period from _____to _____

Commission file number: 000-50549

GTx, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**62-1715807**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
175 Toyota Plaza 7th Floor Memphis, Tennessee	**38103**
(Address of principal executive offices)	(Zip Code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

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

Large accelerated filer o	Accelerated filer ☑	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

As of November 4, 2009, 36,420,901 shares of the registrant's Common Stock were outstanding.

GTx, INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2009
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PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2009 (unaudited)	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 47,457	$ 95,510
Short-term investments	8,085	2,157
Accounts receivable, net	373	487
Inventory	151	92
Prepaid expenses and other current assets	1,514	1,778
Total current assets	57,580	100,024
Property and equipment, net	3,638	3,988
Intangible and other assets, net	3,839	4,097
Total assets	65,057	$ 108,109
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 856	$ 2,821
Accrued expenses	6,047	6,666
Deferred revenue — current portion	11,522	11,490
Total current liabilities	18,425	20,977
Deferred revenue, less current portion	46,145	54,732
Other long term liabilities	463	382
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value: 60,000,000 shares authorized; 36,420,901 shares issued and outstanding at September 30, 2009 and 36,392,443 shares issued and outstanding at December 31, 2008	36	36
Additional paid-in capital	357,287	353,900
Accumulated deficit	(357,299)	(321,918)
Total stockholders' equity	24	32,018
Total liabilities and stockholders' equity	$ 65,057	$ 108,109

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 September 30,		Nine Months Ended September 30,	
	2009	**2008**	**2009**	**2008**
Revenues:				
Product sales, net	$ 719	$ 315	$ 2,427	$ 846
Collaboration revenue	2,881	2,734	8,626	9,684
Total revenue	3,600	3,049	11,053	10,530
Costs and expenses:				
Cost of product sales	344	192	1,123	482
Research and development expenses	8,123	9,244	24,181	33,613
General and administrative expenses	7,982	6,107	21,464	16,781
Total costs and expenses	16,449	15,543	46,768	50,876
Loss from operations	(12,849)	(12,494)	(35,715)	(40,346)
Interest income	29	568	140	2,434
Loss before income taxes	(12,820)	(11,926)	(35,575)	(37,912)
Income tax benefit	—	—	194	—
Net loss	$ (12,820)	$ (11,926)	$ (35,381)	$ (37,912)
Net loss per share:				
Basic and diluted	$ (0.35)	$ (0.33)	$ (0.97)	$ (1.05)
Weighted average shares used in computing net loss per share:				
Basic and diluted	36,418,745	36,348,717	36,413,521	36,277,229

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

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

	Nine Months Ended September 30,	
	2009	**2008**
Cash flows from operating activities:		
Net loss	$ (35,381)	$ (37,912)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	1,335	1,110
Share-based compensation	3,123	2,476
Directors' deferred compensation	128	137
Deferred revenue amortization	(8,626)	(8,200)
Foreign currency transaction (gain) loss	(30)	25
Changes in assets and liabilities:		
Short-term investments	2,157	6,311
Accounts receivable, net	114	(24)
Inventory	(59)	(58)
Receivable from collaboration partners	699	40,563
Prepaid expenses and other assets	(401)	122
Accounts payable	(1,965)	(285)
Accrued expenses and other long term liabilities	(773)	(905)
Net cash (used in) provided by operating activities	(39,679)	3,360
Cash flows from investing activities:		
Purchase of held to maturity short-term investments	(8,085)	—
Purchase of property and equipment, net	(422)	(2,713)
Net cash used in investing activities	(8,507)	(2,713)
Cash flows from financing activities:		
Proceeds from exercise of employee stock options	136	963
Payments on capital lease obligation	(3)	(4)
Net cash provided by financing activities	133	959
Net (decrease) increase in cash and cash equivalents	(48,053)	1,606
Cash and cash equivalents, beginning of period	95,510	100,178
Cash and cash equivalents, end of period	$ 47,457	$ 101,784

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

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

1. Business and Basis of Presentation

Business

GTx, Inc. ("GTx" 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 to prevent and treat cancer, fractures and bone loss, muscle loss and other serious medical conditions. GTx operates in one business segment.

GTx is developing toremifene citrate, a selective estrogen receptor modulator ("SERM"). GTx has completed a pivotal Phase III clinical trial evaluating toremifene 80 mg to reduce fractures and treat other estrogen deficiency side effects of androgen deprivation therapy ("ADT") in men with prostate cancer. In December 2008, the Company submitted a New Drug Application ("NDA") for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT to the U.S. Food and Drug Administration ("FDA"). In October 2009, the Company received a Complete Response Letter from the FDA regarding its NDA for toremifene 80 mg. See further discussion under *Subsequent Events* in this Note 1 regarding the Complete Response Letter. GTx is also developing toremifene 20 mg in an ongoing pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia ("high grade PIN"). GTx has licensed to Ipsen Developments Limited ("Ipsen") exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein, and the Commonwealth of Independent States (collectively, the "European Territory") to develop and commercialize toremifene for all indications which the Company has licensed from Orion Corporation ("Orion"). In December 2007, the Company and Merck & Co., Inc. ("Merck") entered into a collaboration to discover and develop selective androgen receptor modulators ("SARMs"), a new class of drugs with the potential to treat chronic sarcopenia, which is the loss of skeletal muscle mass resulting in reduced physical strength and ability to perform activities of daily living, as well as other musculoskeletal wasting or muscle loss conditions. The Company and Merck are evaluating multiple SARM product candidates, including Ostarine™ (designated by Merck as MK-2866) and MK-0773, for a variety of musculoskeletal wasting indications including chronic sarcopenia and muscle loss in patients with chronic obstructive pulmonary disease. GTx is also developing GTx-758, an oral luteinizing hormone inhibitor for the treatment of advanced prostate cancer.

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

Basis of Presentation

The accompanying unaudited condensed financial statements reflect, in the opinion of management, all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation of GTx's financial position, results of operations and cash flows for each period presented in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted from the accompanying condensed financial statements. These interim condensed financial statements should be read in conjunction with the audited financial statements and related notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2008. Operating results for the three and nine months ended September 30, 2009 are not necessarily indicative of the results that may be expected for the entire fiscal year ending December 31, 2009.

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

Use of Estimates

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

Revenue Recognition

The Company recognizes revenue from net 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 September 30, 2009 and December 31, 2008, the Company's accrual for product returns was $519 and $815, respectively.

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

Research and Development Expenses

Research and development expenses include, but are not limited to, the Company's expenses for personnel and facilities associated with research activities, screening and identification of product candidates, formulation and synthesis activities, manufacturing, preclinical studies, toxicology studies, clinical trials, regulatory affairs, quality assurance activities and license fees. 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.

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

Short-term Investments

At September 30, 2009, 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.

At December 31, 2008, short-term investments consisted of an investment in Bank of America Corporation's Columbia Strategic Cash Portfolio (the "Fund"). The Company's investment in the Fund was liquidated in its entirety during September 2009. For the three months ended September 30, 2009 and 2008, the Company recognized a gain on its investment in the Fund of approximately $16 and a loss of approximately $59, respectively. For the nine months ended September 30, 2009 and 2008, the Company recognized a gain on its investment in the Fund of approximately $98 and a loss of approximately $175, respectively.

The fair values of these investments were determined based on quoted market prices in active markets and other observable market data, or Level 1 and Level 2 inputs. Where quoted market prices in active markets were not available, inputs other than quoted prices that are observable, either directly or indirectly, were used to determine the fair values of these investments.

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 September 30, 2009 and December 31, 2008, 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, 2008.

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

GTx, Inc.
NOTES TO CONDENSED FINANCIAL STATEMENTS
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Recent Accounting Pronouncements

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

Subsequent Events

The Company has evaluated all events or transactions that occurred after September 30, 2009 up through the date the condensed financial statements were issued, or November 9, 2009.

In October 2009, the Company received a Complete Response Letter from the FDA regarding its NDA for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT. The FDA identified two deficiencies in the Complete Response Letter and recommended that the following information be provided to the FDA to address these clinical deficiencies: (i) results of a second adequate and well-controlled Phase III clinical trial demonstrating the safety and efficacy of toremifene 80 mg to reduce fractures in men with prostate cancer on ADT and (ii) results from an adequate and well-controlled clinical trial demonstrating that toremifene 80 mg treatment to reduce fractures in men with prostate cancer on ADT does not have a detrimental effect on either time-to-disease progression or overall survival. The Company has requested a meeting with the FDA to determine the appropriate next steps regarding the NDA.

Other than the Complete Response Letter received from the FDA, there were no material recognizable or nonrecognizable subsequent events.

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 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 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, 2008.

GTx, Inc.
NOTES TO CONDENSED FINANCIAL STATEMENTS
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Total share-based compensation expense for the three months ended September 30, 2009 was $1,128, of which $413 and $715 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 September 30, 2008 was $995, of which $479 and $516 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 nine months ended September 30, 2009 was $3,251, of which $1,182 and $2,069 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 nine months ended September 30, 2008 was $2,613, of which $1,166 and $1,447 were recorded in the condensed statement of operations as research and development expenses and general and administrative expenses, respectively. Share-based compensation expense for the three months ended September 30, 2009 and 2008 included share-based compensation expense related to deferred compensation arrangements for the Company's directors of $44 and $42, respectively. Share-based compensation expense for the nine months ended September 30, 2009 and 2008 included share-based compensation expense related to deferred compensation arrangements for the Company's directors of $128 and $137, respectively.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Expected price volatility	58.4%	53.6%	55.0%	51.5%
Risk-free interest rate	3.2%	3.6%	2.0%	3.5%
Weighted average expected life in years	7.0 years	7.0 years	6.9 years	6.9 years

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

	Number of Shares	Weighted Average Exercise Price Per Share
Options outstanding at December 31, 2008	2,673,976	$ 13.01
Options granted	1,112,650	15.13
Options forfeited	(62,499)	15.33
Options exercised	(18,434)	7.37
Options outstanding at September 30, 2009	3,705,693	13.64

GTx, Inc.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(in thousands, except share and per share data)
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3. Basic and Diluted Net Loss Per Share

Basic net loss per share attributable to common stockholders is calculated based on the weighted average number of common shares outstanding during the period. Diluted net loss per share gives effect to the dilutive potential of common stock consisting of stock options.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Basic net loss per share				
Numerator:				
Net loss	$ (12,820)	$ (11,926)	$ (35,381)	$ (37,912)
Denominator (weighted average shares):				
Common stock outstanding at beginning of period	36,418,234	36,311,490	36,392,443	36,216,263
Exercise of employee stock options and issuance of common stock under deferred compensation arrangements	511	37,227	21,078	60,966
Weighted average shares used in computing basic and diluted net loss per share	36,418,745	36,348,717	36,413,521	36,277,229
Basic and diluted net loss per share	$ (0.35)	$ (0.33)	$ (0.97)	$ (1.05)

Weighted average options outstanding to purchase shares of common stock of 3,666,635 and 2,669,156 for the three months ended September 30, 2009 and 2008, respectively, and 3,585,606 and 2,626,323 for the nine months ended September 30, 2009 and 2008, respectively, were excluded from the calculations of diluted net loss per share as inclusion of the options would have had an anti-dilutive effect on the net loss per share for the periods.

4. Collaboration and License Agreements

University of Tennessee Research Foundation License Agreements

In July 2007, the Company and the University of Tennessee Research Foundation ("UTRF") entered into a consolidated, amended and restated license agreement (the "SARM License Agreement") to consolidate and replace the Company's two previously existing SARM license agreements with UTRF and to modify and expand certain rights and obligations of each of the parties under both license agreements. Pursuant to this agreement, the Company was granted exclusive worldwide rights in all existing SARM technologies owned or controlled by UTRF, including all improvements thereto, and exclusive rights to future SARM technology that may be developed by certain scientists at the University of Tennessee or subsequently licensed to UTRF under certain existing inter-institutional agreements with The Ohio State University.

GTx, Inc.
NOTES TO CONDENSED FINANCIAL STATEMENTS
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In September 2007, the Company and UTRF entered into an amended and restated license agreement (the "SERM License Agreement") to replace its previously existing exclusive worldwide license agreement for toremifene. Pursuant to this agreement, the Company was granted exclusive worldwide rights to UTRF's method of use patents relating to SERMs, including toremifene for chemoprevention of prostate cancer as well as future related SERM technologies that may be developed by certain scientists at the University of Tennessee.

Under the SARM License Agreement and the SERM License Agreement (together, the "License Agreements"), the Company agreed to pay to UTRF a one-time, upfront fee of $290 per License Agreement as consideration for entering into the License Agreements. The Company is also obligated to pay UTRF annual license maintenance fees and royalties on sublicense revenues and net sales of products.

In December 2008, the Company amended the License Agreements (together the "License Amendments") with UTRF. In consideration for the execution of the License Amendments, the Company paid UTRF an aggregate of $540, which was included in research and development expense in the Company's statement of operations for the year ended December 31, 2008.

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 Territory to develop and commercialize toremifene in all indications which the Company has licensed from Orion, which include all indications in humans except the treatment and prevention of breast cancer outside of the United States.

In accordance with the terms of the Ipsen Collaboration Agreement, Ipsen agreed to pay the Company €23,000 as a license fee and expense reimbursement, of which €1,500 was paid in equal installments over a three year period from the date of the Ipsen Collaboration Agreement. In October 2006, the Company received €21,500 (approximately $27,100) from Ipsen as the initial payment for the license fee and expense reimbursement. In September 2007, the Company received €500 (approximately $688) from Ipsen as the first annual installment payment. The second annual installment payment of €500 (approximately $711) was received from Ipsen in September 2008. In September 2009, the Company received the third, and final, installment payment of €500 (approximately $726) from Ipsen. Pursuant to the Ipsen Collaboration Agreement, the Company is also entitled to receive from Ipsen up to an aggregate of €39,000 in milestone payments depending on the successful development and launch of toremifene in certain countries of the European Territory for the high grade PIN indication, subject to certain conditions, and the ADT indication. In February 2008, the Company earned a milestone of €1,000 (approximately $1,482) with the achievement of the primary endpoint in the toremifene 80 mg ADT Phase III clinical trial. This amount was recognized as collaboration revenue in the first quarter of 2008. Ipsen has agreed to be responsible for and to pay all clinical development, regulatory and launch activities to commercialize toremifene in the European Territory for both the high grade PIN indication and ADT indication. Ipsen has agreed to pay the Company a royalty equal to a graduating percentage of aggregate net sales of products containing toremifene which rates will be dependent on whether such sales are for the high grade PIN indication or the ADT indication. The Company will remain responsible for paying upstream royalties on toremifene to both Orion and UTRF for the PIN indication and to Orion only for the ADT indication. Ipsen has agreed to purchase the bulk drug product supply directly from Orion and is responsible for the packaging and labeling of the final product.

GTx, Inc.
NOTES TO CONDENSED FINANCIAL STATEMENTS
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The Company has recorded deferred revenue of $29,330 related to the Ipsen upfront license fee and expense reimbursements which is being amortized into revenue on a straight-line basis over the estimated five year development period for toremifene in the European Territory. The Company recognized as collaboration revenue $1,471 and $1,463 for the three months ended September 30, 2009 and 2008, respectively, and $4,398 and $4,389 for the nine months ended September 30, 2009 and 2008, respectively, from the amortization of the Ipsen deferred revenue.

Merck & Co., Inc. Collaboration and License Agreement

In December 2007, GTx and Merck entered into a global exclusive license and collaboration agreement (the "Merck Collaboration Agreement") governing the Company's and Merck's joint research, development and commercialization of SARM compounds and related SARM products, including SARMs currently being developed by the Company and Merck and those yet to be discovered, for all potential indications of interest.

Under the Merck Collaboration Agreement, the Company granted Merck an exclusive worldwide license under its SARM-related patents and know-how. The Company is conducting preclinical research of SARM compounds and products, and Merck is primarily responsible 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. In addition, Merck has agreed to pay the Company $15,000 in guaranteed cost reimbursements for research and development activities in equal annual installments over a three year period beginning on the first anniversary of the effective date of the Merck Collaboration Agreement. In December 2008, the Company received $5,000 from Merck as the initial payment of the cost reimbursement for research and development activities. The Company is also eligible to receive under the Merck Collaboration Agreement up to $422,000 in future milestone payments associated with the development and regulatory approval of a lead product candidate, including Ostarine™, as defined in the Merck Collaboration Agreement, if multiple indications are developed and receive required regulatory approvals, as well as additional milestone payments for the development and regulatory approval of other product candidates developed under the Merck Collaboration Agreement. Merck has also agreed to pay the Company tiered royalties on net sales of products that may be developed under the Merck Collaboration Agreement. The Company is responsible for any payments owed to UTRF resulting from the Merck Collaboration Agreement.

Unless terminated earlier, the Merck Collaboration Agreement will remain in effect in each country of sale at least until the expiration of all valid claims of the licensed patents in such country. However, Merck may terminate the Merck Collaboration Agreement at its election at any time after a specified period of time following the effectiveness of the Merck Collaboration Agreement, and either party may terminate the Merck Collaboration Agreement at any time for the other party's uncured material breach or bankruptcy. Under certain conditions, Merck will continue to owe royalties on certain products after it terminates the Merck Collaboration Agreement without cause.

The Company and Merck also entered into a Stock Purchase Agreement pursuant to which the Company sold to Merck on December 18, 2007, 1,285,347 newly-issued shares of the Company's common stock for an aggregate purchase price of approximately $30,000, or $23.34 per share.

GTx, Inc.
NOTES TO CONDENSED FINANCIAL STATEMENTS
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The Company deferred the recognition of the upfront licensing fee of $40,000 and the $10,800 in equity premium received that represents 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 are being recognized as revenue over the period of the Company's performance obligation, which the Company estimates to be ten years. The $5,000 of cost reimbursement received in December 2008 is being recognized as collaboration revenue over the remaining period of the Company's performance obligation. The Company recognized as collaboration revenue $1,410 and $1,271 for the three months ended September 30, 2009 and 2008, respectively, and $4,228 and $3,813 for the nine months ended September 30, 2009 and 2008, respectively, from the amortization of the Merck deferred revenue. The remaining cost reimbursements for research and development activities will begin to be recognized as collaboration revenue when the amounts are determinable and collection of the related receivable is reasonably assured.

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 and our collaborators' research, development and clinical programs, including the timing of regulatory submissions and related regulatory actions, and whether future clinical trials will achieve similar results to clinical trials that we have successfully concluded;
- potential future licensing fees, milestone payments and royalty payments, including any milestone payments or royalty payments that we may receive under our collaborative arrangements with Ipsen Developments Limited and Merck & Co., Inc.;
- our and our collaborators' ability to obtain and maintain regulatory approvals of our product candidates and any related restrictions, limitations, and/or warnings;
- our and our collaborators' ability to market, commercialize and achieve market acceptance for our product candidates or products that we may develop;
- our and our collaborators' ability to generate additional product candidates for clinical testing;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; and
- our estimates regarding the sufficiency of our cash resources.

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

Overview

We are a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules that selectively target hormone pathways to prevent and treat cancer, fractures and bone loss, muscle loss and other serious medical conditions. We are developing toremifene citrate, a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men.

We commenced a pivotal Phase III clinical trial of toremifene 80 mg under a Special Protocol Assessment, or SPA, with the U.S. Food and Drug Administration, or FDA, to reduce fractures and treat other estrogen deficiency related side effects of androgen deprivation therapy, or ADT, in men with prostate cancer in November 2003. In the first quarter of 2008, we announced that the Phase III clinical trial results for toremifene 80 mg to reduce fractures and treat other estrogen deficiency side effects of ADT in men with prostate cancer showed that toremifene 80 mg reduced new morphometric vertebral fractures, met other key endpoints of bone mineral density, or BMD, lipid profiles and gynecomastia, and also showed that toremifene 80 mg demonstrated a reduction in hot flashes in a subset of patients. In December 2008, we submitted a New Drug Application, or NDA, for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT to the FDA. 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. The FDA identified two deficiencies in the Complete Response Letter and recommended that the following information be provided to the FDA to address these clinical deficiencies: (i) results of a second adequate and well-controlled Phase III clinical trial demonstrating the safety and efficacy of toremifene 80 mg to reduce fractures in men with prostate cancer on ADT and (ii) results from an adequate and well-controlled clinical trial demonstrating that toremifene 80 mg treatment to reduce fractures in men with prostate cancer on ADT does not have a detrimental effect on either time-to-disease progression or overall survival. We have requested a meeting with the FDA to determine the appropriate next steps regarding the NDA.

We are also developing toremifene 20 mg in an ongoing pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia, or high grade PIN. In January 2005, we initiated a pivotal Phase III clinical trial of toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, which is being conducted under a SPA with the FDA. A planned efficacy interim analysis conducted in the second quarter of 2008 did not reach the specified statistical outcome of $p<0.003$. Following the conclusion of the trial in the first quarter of 2010, we will conduct the final analyses of the clinical trial. We plan to announce results of the trial and, if successful, our plans to submit a NDA for toremifene 20 mg to the FDA in 2010. In September 2009, an independent Data Safety Monitoring Board conducted a planned, semi-annual review of unblinded safety data from approximately 1,590 patients participating in the trial and recommended that the trial continue as planned.

We have licensed to Ipsen Developments Limited, or Ipsen, exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States, which we refer to collectively as the European Territory, to develop and commercialize toremifene in all indications which we have licensed from Orion Corporation, or Orion, which include all indications in humans except the treatment and prevention of breast cancer outside of the United States.

In our third clinical program, selective androgen receptor modulators, or SARMs, are being developed to treat chronic sarcopenia, which is the loss of skeletal muscle mass resulting in reduced physical strength and ability to perform activities of daily living, muscle loss in patients with chronic obstructive pulmonary disease, or COPD, and other musculoskeletal wasting or muscle loss conditions. In December 2006, we announced that Ostarine™ (designated by Merck & Co. Inc., or Merck, as MK-2866) met its primary endpoint in a Phase II proof of concept, double blind, randomized, placebo controlled clinical trial in 60 elderly men and 60 postmenopausal women. In December 2007, we and Merck entered into a collaboration to discover and develop SARMs, a new class of drugs with the potential to treat chronic sarcopenia, as well as other musculoskeletal wasting or muscle loss conditions. We and Merck are evaluating multiple SARM product candidates, including Ostarine™ and MK-0773, for a variety of musculoskeletal wasting indications including chronic sarcopenia and muscle loss in patients with COPD. In October 2008, we announced topline results of a Phase II clinical trial evaluating Ostarine™ in patients with cancer cachexia. In this analysis, the trial met its primary endpoint of absolute change in total lean body mass (muscle) compared to placebo and the secondary endpoint of muscle function (performance) after 16 weeks of treatment in 159 cancer patients with reported weight loss. In the fourth quarter of 2009, we and Merck expect to complete an ongoing Phase II clinical trial evaluating MK-0773 in chronic sarcopenia. We and Merck are finalizing clinical development plans to evaluate Ostarine™ for the treatment of muscle loss in patients with COPD and for the treatment of chronic sarcopenia with the goal of initiating an Ostarine™ Phase II COPD clinical trial in the first quarter of 2010 and an Ostarine™ Phase IIb chronic sarcopenia clinical trial in 2010. We and Merck are evaluating additional indications, including cancer cachexia, for SARM clinical development.

We are also developing GTx-758, an oral luteinizing hormone, or LH, inhibitor for the treatment of advanced prostate cancer. In preclinical animal models, GTx-758 has demonstrated the potential to reduce testosterone concentrations in blood to castrate levels, increase BMD, and prevent hot flashes. In 2009, we evaluated GTx-758 in healthy male volunteers in two Phase I clinical trials, a single ascending dose clinical trial completed in the second quarter and a multiple ascending dose clinical trial completed in October 2009. GTx-758 was well tolerated in both trials. We are planning to initiate Phase II clinical development of GTx-758 in 2010.

We currently market FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of metastatic breast cancer in postmenopausal women in the United States. The active pharmaceutical ingredient in FARESTON® is the same as in our toremifene 80 mg and toremifene 20 mg product candidates.

Our net loss for the nine months ended September 30, 2009 was $35.4 million. Our net loss included FARESTON® net product sales of $2.4 million and the recognition of collaboration revenue of $8.6 million. We have financed our operations and internal growth primarily through public offerings and private placements of our common stock and preferred stock, as well as proceeds from our collaborations. We expect to continue to incur net losses as we continue our clinical development and research and development activities, apply for and address issues related to potential regulatory approvals, expand our sales and marketing capabilities and grow our operations.

Research and Development

Since our inception in 1997, we have been focused on drug discovery and development programs. Research and development expenses include, but are not limited to, our expenses for personnel associated with our research activities, screening and identification of product candidates, formulation and synthesis activities, manufacturing, preclinical studies, toxicology studies, clinical trials, regulatory affairs activities, quality assurance activities and license fees.

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

- activities relating to our efforts to obtain regulatory approvals of toremifene 80 mg to reduce fractures and treat other estrogen deficiency side effects of ADT in men with prostate cancer;
- the continuation of the pivotal Phase III clinical trial of toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN;
- our ongoing SARM research and development efforts with Merck as a part of our collaboration; and
- the continued preclinical and clinical development of other product candidates, including GTx-758.

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

Product Candidates

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

Program	Product Candidate/ Proposed Indication	Development Phase	Status
SERM	**Toremifene 80 mg** To reduce fractures in men with prostate cancer on ADT	Received a Complete Response Letter from the FDA regarding the NDA in October 2009	Post action meeting request with the FDA pending.
	Toremifene 20 mg Prevention of prostate cancer in high risk men with high grade PIN	Pivotal Phase III clinical trial	Phase III clinical trial ongoing under a SPA will be completed in the first quarter of 2010; Results will be announced in 2010.
SARM	**MK-0773 * and Ostarine™ (MK-2866) *** Treatment of chronic sarcopenia	Phase II clinical trial	MK-0773 Phase II clinical trial ongoing and expected to be completed in the fourth quarter of 2009.
		Phase IIb clinical trial	Ostarine™ (MK-2866) Phase IIb clinical trial planned to be initiated in 2010.
	Ostarine™ (MK-2866) * Treatment of muscle loss in patients with chronic obstructive pulmonary disease	Phase II clinical trial	Phase II chronic obstructive pulmonary disease clinical trial planned to be initiated in the first quarter of 2010.
LH inhibitor	**GTx-758** Treatment of advanced prostate cancer	Phase I clinical trial	Phase I single ascending dose clinical trial completed in the second quarter of 2009; Phase I multiple ascending dose clinical trial completed in October 2009; Phase II clinical development planned to be initiated in 2010.

***** Compound being jointly developed under the GTx and Merck exclusive license and collaboration agreement

Sales and Marketing

We currently market FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of metastatic breast cancer in postmenopausal women in the United States. The active pharmaceutical ingredient in FARESTON® is the same as in our toremifene 80 mg and toremifene 20 mg product candidates, but in a different dose. In January 2005, we acquired from Orion the right to market FARESTON® tablets in the United States for the metastatic breast cancer in postmenopausal women indication. We also acquired from Orion a license to toremifene for all indications in humans worldwide, except breast cancer outside of the United States. In order to commercialize any future products, we must broaden our sales and marketing infrastructure or collaborate with third parties with sales and marketing experience and personnel. We plan to build a specialty sales and marketing infrastructure, which we expect to include approximately 65 sales consultants, to market toremifene 80 mg and toremifene 20 mg, if approved by the FDA, to the relatively small and concentrated community of urologists and medical oncologists in the United States. We have partnered with Ipsen to commercialize toremifene in Europe if approved for commercial sale. We are currently seeking partners to market toremifene in Asia and other markets outside of the United States and Europe.

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, medical affairs and sales and marketing functions. Other costs include facility costs not otherwise included in research and development expenses and professional fees for legal, accounting, public relations, and marketing services. General and administrative expenses also include insurance costs and FARESTON® selling and distribution expenses. Subject to regulatory approval of any of our product candidates, we expect that our general and administrative expenses will increase in future periods as we expand our sales and marketing efforts which will result in increased sales and marketing expenses in future years.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America 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, 2008 filed with the SEC, we believe that the following accounting policies are most critical to aid you in fully understanding and evaluating our reported financial results.

Revenue Recognition

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

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

We estimate the performance obligation period to be ten years for our collaboration agreement with Merck and five years for the development of toremifene for both the high grade PIN and ADT indications in the European Territory under our collaboration agreement with Ipsen. The factors that drive the actual development period of a pharmaceutical product are inherently uncertain and include determining the timing and expected costs to complete the project, projecting regulatory approvals and anticipating potential delays. We use all of these factors in initially estimating the economic useful lives of our performance obligations, and we also continually monitor these factors for indications of appropriate revisions.

We recognize revenue from net 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 approximately 95% of our product sales of FARESTON® for the nine months ended September 30, 2009. Based on this information and other factors, we estimate an accrual for product returns. At September 30, 2009 and December 31, 2008, our accrual for product returns was $519,000 and $815,000, respectively.

Research and Development Expenses

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

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 directors and deferred compensation arrangements for our 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 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 September 30, 2009 was $1.1 million, of which $413,000 and $715,000 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 September 30, 2008 was $995,000, of which $479,000 and $516,000 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 nine months ended September 30, 2009 was $3.3 million, of which $1.2 million and $2.1 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 nine months ended September 30, 2008 was $2.6 million, of which $1.2 million and $1.4 million were recorded in the condensed statement of operations as research and development expenses and general and administrative expenses, respectively. Included in share-based compensation expense for the three months ended September 30, 2009 and 2008 is share-based compensation expense related to deferred compensation arrangements for our directors of $44,000 and $42,000, respectively, and $128,000 and $137,000 for the nine months ended September 30, 2009 and 2008, respectively. At September 30, 2009, the total compensation cost related to non-vested awards not yet recognized was approximately $12.5 million with a weighted average expense recognition period of 2.4 years.

Results of Operations

Three Months Ended September 30, 2009 and 2008

Revenues. Revenues for the three months ended September 30, 2009 were $3.6 million, as compared to $3.0 million for the same period of 2008. Revenues included net sales of FARESTON® marketed for the treatment of metastatic breast cancer in postmenopausal women and collaboration revenue from Ipsen and Merck. During the three months ended September 30, 2009 and 2008, FARESTON® net product sales were $719,000 and $315,000, respectively, while cost of product sales were $344,000 and $192,000, respectively. FARESTON® net product sales for the three months ended September 30, 2009 increased from the same period in the prior year as a result of a price increase instituted in the fourth quarter of 2008, partially offset by a decrease of approximately 24% in sales volume of FARESTON® as compared to the three months ended September 30, 2008. The increase in cost of product sales was due to an increase in royalty expenses which was based on our net sales of FARESTON®. We expect FARESTON® sales volume to continue to decline in future periods, particularly as a result of aromatase inhibitors continuing to capture breast cancer market share from SERMs, including FARESTON®. Collaboration revenue was $2.9 million for the three months ended September 30, 2009 and $2.7 million for the three months ended September 30, 2008. Collaboration revenue for the three months ended September 30, 2009 consisted of approximately $1.5 million and approximately $1.4 million from the amortization of deferred revenue from Ipsen and Merck, respectively. Collaboration revenue for the three months ended September 30, 2008 consisted of approximately $1.5 million and approximately $1.3 million from the amortization of deferred revenue from Ipsen and Merck, respectively.

Research and Development Expenses. Research and development expenses decreased 12% to $8.1 million for the three months ended September 30, 2009 from $9.2 million for the three months ended September 30, 2008. 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. The decrease in research and development expenses during the three months ended September 30, 2009 compared to the three months ended September 30, 2008 was due primarily to the completion of the toremifene 80 mg Phase III clinical trial, a decreased number of subject visits in the toremifene 20 mg clinical trial due to a portion of the subjects having completed the trial prior to or during the third quarter of 2009, and the completion of the Ostarine™ Phase II cancer cachexia clinical trial during 2008. This decrease was partially offset by research and development spending on our Phase I multiple ascending dose clinical trial for GTx-758 which was initiated in the first quarter of 2009. We expect research and development expenses for the full year of 2009 to be less than 2008 due to the completion of the toremifene 80 mg Phase III clinical trial and the completion of the Ostarine™ Phase II cancer cachexia clinical trial. Commencing in 2010, research and development expense for future periods may increase from current levels, perhaps significantly, if we agree to complete an additional Phase III clinical trial evaluating toremifene 80 mg required by the FDA to address the deficiencies asserted in the Complete Response Letter.

Program	Product Candidate/ Proposed Indication	Three Months Ended September 30, 2009	Three Months Ended September 30, 2008	Increase/ (Decrease)
		(in thousands)		
SERM	**Toremifene 80 mg** To reduce fractures in men with prostate cancer on ADT	$ 558	$ 1,550	$ (992)
	Toremifene 20 mg Prevention of prostate cancer in high risk men with high grade PIN	1,249	2,155	(906)
SARM	**Ostarine™ (MK-2866) *** Treatment of cancer cachexia	—	1,123	(1,123)
LH inhibitor	**GTx-758** Treatment of advanced prostate cancer	3,112	1,289	1,823
Other research and development		3,204	3,127	77
Total research and development expenses		$ 8,123	$ 9,244	$ (1,121)

***** Compound being jointly developed under the GTx and Merck exclusive license and collaboration agreement

General and Administrative Expenses. General and administrative expenses increased during the three months ended September 30, 2009 to $8.0 million from $6.1 million for the three months ended September 30, 2008. This increase was primarily due to increased personnel and personnel related expenses of $1.4 million and increased marketing expenses of approximately $335,000 primarily related to preparation for the planned commercialization of our toremifene product candidates and an increase of approximately $361,000 in intellectual property and other legal expenses. These increases were partially offset by a decrease in medical education expenses of $458,000 due to lower spending on continuing medical education programs in the current period as compared to the same period in 2008.

Interest Income. Interest income decreased to $29,000 for the three months ended September 30, 2009 from $568,000 for the three months ended September 30, 2008. The decrease was due to lower average interest rates and lower average cash balances during the three months ended September 30, 2009 as compared to the same period in 2008.

Nine Months Ended September 30, 2009 and 2008

Revenues. Revenues for the nine month periods ended September 30, 2009 and 2008 were $11.1 million and $10.5 million, respectively. Revenues include net sales of FARESTON® marketed for the treatment of metastatic breast cancer and collaboration revenue from Ipsen and Merck. In the first nine months of 2009 and 2008, FARESTON® net product sales were $2.4 million and $846,000, respectively, while cost of product sales were $1.1 million and $482,000 respectively. FARESTON® net product sales for the nine months ended September 30, 2009 increased from the same period in the prior year as a result of a price increase instituted in the fourth quarter of 2008, partially offset by a decrease of approximately 21% in sales volume of FARESTON® as compared to the nine months ended September 30, 2008. The increase in cost of product sales was due to an increase in royalty expenses which was based on our net sales of FARESTON®. Collaboration revenue was $8.6 million for the nine months ended September 30, 2009, which consisted of approximately $4.4 million and approximately $4.2 million from the amortization of deferred revenue from Ipsen and Merck, respectively. Collaboration revenue was approximately $9.7 million for the nine months ended September 30, 2008, which consisted of approximately $4.4 million and approximately $3.8 million from the amortization of deferred revenue from Ipsen and Merck, respectively, and approximately $1.5 million from an earned milestone from Ipsen resulting from the achievement of the primary endpoint in the toremifene 80 mg ADT Phase III clinical trial during the first quarter of 2008.

Research and Development Expenses. Research and development expenses decreased by 28% to $24.2 million for the nine months ended September 30, 2009 from $33.6 million for the nine months ended September 30, 2008. 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. The decrease in research and development expenses during the nine months ended September 30, 2009 compared to the nine months ended September 30, 2008 was primarily due to the completion of the toremifene 80 mg Phase III clinical trial, a decreased number of subject visits in the toremifene 20 mg clinical trial due to a portion of the subjects having completed the trial prior to or during the current year, and the completion of the Ostarine™ Phase II cancer cachexia clinical trial during 2008. This decrease was partially offset by research and development spending on our Phase I clinical trials for GTx-758.

Program	Product Candidate/ Proposed Indication	Nine Months Ended September 30,		Increase/ (Decrease)
		2009	2008	
		(in thousands)		
SERM	**Toremifene 80 mg** To reduce fractures in men with prostate cancer on ADT	$ 1,748	$ 9,057	$ (7,309)
	Toremifene 20 mg Prevention of prostate cancer in high risk men with high grade PIN	4,841	7,227	(2,386)
SARM	**Ostarine™ (MK-2866) *** Treatment of cancer cachexia	538	5,297	(4,759)
LH inhibitor	**GTx-758** Treatment of advanced prostate cancer	7,592	2,854	4,738
Other research and development		9,462	9,178	284
Total research and development expenses		$ 24,181	$ 33,613	$ (9,432)

***** Compound being jointly developed under the GTx and Merck exclusive license and collaboration agreement

General and Administrative Expenses. General and administrative expenses increased during the nine months ended September 30, 2009 to $21.5 million from $16.8 million for the nine months ended September 30, 2008. This increase was primarily due to increased personnel and personnel related expenses of $4.1 million and increased marketing expenses of approximately $274,000 primarily related to preparation for the planned commercialization of our toremifene product candidates and an increase of approximately $414,000 in intellectual property and other legal expenses.

Interest Income. Interest income decreased to $140,000 for the nine months ended September 30, 2009 from $2.4 million for the nine months ended September 30, 2008. The decrease was due to lower average interest rates and lower average cash and short-term investment balances during the nine months ended September 30, 2009 as compared to the same period in 2008.

Income Tax Benefit. The income tax benefit of approximately $194,000 for the nine months ended September 30, 2009 resulted from a provision in the Housing and Economic Recovery Act of 2008 that allowed us to claim a refund for a portion of our pre-2006 research and development tax credits.

Liquidity and Capital Resources

At September 30, 2009, we had cash, cash equivalents and short-term investments of $55.5 million, compared to $97.7 million at December 31, 2008. Net cash used in operating activities was $39.7 million for the nine months ended September 30, 2009 and resulted primarily from funding our net loss. This was offset slightly by the receipt of approximately $726,000 related to the third and final annual license fee and expense reimbursement installment payment from Ipsen in conjunction with our collaboration and license agreement and approximately $2.3 million in distributions from our investment in Bank of America Corporation's Columbia Strategic Cash Portfolio. Net cash provided by operating activities was $3.4 million for the nine months ended September 30, 2008 and consisted primarily of the receipt of $40.0 million from Merck in conjunction with our exclusive license and collaboration agreement, approximately $1.5 million from Ipsen due to the achievement of the primary endpoint in the toremifene 80 mg ADT Phase III clinical trial, approximately $711,000 related to the second annual license fee and expense reimbursement installment payment from Ipsen in conjunction with our collaboration and license agreement, and approximately $6.1 million in distributions from our investment in Bank of America Corporation's Columbia Strategic Cash Portfolio. These cash receipts were offset by funding our net loss for the period.

Net cash used in investing activities was $8.5 million and $2.7 million for the nine months ended September 30, 2009 and 2008, respectively. Net cash used in investing activities for the nine months ended September 30, 2009 was primarily for the purchase of short-term investments in certificates of deposit of approximately $8.1 million and the purchase of information technology equipment, research and development equipment, and software. Net cash used in investing activities for the nine months ended September 30, 2008 was primarily for the purchase of furniture and fixtures and leasehold improvements related to the additional office space added in 2008, as well as the purchase of research and development equipment, software, and information technology equipment. We currently expect to make capital expenditures of approximately $100,000 for the remainder of 2009.

Net cash provided by financing activities was $133,000 and $959,000 for the nine months ended September 30, 2009 and 2008, respectively. In each case, the net cash was provided primarily from proceeds from the exercises of employee stock options.

As of September 30, 2009, we had outstanding purchase obligations due within the next twelve months of approximately $1.7 million, which are primarily related to preparations for the planned commercialization of our toremifene 80 mg product candidate.

We estimate that our current cash and cash equivalent balances, short-term investments, interest income and product revenue from the sale of FARESTON® will be sufficient to meet our projected operating requirements through at least the next twelve months. This estimate does not include any costs related to additional clinical development of our toremifene 80 mg product candidate that we may undertake in connection with the Complete Response Letter we received from the FDA in October 2009. This estimate also does not include funding from future milestone payments that we may receive under our existing collaborations with Merck and Ipsen, nor does it include any funding that we may receive under potential future collaboration arrangements with other pharmaceutical companies or potential issuances and sales of our securities.

Our forecast of the period of time through which our financial resources will be adequate to support our projected operating requirements is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed under Part II, Item 1A “Risk Factors” section of this Quarterly Report on Form 10-Q. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and potential commercialization of our product candidates and other research and development activities, including risks and uncertainties that could impact the rate of progress of our development and commercialization activities, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials, other research and development activities, and commercialization activities. Our future funding requirements will depend on many factors, including:

- the results of our discussions with the FDA regarding the appropriate next steps to address the deficiencies asserted by the FDA in the Complete Response Letter we received in October 2009 regarding our NDA for toremifene 80 mg;
- the scope, rate of progress and cost of our and/or our collaborators’ clinical trials and other research and development activities;
- future clinical trial results;
- the achievement of certain milestone events under, and other matters related to, our collaborative arrangements with Merck and Ipsen;
- the terms and timing of any future collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory filings and/or approvals to commercialize our product candidates, and any related restrictions, limitations, and/or warnings;
- potential future licensing fees, milestone payments and royalty payments, including any milestone payments or royalty payments that we may receive under our collaborative arrangements with Merck and Ipsen;
- the cost and timing of establishing medical education, sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we and/or our collaborators may develop;
- the effect of competing technological and market developments;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, and the cost of defending any other litigation claims; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Until we can generate a sufficient amount of product revenue, we expect to finance future cash needs through public or private equity offerings, debt financings or collaboration and licensing arrangements, such as our arrangements with Merck and Ipsen, as well as through interest income earned on the investment of our cash balances and short-term investments, and revenues from the sale of FARESTON®. With the exception of payments that we may receive under our collaborations with Merck and Ipsen, we do not currently have any commitments for future external funding. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, such as our arrangements with Merck and Ipsen, it may be necessary to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. Our ability to raise additional funds may be adversely impacted by our receipt of the Complete Response Letter from the FDA in October 2009 regarding our NDA for toremifene 80 mg and the related uncertainty regarding our NDA for toremifene 80 mg, as well as current economic conditions, including the effects of the disruptions to and continuing volatility in the credit and financial markets in the United States and worldwide. As a result of these and other factors, we cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available when we need them, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or obtain funds through collaborations with others that are on unfavorable terms or that may require us to relinquish rights to some of our technologies or product candidates that we would otherwise seek to develop on our own.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the nine months ended September 30, 2009, 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, 2008.

ITEM 4. CONTROLS AND PROCEDURES

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

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

There were no changes in our internal control over financial reporting during the third quarter of 2009 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 3, 2009.

Risks Related to Our Financial Results and Need for Additional Financing

***We have incurred losses since inception, and we anticipate that we will incur continued losses for at least the next several years and potentially thereafter. **

We have a limited operating history. As of September 30, 2009, we had an accumulated deficit of $357.3 million, of which $96.3 million related to non-cash dividends and adjustments to the preferred stock redemption value. We have incurred losses in each year since our inception in 1997. Net losses were $35.4 million for the nine months ended September 30, 2009, $51.8 million in 2008, $40.4 million in 2007, and $35.5 million in 2006. We expect to continue to incur significant and potentially increasing operating losses for at least the next several years and potentially thereafter, particularly if our New Drug Application, or NDA, filed with the U.S. Food and Drug Administration, or FDA, to market toremifene 80 mg to reduce fractures in men with prostate cancer on androgen deprivation therapy, or ADT, is not approved by the FDA in a timely manner or at all. These losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. In October 2009, the Company received a Complete Response Letter from the FDA regarding its NDA for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT. The FDA identified two deficiencies in the Complete Response Letter and recommended that the following information be provided to the FDA to address these clinical deficiencies: (i) results of a second adequate and well-controlled Phase III clinical trial demonstrating the safety and efficacy of toremifene 80 mg to reduce fractures in men with prostate cancer on ADT and (ii) results from an adequate and well-controlled clinical trial demonstrating that toremifene 80 mg treatment to reduce fractures in men with prostate cancer on ADT does not have a detrimental effect on either time-to-disease progression or overall survival. The Company has requested a meeting with the FDA to determine the appropriate next steps regarding the NDA. As a result of the deficiencies identified in the Complete Response Letter, FDA approval of our NDA for toremifene 80 mg, if it occurs, may be substantially delayed. If significant additional development of toremifene 80 mg is required, particularly the completion of an additional Phase III clinical trial, we may not be able to raise sufficient additional funds on acceptable terms or at all to complete the development of toremifene 80 mg, and we may be required to delay or eliminate our toremifene 80 mg development program which would have a material adverse effect on our business and growth prospects, and we may never become profitable.

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 primarily financed our operations and internal growth through sales of common stock and preferred stock. In addition, we have received upfront license fees and milestone and other payments pursuant to our collaborative arrangements with third parties, including $40.0 million in upfront license fees from Merck received in January 2008, a $1.5 million milestone payment from Ipsen Developments Limited, or Ipsen, received in April 2008, and $5.0 million received from Merck in guaranteed cost reimbursements for research and development activities in December 2008. FARESTON® is currently our only commercial product and, until such time that we receive regulatory approval to market any of our product candidates, we expect that FARESTON® will account for all of our product revenue. For the nine months ended September 30, 2009, we recognized $2.4 million in net revenues from the sale of FARESTON®. If we and/or our collaborators are unable to develop and commercialize any of our product candidates, if development is delayed or if sales revenue from any product candidate that receives marketing approval is insufficient, we may never become profitable. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

We expect our general and administrative expenses for fiscal year 2009 to be greater than fiscal year 2008 due primarily to increased spending on sales and marketing, medical education, and other supporting activities for the planned commercialization of our toremifene product candidates. Further, subject to regulatory approval of any of our product candidates, we expect to incur additional sales and marketing expenses. Additionally, we expect our research and development efforts for the remainder of 2009 to focus on addressing whether regulatory approval can be obtained for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT, our ongoing clinical trials, our ongoing SARM research and development efforts with Merck as a part of our collaboration, and the continued preclinical and clinical development of other product candidates, including GTx-758.

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

We will need to raise additional capital to:

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

We estimate that our current cash and cash equivalent balances, short-term investments, interest income and product revenue from the sale of FARESTON® will be sufficient to meet our projected operating requirements through at least the next twelve months. This estimate does not include any costs related to additional clinical development of our toremifene 80 mg product candidate that we may undertake in connection with the Complete Response Letter we received from the FDA in October 2009. This estimate also does not include funding from future milestone payments that we may receive under our existing collaborations with Merck and Ipsen, nor does it include any funding that we may receive under potential future collaboration arrangements with other pharmaceutical companies or potential issuances and sales of our securities. Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our and/or our collaborators' clinical trials and other research and development activities;
- future clinical trial results;
- the achievement of certain milestone events under, and other matters related to, our collaborative arrangements with Merck and Ipsen;
- the terms and timing of any future collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory filings and/or approvals to commercialize our product candidates and any related restrictions, limitations, and/or warnings;
- potential future licensing fees, milestone payments and royalty payments, including any milestone payments or royalty payments that we may receive under our collaborative arrangements with Merck and Ipsen;
- the cost and timing of establishing medical education, sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we and/or our collaborators may develop;
- the effect of competing technological and market developments;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, and the cost of defending any other litigation claims; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Until we can generate a sufficient amount of product revenue, we expect to finance future cash needs through public or private equity offerings, debt financings or collaboration and licensing arrangements, such as our arrangements with Merck and Ipsen, as well as through interest income earned on the investment of our cash balances and short-term investments, and revenues from the sale of FARESTON®. With the exception of payments that we may receive under our collaborations with Merck and Ipsen, we do not currently have any commitments for future external funding.

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve restrictive covenants. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and/or licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or product candidates, or we may be required to grant licenses on terms that are not favorable to us. Our ability to raise additional funds may be adversely impacted by our receipt of the Complete Response Letter from the FDA in October 2009 regarding our NDA for toremifene 80 mg and the related uncertainty regarding our NDA for toremifene 80 mg, as well as current economic conditions, including the effects of the disruptions to and continuing volatility in the credit and financial markets in the United States and worldwide. As a result of these and other factors, we cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available when we need them, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or obtain funds through collaborations with others that are on unfavorable terms or that may require us to relinquish rights to some of our technologies or product candidates that we would otherwise seek to develop on our own.

Risks Related to Development of Product Candidates

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

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

In clinical studies, the efficacy and/or safety results from the trial may be insufficient to support the submission or approval of a NDA with the FDA. For example, we received a Complete Response Letter in October 2009 from the FDA regarding our NDA for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT identifying two deficiencies in our application and requesting that additional information be submitted to obtain approval. In addition, in connection with our pivotal Phase III clinical trial of toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, a planned efficacy interim analysis was conducted in the second quarter of 2008, which concluded that the efficacy results did not reach the specified statistical outcome, and we were therefore unable to submit a NDA to the FDA based on this efficacy interim analysis. Until such time as we conclude the clinical trial and analyze the data, which we expect will occur in 2010, we will not be able to determine if the clinical trial successfully demonstrated a statistically significant positive outcome to allow us to submit a NDA to the FDA to seek marketing approval for this product candidate.

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

- regulators or institutional review boards may not authorize us or our collaborators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- preclinical or clinical trials may produce negative or inconclusive results, which may require us or our collaborators to conduct additional preclinical or clinical testing or to abandon projects that we expect to be promising;
- registration or enrollment in clinical trials may be slower than we currently anticipate, resulting in significant delays;
- we or our 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 our collaborators have significant delays in or termination of clinical trials, our costs could increase and our ability to generate revenue could be impaired, which would adversely impact our financial results.

For some of the indications for which we intend to conduct or are currently conducting clinical trials for our product candidates, we do not currently have evidence from prior preclinical studies in animals or clinical trials in humans of the potential effectiveness of such product candidates for such indications. In the absence of preclinical or clinical data, our beliefs regarding the potential effectiveness of our product candidates for these indications is generally based on pharmacokinetic data and analyses and pharmacological rationales. Our or our collaborators' preclinical or clinical trials may produce negative or inconclusive results that would not support our beliefs regarding the potential effectiveness of our product candidates.

If we or our 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 our 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 III clinical trial for toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, some patients have experienced venous thromboembolic events, or VTEs, such as deep vein thromboses and pulmonary embolisms, as well as myocardial infarctions, or heart attacks, which have been considered by investigators as possibly related to treatment with toremifene 20 mg. Because this trial is blinded, we do not know whether these patients received placebo or toremifene 20 mg in this trial. In addition, although the results from our Phase III clinical trial for toremifene 80 mg to reduce fractures and treat other estrogen deficiency side effects of ADT in men with prostate cancer showed that the drug had a generally favorable safety profile compared to placebo and was well tolerated, there were a higher number of subjects experiencing a VTE in the toremifene 80 mg treatment group, 17 (2.6%) versus 7 (1.1%) in the placebo group. Even though the majority of VTEs recorded in the clinical trial occurred in men who were at high risk for a VTE (including: age greater than 80 years, history of VTEs, recent surgical procedure or immobilization) and data from the clinical trial showed that the number of men without any of these independent risk factors for VTEs in whom a VTE occurred during the clinical trial was 5 in the toremifene 80 mg treatment group versus 3 in the placebo group, the FDA will consider the overall safety profile from the clinical trial when making its determination to grant marketing approval and to require potential warnings in the label if approval is granted.

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

Orion may terminate its obligation to supply us and Ipsen with toremifene if Orion ceases its manufacture of toremifene permanently, or Orion may terminate its obligation to supply us with toremifene if one of our toremifene product candidates is not approved for commercial sale in the United States prior to December 31, 2009. We do not currently expect that any of our toremifene product candidates will be approved for commercial sale in the United States prior to December 31, 2009. In addition, Orion may terminate its obligation to supply us or Ipsen with toremifene if we or Ipsen are in material breach of our respective supply agreements with Orion, or in connection with certain bankruptcy events involving us or Ipsen, respectively. If Orion elects to terminate its obligation to manufacture and supply us and Ipsen with toremifene, any arrangements we make for an alternative supply would have to be made with a qualified alternative supplier with appropriate FDA approval in order for us to obtain our supply requirements for toremifene. In addition, although Orion's composition of matter patents have expired, and as such, neither we nor Ipsen would be prevented from manufacturing toremifene within the United States or European Territory, there is no obligation on the part of Orion to transfer its manufacturing technology to us or Ipsen or to assist us or Ipsen in developing manufacturing capabilities to meet our respective supply needs. We and Ipsen have mutually agreed to cooperate in the manufacture of toremifene in the event Orion ceases manufacture of toremifene for any of the above-mentioned reasons. Although we and Ipsen have agreed to cooperate with each other in the event either of our supply rights are terminated by Orion for any reason, a disruption in the supply of toremifene could delay the development of and impair our and Ipsen's ability to commercialize toremifene.

We also rely on Orion to cooperate with us in the filing and maintenance of regulatory filings with respect to the manufacture of toremifene. Orion may terminate its obligation to assist us in obtaining and maintaining regulatory approval of toremifene if we do not receive regulatory approval for one of our toremifene product candidates in the United States prior to December 31, 2009, and we do not currently expect that any of our toremifene product candidates will be approved for commercial sale in the United States prior to December 31, 2009. If Orion terminates its obligation to cooperate in these activities, or does not cooperate with us or otherwise does not successfully file or maintain these regulatory filings, we would be required to make arrangements with a qualified alternative supplier, which could further delay or prevent regulatory approval of toremifene.

Historically, we have relied on third party vendors for the manufacture of Ostarine™ drug substance. However, Merck has assumed primary manufacturing responsibilities for Ostarine™ and other SARM products developed under our exclusive license and collaboration agreement with Merck. If Merck does not manufacture and supply sufficient quantities of clinical trial materials to support our clinical trials, we could experience a delay in conducting clinical trials of Ostarine™ or other SARM product candidates. We may not be able to maintain or renew our existing or any other third-party manufacturing arrangements on acceptable terms, if at all. If we are unable to continue relationships with Orion for toremifene and Merck for Ostarine™ and other SARM product candidates, or to do so at an acceptable cost, or if Merck or other suppliers fail to meet our requirements for Ostarine™ or other SARM product candidates for any reason, we would be required to obtain alternate suppliers. Any inability to obtain alternate suppliers, including an inability to obtain approval from the FDA of an alternate supplier, would delay or prevent the clinical development and commercialization of these product candidates.

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

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

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party because of factors beyond our control;
- the possible termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us;

- drug product supplies not meeting the requisite requirements for clinical trial use; and
- the possible exercise by Orion of its right to terminate its obligation to supply us with toremifene:
  - if it permanently ceases manufacture of toremifene or if we do not obtain regulatory approval of one of our toremifene product candidates in the United States prior to December 31, 2009; or
  - if Orion terminates due to our uncured material breach or bankruptcy.

If we are not able to obtain adequate supplies of our product candidates, it will be more difficult for us to develop our product candidates and compete effectively. Our product candidates and any products that we and/or our collaborators may develop may compete with other product candidates and products for access to manufacturing facilities. For example, the active pharmaceutical ingredient in our toremifene 80 mg and toremifene 20 mg product candidates is also the active pharmaceutical ingredient in FARESTON®. Further, Orion has agreed to supply toremifene tablets to Ipsen for clinical trials and commercial supply in the European Territory. Orion also manufactures toremifene for third parties for sale outside the United States for the treatment of metastatic breast cancer in postmenopausal women.

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

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

The loss of Ipsen or Merck as a collaborator in the development or commercialization of toremifene or SARM compounds and related SARM products, respectively, any dispute over the terms of our collaborations with Ipsen or Merck, or any other adverse developments in our relationships with Ipsen or Merck could materially harm our business and might accelerate our need for additional capital. For example, Ipsen is obligated to initiate and conduct appropriate clinical studies as required by the appropriate regulatory authorities in order to obtain marketing approvals of toremifene within the European Territory. Any failure on the part of Ipsen to initiate these studies could delay the commercialization of toremifene within the European Territory. Likewise, Merck is responsible for conducting all clinical trials for SARM product candidates developed under the collaboration, and the failure of Merck to initiate one or more of these clinical trials would adversely affect the development of our SARM product candidates.

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

Dependence on collaborative arrangements, including our arrangements with Ipsen and Merck for the development and commercialization of toremifene and SARM compounds and products, respectively, subjects us to a number of risks, including:

- we are not able to control either the amount and timing of resources that Ipsen devotes to toremifene or the amount and timing of resources that Merck devotes to SARM compounds and products developed under our collaboration with Merck;
- we may not be able to control the amount and timing of resources that our potential future partners may devote to our product candidates;
- our partners may experience financial difficulties or changes in business focus;
- we may be required to relinquish important rights such as marketing and distribution rights;
- under certain circumstances, Ipsen may not be required to commercialize toremifene in certain countries of the European Territory if Ipsen determines that it is not commercially reasonable for it to do so;
- pricing reimbursement constraints within the European Territory may diminish the prospects of our receiving royalty payments from Ipsen on aggregate net sales of toremifene in some or all of the countries within the European Territory;
- should a collaborator fail to develop or commercialize one of our compounds or product candidates, we may not receive any future milestone payments and will not receive any royalties for 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 would delay the development and may increase the cost of developing our product candidates.

We may not realize the anticipated benefits from our collaborative arrangements with Ipsen and Merck. *

We may not receive any future milestone payments provided for under our collaborative arrangements with Ipsen and Merck if our agreements with them are terminated, if certain clinical development and regulatory milestones under our agreements with them are not achieved, with respect to our agreement with Ipsen, if Ipsen fails to develop and commercialize toremifene in the European Territory, or, with respect to our agreement with Merck, if we and Merck fail to develop and commercialize any of the SARMs included in or arising from our collaboration. In addition, even if required regulatory approvals are obtained, it is possible that neither Ipsen nor Merck will successfully market and sell toremifene or any SARM products, respectively, in which case we would not receive royalties to the extent that we currently anticipate. Furthermore, our royalty rates under our collaboration and license agreement with Ipsen are subject to a possible reduction if a generic version of toremifene achieves specified sales levels in a major country within the European Territory, and each of Ipsen and Merck may be entitled to offset a portion of any royalties due to us if Ipsen or Merck licenses patent rights from a third party that would otherwise be infringed by Ipsen's or Merck's use, manufacture, sale or import of toremifene or SARM compounds, respectively.

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

Under our agreement with Merck, we and Merck have agreed that neither party will engage in the development and commercialization of SARMs with any third party for an agreed upon period of time. However, there can be no assurance that we and Merck will be able to successfully develop new SARM products or identify new indications for existing and/or future SARM products under our collaboration with Merck.

Merck has the right to terminate our agreement with Merck for any reason after a specified period of time with prior written notice, and Ipsen has the right to terminate our agreement with Ipsen with 12 months prior written notice for any reason and with 30 days prior written notice as a result of legitimate and documented safety concerns. In addition, both Ipsen and Merck may terminate their agreements with us following our uncured material breach or bankruptcy. If our agreements with Ipsen and Merck are terminated, the anticipated future benefits to us from these agreements would be eliminated, the development and commercialization of toremifene in the European Territory and the development and commercialization of our SARM product candidates could be delayed, and our costs of development would increase. For example, Merck's obligation to pay us the remaining $10.0 million of the $15.0 million in guaranteed cost reimbursements for research funding over a two year period is subject to our exclusive license and collaboration agreement with Merck not being terminated for cause and there not occurring certain change of control events involving us during such period. In any such or similar events, we may not realize the anticipated benefits from our collaborative arrangements with Ipsen and Merck.

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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

Off-label sale or use of toremifene products could decrease sales of toremifene 80 mg and toremifene 20 mg tablets if approved for commercial sale, and could lead to pricing pressure if such products become available at competitive prices and in dosages that are appropriate for the indications for which we and Ipsen are developing toremifene. *

In all countries in which we hold or have licensed rights to patents or patent applications related to toremifene, the composition of matter patents we license from Orion have expired. As a result, we will need to rely primarily on the protection afforded by method of use patents. Our method of use patents may not protect toremifene from the risk of off-label sale or use of other toremifene products in place of toremifene 80 mg and toremifene 20 mg tablets. Physicians are permitted to prescribe legally available drugs for uses that are not described in the drug's labeling and that differ from those uses tested and approved by the FDA or its equivalent. Such off-label uses are common across medical specialties and are particularly prevalent for cancer treatments. Any off-label sales of other toremifene products may adversely affect our or Ipsen's ability to generate revenue from the sale of toremifene 80 mg and 20 mg tablets, if approved for commercial sale.

Even in the event that patents are issued from our pending method of use patent applications, competitors could market and sell toremifene products for uses for which FARESTON® has already been approved. Thus, physicians in such countries would be permitted to prescribe these other toremifene products for indications that are protected by our method of use patents or method of use patents issuing from pending patent applications, even though these other toremifene products would not have been approved for those uses, and in most cases, the physician would not be liable for contributing to the infringement of our patents or potential patents. Moreover, because Orion has licensed and could further license other parties to market, sell and distribute toremifene for breast cancer outside the United States, physicians in such countries could prescribe these products sold pursuant to another Orion license off-label. This further increases the risk of off-label competition developing for toremifene for the indications for which we and Ipsen are developing this product candidate. In addition, if no patents are issued with respect to our pending method of use patent applications related to the use of toremifene in the countries outside of the United States where these applications are currently pending, we would not have as extensive patent coverage to prevent competitors from marketing and selling generic versions of toremifene at doses and in formulations equivalent to toremifene 80 mg and toremifene 20 mg tablets for the indications covered by our pending method of use patent applications. Also, regulatory authorities may not recognize marketing and data exclusivity for toremifene in the European Union for the treatment of prostate cancer and estrogen deficiency related side effects resulting from ADT. If generic versions of toremifene are able to be sold in countries within the European Territory for the indications for which Ipsen anticipates marketing toremifene, the royalties to be paid to us by Ipsen will be reduced if the total generic sales exceed a certain threshold for a certain period of time. Similarly, the royalties we will be paying to Orion for its licensing and supply of toremifene will be reduced if generic sales thresholds are reached.

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

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

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

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

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

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

- be prohibited from selling or licensing any product that we and/or collaborators may develop unless the patent holder licenses the patent to us, which the patent holder is not required to do;
- be required to pay substantial royalties or grant a cross license to our patents to another patent holder; or
- be required to redesign the formulation of a product candidate so that it does not infringe, which may not be possible or could require substantial funds and time.

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

Risks Related to Regulatory Approval of Our Product Candidates

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

Our product candidates and the activities associated with their development and commercialization are subject to comprehensive regulation by the FDA, 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 our collaborators from commercializing the product candidate. We have not received regulatory approval to market any of our product candidates in any jurisdiction. In addition, we will not receive a substantial majority of the milestone payments provided under our collaboration and license agreement with Ipsen or any royalty payments if Ipsen is unable to obtain the necessary regulatory approvals to commercialize toremifene within the European Territory. Likewise, we may not receive a majority of the milestone payments or any royalty payments provided for under our exclusive license and collaboration agreement with Merck if Merck is not able to obtain the necessary regulatory approvals to commercialize any SARM products, including Ostarine™, developed under the collaboration. 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. If the FDA were to miss a PDUFA timing goal for one of our product candidates, the development and commercialization of the product candidate could be delayed. In addition, the Food and Drug Administration Amendments Act of 2007, or the FDA Amendments Act, which was enacted in September 2007, expands the FDA's authority to regulate drugs throughout the product life cycle, including enhanced authority to require post-approval studies and clinical trials. Other proposals have been made to impose additional requirements on drug approvals, further expand post-approval requirements and restrict sales and promotional activities. This new legislation, and the additional proposals if enacted, may make it more difficult or burdensome for us or our 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 identifying two deficiencies in our application and requesting that additional information be submitted to obtain approval. We have requested a meeting with the FDA to determine the appropriate next steps regarding the NDA. As a result of the deficiencies identified in the Complete Response Letter, FDA approval of our NDA for toremifene 80 mg, if it occurs, may be substantially delayed. In addition, we completed our Phase III clinical trial of toremifene 80 mg to reduce fractures and treat other estrogen deficiency side effects of ADT in men with prostate cancer and are conducting our Phase III clinical trial of toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, under Special Protocol Assessments, or SPAs, with the FDA. A SPA is designed to facilitate the FDA's review and approval of drug products by allowing the FDA to evaluate the proposed design and size of clinical trials that are intended to form the primary basis for determining a drug product's efficacy. If agreement is reached with the FDA, a SPA documents the terms and conditions under which the design of the subject trial will be adequate for submission of the efficacy and human safety portion of a NDA. However, there are circumstances under which we may not receive the benefits of a SPA, notably if the FDA subsequently identifies a substantial scientific issue essential to determining the product's safety or efficacy, and we may be required to conduct significant additional development in order to obtain regulatory approval notwithstanding a SPA with the FDA. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Furthermore, even if we submit an application to the FDA for marketing approval of a product candidate, it may not result in marketing approval from the FDA.

We may not receive regulatory approval for the commercial sale of any of our product candidates that are in development, including toremifene 80 mg, for at least the next several months, if ever. In October 2009, we received a Complete Response Letter from the FDA regarding our NDA for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT identifying two deficiencies in our application and requesting that additional information be submitted to obtain approval. Furthermore, it is not anticipated that Ipsen will receive the appropriate regulatory approvals to market toremifene within the European Territory any sooner than we will achieve regulatory approval in the United States, and it likely will be thereafter. The inability to obtain FDA approval or approval from comparable authorities in other countries for our product candidates would prevent us or our collaborators from commercializing these product candidates in the United States or other countries. See the section entitled "Business — Government Regulation" under Part I, Item 1 of our Annual Report on Form 10-K, filed with the SEC on March 3, 2009, for additional information regarding risks associated with marketing approval, as well as risks related to post-approval requirements.

Risks Related to Commercialization

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

Any products that we and/or our 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;
- the ability to offer our product candidates for sale at competitive prices;
- relative convenience and ease of administration;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

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

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

FARESTON® is currently our only marketed product. The sales volume of FARESTON® in the United States has been declining, and we anticipate that it will continue to do so. Sales of pharmaceuticals for breast cancer in the SERM class have declined in recent years as aromatase inhibitors have gained market share. We believe that aromatase inhibitors will continue to capture breast cancer market share from SERMs, including from FARESTON®, resulting in a continued decline in FARESTON® sales volume. Continued sales of FARESTON® also could be impacted by many other factors. The occurrence of one or more of the following risks may cause sales of FARESTON® to decline more than we currently anticipate:

- the loss of the availability of Orion's website to market FARESTON®, which is an important source of advertising;
- the loss of one or more of our three largest wholesale drug distributors, which together accounted for approximately 95% of our product sales of FARESTON® for the nine months ended September 30, 2009;
- any restrictions, limitations, and/or warnings added to the FARESTON® label as a result of our studies of toremifene, including a Thorough QT study and drug interaction studies, or otherwise;
- the continued success of competing products, including aromatase inhibitors;
- the loss of coverage or reimbursement for FARESTON® from Medicare and Medicaid, private health insurers or other third-party payors;
- exposure to product liability claims related to the commercial sale of FARESTON®, which may exceed our product liability insurance;
- the failure of Orion to maintain regulatory filings or comply with applicable FDA requirements with respect to FARESTON®;
- the introduction of generic toremifene products that compete with FARESTON® for the treatment of breast cancer; and
- the loss of Orion, upon which we rely as a single source, as our supplier of FARESTON®.

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

We have limited experience as a company in the sales, marketing and distribution of pharmaceutical products. There are risks involved with building our own sales and marketing capabilities, as well as entering into arrangements with third parties to perform these services. We currently plan to build a specialty sales force to market our product candidates, if approved for commercial sale, to urologists and medical oncologists in the United States. In the event we are unable to hire a sufficient number of qualified sales personnel consistent with our plans, this could delay the commercialization of any of our product candidates if approved for commercial sale. We are relying on Ipsen to market and distribute our toremifene product candidates through Ipsen's established sales and marketing network within the European Territory. If our collaboration and license agreement with Ipsen is terminated for any reason, our ability to sell our toremifene product candidates in the European Territory would be adversely affected, and we may be unable to develop or engage an effective sales force to successfully market and sell our toremifene product candidates in the European Territory. Currently, we do not have a partner outside of the European Territory and our success in regions other than the European Territory may be dependent on our ability to find suitable partners in other regions of the world. Similarly, we are relying on Merck for the commercialization of any SARM products developed under our collaboration with Merck, and if our exclusive license and collaboration agreement with Merck is terminated for any reason, our ability to successfully market and sell any of our SARM product candidates would be adversely affected, and we may be unable to develop or engage an effective sales force to successfully market and sell any SARM products that we may develop, including Ostarine™. 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 or our collaborators are unable to obtain adequate coverage and reimbursement from third-party payors for products we sell at acceptable prices, our revenues and prospects for profitability will suffer.

Many patients will not be capable of paying for any products that we and/or our collaborators may develop and will rely on Medicare and Medicaid, private health insurers and other third-party payors to pay for their medical needs. If third-party payors do not provide coverage or reimbursement for any products that we and/or our collaborators may develop, our revenues and prospects for profitability may suffer. For example, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 created a prescription drug benefit program for Medicare recipients. The prescription drug program established by this legislation may have the effect of reducing the prices that we or our collaborators are able to charge for products we and/or our 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 our collaborators may develop or to lower the amount that they pay. In addition, members of the United States Congress have stated their desire to reduce the government's cost for reimbursements of prescription drugs by amending this legislation.

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

A primary trend in the United States health care industry is toward cost containment. In addition, in some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to 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 our collaborators may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our or our 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 our collaborators may develop or sell. Cost-control initiatives could decrease the price we might establish for products that we or our collaborators may develop or sell, which would result in lower product revenues or royalties payable to us.

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

Healthcare 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 changes in health care systems to contain health care costs and improve quality. While reform proposals often involve expanding coverage to more individuals, health care reform may also involve increased government price controls, additional regulatory mandates and other measures designed to lower medical and pharmaceutical costs which could have an adverse impact on our business.

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

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

We have product liability insurance that covers our clinical trials and commercial products up to a $25 million annual aggregate limit. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

If our competitors are better able to develop and market products than any products that we and/or our 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 our collaborators may develop. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before us and impair our or our collaborators' ability to commercialize our product candidates.

Various products are currently marketed or used off-label for some of the diseases and conditions that we are targeting, and a number of companies are or may be developing new treatments. These product uses, as well as promotional efforts by competitors and/or clinical trial results of competitive products, could significantly diminish our or our collaborators' ability to market and sell any products that we and/or our collaborators may develop. For example, although there are no products that have been approved by the FDA to reduce fractures and treat estrogen deficiency related side effects of ADT, we are aware of a number of drugs, including drugs marketed by Eli Lilly (Evista®), Merck (Fosamax®), Sanofi-Aventis and Warner Chilcott (Actonel®), Pfizer Inc. (Effexor®), Boehringer Ingelheim (Catapres®), Novartis (Zometa®) and Bristol Myers Squibb (Megace®), that are prescribed to treat single side effects of androgen deprivation therapy; that external beam radiation and tamoxifen are used to treat breast pain and enlargement, or gynecomastia; and that Amgen is developing a product candidate for the treatment of osteoporosis in prostate cancer patients. While we have the only pharmaceutical product in clinical development to prevent prostate cancer in high risk men with high grade PIN, GlaxoSmithKline has submitted a supplemental NDA for Avodart® for prostate cancer risk reduction among men at increased risk of developing the disease. Additionally, recent literature has suggested that finasteride and dutasteride may be effective in reducing the risk of prostate cancer progression. Testosterone and other anabolic agents are used to treat involuntary weight loss in patients who have acute muscle loss. There are other SARM product candidates in development that may compete with our product candidates. Pfizer Inc, Eli Lilly and Amgen have myostatin inhibitors in development which may compete for similar patients as Ostarine™. In addition, Cytokinetics, Inc. is developing a troponin activator with a muscle specific mechanism in a Phase I study. Moreover, there are other categories of drugs in development, including ghrelin receptor agonists and growth hormone secretagogues that may have some muscle activity. Competition could result in reduced sales and pricing pressure on our product candidates, if approved, which in turn would reduce our ability to generate revenue and have a negative impact on our results of operations.

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

Risks Related to Employees and Growth

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

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

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

In order to continue our clinical trials and commercialize our product candidates, we will need to expand the number of our managerial, operational, financial and other employees. We currently anticipate that we will need between 100 and 150 additional employees in order to commercialize toremifene 80 mg or toremifene 20 mg, including approximately 65 sales consultants. The competition for qualified personnel in the biotechnology field is intense.

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

Risks Related to Our Common Stock

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

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

- adverse results or delays in our clinical trials;
- the timing of achievement of, or failure to achieve, our and our collaborators' clinical, regulatory and other milestones, such as the commencement of clinical development, the completion of a clinical trial or the receipt of regulatory approval;
- announcement of FDA approval or non-approval of our product candidates or delays in the FDA review process;
- actions taken by regulatory agencies with respect to our product candidates or products, our clinical trials or our sales and marketing activities, including regulatory actions requiring or leading to restrictions, limitations and/or warnings in the label of FARESTON® or an approved product candidate;
- the commercial success of any product approved by the FDA or its foreign counterparts;
- developments with respect to our collaborations with Ipsen and Merck;
- introductions or announcements of technological innovations or new products by us, our collaborators, or our competitors, and the timing of these introductions or announcements;
- market conditions for equity investments in general, or the biotechnology or pharmaceutical industries in particular;
- the terms and timing of any collaborative, licensing or other arrangements that we may establish;
- regulatory developments in the United States and foreign countries;
- changes in the structure or reimbursement policies of health care payment systems;
- any intellectual property infringement lawsuit involving us;
- actual or anticipated fluctuations in our results of operations;
- changes in financial estimates or recommendations by securities analysts;
- sales of large blocks of our common stock;
- sales of our common stock by our executive officers, directors and significant stockholders;
- changes in accounting principles; and
- the loss of any of our key scientific or management personnel.

The stock markets in general, and the markets for biotechnology stocks in particular, have experienced significant volatility that has often been unrelated to the operating performance of particular companies. Recently, the financial markets have faced almost unprecedented turmoil, resulting in a decline in investor confidence and concerns about the proper functioning of the securities markets, which decline in general investor confidence has resulted in depressed stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. These broad market fluctuations may adversely affect the trading price of our common stock.

In the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs, which would hurt our financial condition and results of operations and divert management's attention and resources, which could result in delays of our clinical trials or commercialization efforts.

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

As of September 30, 2009, our executive officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 75.7% of our outstanding common stock, and our executive officers and directors alone beneficially owned approximately 46.6% of our outstanding common stock. As a result, these stockholders, acting together, will be able to control all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders.

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

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

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

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

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 September 30, 2009, the average daily trading volume of our common stock on the NASDAQ Global Market was approximately 228,380 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 September 30, 2009, we had 36,420,901 shares of common stock outstanding.

Moreover, J.R. Hyde, III, and Oracle Partners, L.P., two of our largest stockholders, and their affiliates, have rights, subject to some conditions, to require us to file registration statements covering the approximately 10.8 million shares of common stock they hold in the aggregate which are subject to registration rights or to include these shares in registration statements that we may file for ourselves or other stockholders. 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: November 9, 2009

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

Date: November 9, 2009

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

Table of Contents

EXHIBIT INDEX

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

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* Filed herewith.

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

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

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

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

(5) Filed as the like numbered Exhibit to the Registrant's Current Report on Form 8-K (File No. 000-50549), filed with the Securities and Exchange Commission on December 18, 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.

Exhibit 12.1

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

	Nine Months Ended September 30, 2009	Year Ended December 31, 2008	2007	2006	2005	2004
Loss:						
Pretax loss from continuing operations	$ (35,381)	$ (51,780)	$ (40,359)	$ (35,510)	$ (36,839)	$ (22,348)
Fixed charges (from below)	77	89	35	32	32	21
Total loss	$ (35,304)	$ (51,691)	$ (40,324)	$ (35,478)	$ (36,807)	$ (22,327)
Fixed charges:						
Estimated interest portion of rent expenses	$ 77	$ 89	$ 35	$ 32	$ 32	$ 21
Total fixed charges	$ 77	$ 89	$ 35	$ 32	$ 32	$ 21
Coverage deficiency	$ (35,381)	$ (51,780)	$ (40,359)	$ (35,510)	$ (36,839)	$ (22,348)

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: November 9, 2009

/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: November 9, 2009

/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 September 30, 2009, 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: November 9, 2009

/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 September 30, 2009, 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: November 9, 2009

/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.