GTX INC /DE/
Form 10-Q
November 08, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2012

OR

¨ **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 x No ¨

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 x No ¨

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 ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

As of November 5, 2012, 62,816,924 shares of the registrant s Common Stock were outstanding.

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GTx, INC.

FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2012

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PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

GTx, Inc.

CONDENSED BALANCE SHEETS

(in thousands, except share data)

	September 30, 2012 (unaudited)	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 38,731	$ 63,745
Short-term investments	8,555	10,695
Accounts receivable, net	1,152	981
FARESTON® sale proceeds receivable	21,671	
Inventory		161
Prepaid expenses and other current assets	1,233	1,266
Total current assets	71,342	76,848
Property and equipment, net	640	1,096
Intangible and other assets, net	186	240
Total assets	$ 72,168	$ 78,184
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,214	$ 1,219
Accrued expenses and other current liabilities	10,263	4,142
Total current liabilities	11,477	5,361
Other long-term liabilities	786	949
Commitments and contingencies		
Stockholders equity:		
Common stock, $0.001 par value: 120,000,000 shares authorized at both September 30, 2012 and December 31, 2011; 62,816,924 and 62,790,223 shares issued and outstanding at September 30, 2012 and December 31, 2011, respectively	63	63
Additional paid-in capital	460,073	457,985
Accumulated deficit	(400,231)	(386,174)
Total stockholders equity	59,905	71,874
Total liabilities and stockholders equity	$ 72,168	$ 78,184

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

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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,	
	2012	2011	2012	2011
Revenues:				
Collaboration revenue	$	$	$	$ 8,066
Expenses:				
Research and development expenses	9,764	8,181	28,836	23,075
General and administrative expenses	2,999	2,708	7,987	8,886
Total expenses	12,763	10,889	36,823	31,961
Loss from operations	(12,763)	(10,889)	(36,823)	(23,895)
Other (expense) income, net	(47)	23	14	332
Loss from operations before income taxes	(12,810)	(10,866)	(36,809)	(23,563)
Income tax benefit	7,861	591	8,848	398
Net loss from continuing operations	(4,949)	(10,275)	(27,961)	(23,165)
Income from discontinued operations before income taxes	20,214	1,522	22,752	951
Income tax expense	(7,861)	(591)	(8,848)	(398)
Net income from discontinued operations	12,353	931	13,904	553
Net income (loss)	$ 7,404	$ (9,344)	$ (14,057)	$ (22,612)
Net income (loss) per share basic and diluted:				
Net loss from continuing operations	$ (0.08)	$ (0.16)	$ (0.44)	$ (0.42)
Net income from discontinued operations	0.20	0.01	0.22	0.01
Net income (loss) per share	$ 0.12	$ (0.15)	$ (0.22)	$ (0.41)
Weighted average shares outstanding:				
Basic and diluted	62,815,549	62,778,575	62,806,440	55,529,320

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

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GTx, Inc.

CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2012	**2011**
Cash flows from operating activities:		
Net loss	$ (14,057)	$ (22,612)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on sale of FARESTON®	(18,831)	
Deferred revenue amortization		(8,066)
Impairment of intangible assets		1,598
Depreciation and amortization	596	819
Share-based compensation	1,878	3,178
Directors deferred compensation	128	141
Changes in assets and liabilities:		
Accounts receivable, net	(171)	(147)
Inventory	133	(27)
Prepaid expenses and other assets	34	(476)
Accounts payable	(12)	(19)
Accrued expenses and other liabilities	3,258	1,062
Net cash used in operating activities	(27,044)	(24,549)
Cash flows from investing activities:		
Purchase of property and equipment	(125)	(45)
Purchase of short-term investments, held to maturity	(7,815)	(12,450)
Proceeds from maturities of short-term investments, held to maturity	9,955	3,185
Net cash provided by (used in) investing activities	2,015	(9,310)
Cash flows from financing activities:		
Proceeds from issuance of common stock		48,982
Payments on capital lease and financed equipment obligations	(67)	(63)
Proceeds from exercise of employee stock options	82	55
Net cash provided by financing activities	15	48,974
Net (decrease) increase in cash and cash equivalents	(25,014)	15,115
Cash and cash equivalents, beginning of period	63,745	58,181
Cash and cash equivalents, end of period	$ 38,731	$ 73,296

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

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GTx, Inc.

NOTES TO THE CONDENSED FINANCIAL STATEMENTS

(in thousands, except share and per share data)

(unaudited)

1. Business and Basis of Presentation

Business

GTx, Inc. (GTx or the Company), a Delaware corporation incorporated on September 24, 1997 and headquartered in Memphis, Tennessee, is a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules for the treatment of cancer, cancer supportive care, and other serious medical conditions.

The Company is developing selective androgen receptor modulators (SARMs), including enobosarm (also known as Ostarine® or GTx-024). SARMs are a new class of drugs with the potential to prevent and treat muscle wasting in patients with cancer and other musculoskeletal wasting or muscle loss conditions, including chronic sarcopenia (age related muscle loss). The Company is enrolling two pivotal Phase III clinical trials evaluating enobosarm for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer.

Additionally, the Company is developing Capesaris® (GTx-758), an oral nonsteroidal selective estrogen receptor alpha agonist, for secondary hormonal therapy in men with castration resistant prostate cancer, and, potentially, as a primary treatment for advanced prostate cancer used in combination with androgen deprivation therapy. Based upon feedback from the FDA, the Company initiated in the third quarter of 2012 a Phase II clinical trial to evaluate the safety and efficacy of three lower doses of Capesaris® as secondary hormonal therapy in men with metastatic castration resistant prostate cancer.

Effective September 30, 2012, the Company sold its rights and certain assets related to FARESTON® to Strakan International S.á r.l., an affiliate of ProStrakan Group plc (ProStrakan) for $21,671 in cash. Through September 30, 2012, the Company sold FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of metastatic breast cancer in postmenopausal women, in the United States. See Note 4, *Discontinued Operations*, for further discussion.

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, 2011. Operating results for the three and nine months ended September 30, 2012 are not necessarily indicative of the results that may be expected for the entire fiscal year ending December 31, 2012.

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.

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GTx, Inc.

NOTES TO THE CONDENSED FINANCIAL STATEMENTS

(in thousands, except share and per share data)

(unaudited)

Discontinued Operations

On September 28, 2012, the Company entered into an asset purchase agreement (the FARESTON® Purchase Agreement) with ProStrakan pursuant to which the Company agreed to transfer, sell and assign to ProStrakan all of the Company s rights and certain assets related to FARESTON®. Effective September 30, 2012, the Company completed the sale of FARESTON® pursuant to the FARESTON® Purchase Agreement for a total cash purchase price of $21,671, including payment for purchased inventory. The Company has accounted for FARESTON® as a discontinued operation. As a result, revenue, cost of goods sold, and operating expenses relating to FARESTON® have been excluded from their respective captions in the condensed statements of operations and have been included in discontinued operations for the three and nine months ended September 30, 2012. The Company has also applied retroactive adjustments to the condensed statements of operations for the three and nine months ended September 30, 2011 to reflect the effects of the discontinued operations. The Company has set forth the assets and liabilities relating to the FARESTON® discontinued operations in Note 4, *Discontinued Operations*. See Note 4, *Discontinued Operations*, for further discussion.

FARESTON® Revenue Recognition

Revenue from product sales of FARESTON®, which is included in income from discontinued operations before income taxes, was recognized less deductions for estimated sales discounts and sales returns. Revenue from product sales was recognized when persuasive evidence of an arrangement existed, title passed, the price was fixed or determinable, and collectability was reasonably assured. The Company accounted 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. Although the Company sold its rights and certain assets related to FARESTON® effective September 30, 2012, the Company retains the liability for future product returns relating to sales of FARESTON® by the Company prior to September 30, 2012. Therefore, the Company estimates an accrual for product returns 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, 2012 and December 31, 2011, the Company s accrual for product returns, was $1,189 and $1,114, respectively. Of these amounts, $528 and $715 have been included in Other long-term liabilities in the condensed balance sheets at September 30, 2012 and December 31, 2011, respectively, and represents the portion of the Company s product returns accrual estimated to be payable after one year. See Note 4, *Discontinued Operations*, for further discussion.

Collaboration Revenue Recognition

Collaboration revenue consisted of non-refundable upfront payments, license fees, reimbursements for research and development activities, and milestone payments associated with the Company s former collaboration and license agreements. Revenues from the Company s prior collaboration and license agreements were recognized based on the performance requirements of the specific agreements. The Company analyzed agreements with multiple element arrangements to determine whether the deliverables under the agreement, including license and performance obligations such as joint steering committee participation and research and development activities, could have been separated or whether all of the deliverables must have been accounted for as a single unit of accounting. See Note 5, *Collaboration and License Agreements*, for further discussion.

Research and Development Expenses

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

the services in accordance with the specific third party contract.

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(in thousands, except share and per share data)

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Cash, Cash Equivalents and Short-term Investments

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

At September 30, 2012 and December 31, 2011, short-term investments consisted of Federal Deposit Insurance Corporation insured 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. The Company considers these to be Level 2 investments as the fair values of these investments are determined using third-party pricing sources, which generally utilize observable inputs, such as interest rates and maturities of similar assets.

Impairment of Long-Lived Assets

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

Based upon the Company s decision to discontinue toremifene 80 mg development and after analyzing future cash flows and estimates of fair market value from a market participant perspective, the Company determined that its toremifene 80 mg intangible asset was impaired and recorded an impairment charge of $1,598 during the nine months ended September 30, 2011. The impaired intangible asset consisted of the unamortized portion of capitalized license fees paid to Orion Corporation (Orion) related to the Company s former toremifene 80 mg program. This license fee was paid under the former amended and restated license and supply agreement for the Company s exclusive license from Orion to develop and commercialize toremifene-based products.

The impairment charge was included in research and development expenses in the condensed statement of operations for the nine months ended September 30, 2011.

Income Taxes

The Company accounts for deferred taxes by recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. Accordingly, at September 30, 2012 and December 31, 2011, 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, 2011.

The Company has recognized the tax effect of discontinued operations in the condensed statements of operations in accordance with the intra-period accounting rules. An offsetting tax benefit is recorded in continuing operations in each period.

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GTx, Inc.

NOTES TO THE CONDENSED FINANCIAL STATEMENTS

(in thousands, except share and per share data)

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Other (Expense) Income, net

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

Reclassification

Certain prior period results have been reclassified to conform with the discontinued operations presentation. See Note 4, *Discontinued Operations*, for further discussion.

Subsequent Events

The Company has evaluated all events or transactions that occurred after September 30, 2012 up through the date the condensed financial statements were issued. There were no material recognizable or nonrecognizable subsequent events during the period evaluated.

2. Share-Based Compensation

Share-based payments include stock option grants under the Company s stock option and equity incentive plans and deferred compensation arrangements for the Company s non-employee directors. The Company recognizes compensation expense for its share-based payments based on the fair value of the awards over the period during which an employee or non-employee director is required to provide service in exchange for the award. The Company s share-based compensation plans are described more fully in Note 3 to the Company s financial statements included in the Company s Annual Report on Form 10-K for the year ended December 31, 2011.

The following table summarizes share-based compensation expense included within the condensed statements of operations for the three and nine months ended September 30, 2012 and 2011:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Research and development expenses	$ 335	$ 503	$ 696	$ 1,410
General and administrative expenses	458	623	1,310	1,909
Total share-based compensation	$ 793	$ 1,126	$ 2,006	$ 3,319

Share-based compensation expense recorded as general and administrative expense for the three months ended September 30, 2012 and 2011 included share-based compensation expense related to deferred compensation arrangements for the Company s non-employee directors of $40 and $45, respectively. Share-based compensation expense related to deferred compensation arrangements for the Company s non-employee directors of $128 and $141 was included in share-based compensation expense recorded as general and administrative expenses for the nine months ended September 30, 2012 and 2011, respectively. Share-based compensation expense recorded as research and development expenses for the nine months ended September 30, 2012 was offset by the reversal of previously recognized share-based compensation expense for non-vested stock options that were canceled in conjunction with the resignation of an executive officer during the nine months ended September 30, 2012.

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.

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GTx, Inc.

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(in thousands, except share and per share data)

(unaudited)

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,	
	2012	2011	2012	2011
Expected price volatility	73.8%	65.3%	69.6%	64.9%
Risk-free interest rate	1.1%	2.3%	1.2%	2.5%
Weighted average expected life in years	6.5 years	6.5 years	6.5 years	6.5 years

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

	Number of Shares	Weighted Average Exercise Price Per Share
Options outstanding at December 31, 2011	4,945,565	$ 9.12
Options granted	1,129,250	3.34
Options forfeited or expired	(669,754)	8.86
Options exercised	(26,701)	3.07
Options outstanding at September 30, 2012	5,378,360	7.97

3. Basic and Diluted Net Loss Per Share

Basic and diluted 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.

Weighted average options outstanding to purchase shares of common stock of 5,408,065 and 5,113,943 for the three months ended September 30, 2012 and 2011, respectively, and 5,639,672 and 5,455,700 for the nine months ended September 30, 2012 and 2011, respectively, were excluded from the calculations of diluted 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. Discontinued Operations

On September 28, 2012, the Company entered into the FARESTON® Purchase Agreement with ProStrakan pursuant to which the Company agreed to transfer, sell and assign to ProStrakan all of the Company s rights to FARESTON® and certain assets related thereto. Effective September 30, 2012, the Company completed the sale of FARESTON® pursuant to the FARESTON® Purchase Agreement for a total cash purchase price of $21,671, including payment for purchased inventory. The Company recognized a gain of $18,831 on the sale of FARESTON® for the three and nine months ended September 30, 2012. The gain represents the gross proceeds received from the sale reduced by a contract termination fee of $1,000 due to Orion (as discussed further in Note 5, *Collaboration and License Agreements)*, a financial advisory fee related to the transaction of $1,712, and other transaction expenses of approximately $128.

The Company has accounted for FARESTON® as a discontinued operation. The FARESTON® operating income, along with the gain recognized on the sale of FARESTON® for the three and nine months ended September 30, 2012, has been reported as net income from discontinued operations in the condensed statements of operations. In addition, the assets and liabilities related to FARESTON® that are included in the condensed balance sheets for the periods presented have been presented below.

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GTx, Inc.

NOTES TO THE CONDENSED FINANCIAL STATEMENTS

(in thousands, except share and per share data)

(unaudited)

FARESTON® operating income for each period presented was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Product sales, net	$ 1,826	$ 2,029	$ 5,294	$ 4,903
Cost of product sales	(263)	(311)	(782)	(780)
Operating expenses	(180)	(196)	(591)	(3,172)
FARESTON® operating income	$ 1,383	$ 1,522	$ 3,921	$ 951

Under the FARESTON® Purchase Agreement, the Company remains responsible for and benefits from the collection of accounts receivable and remains liable for future product returns, in each case relating to sales of FARESTON® made by the Company prior to September 30, 2012. The Company has also recognized liabilities in its condensed balance sheet at September 30, 2012 for the $1,000 termination fee due to Orion and the $1,712 financial advisory fee related to the transaction within accrued expenses and other current liabilities . The assets and liabilities related to FARESTON® discontinued operations included in the condensed balance sheets for the periods presented were as follows:

	September 30, 2012	December 31, 2011
Accounts receivable, net	$ 1,152	$ 981
FARESTON® sale proceeds receivable	21,671	
Inventory		161
Prepaid expenses and other assets	279	178
Total assets	23,102	1,320
Accounts payable	35	116
Accrued expenses and other current liabilities	4,209	919
Other long-term liabilities	528	715
Total liabilities	4,772	1,750
Net assets (liabilities)	$ 18,330	$ (430)

5. Collaboration and License Agreements

Former Orion Corporation License and Supply Agreement

In connection with the Company s sale of its rights and certain assets related to FARESTON® to ProStrakan, the Company and Orion agreed to terminate the Amended and Restated License and Supply Agreement, dated January 1, 2005, as amended, between the Company and Orion (the Orion Supply Agreement) as well as certain other agreements between the Company and Orion related to the Orion Supply Agreement

(collectively, the Orion Agreements). Pursuant to the Orion Supply Agreement, the Company obtained an exclusive license from Orion to develop and commercialize toremifene-based products for all human indications worldwide, except breast cancer outside of the United States, and Orion agreed to manufacture and supply all of the Company s needs for clinical trial and commercial grade material for toremifene-based products developed and marketed in the United States and abroad, including toremifene globally and FARESTON® in the United States. The termination of the Orion Agreements was effective September 30, 2012. As consideration for Orion s agreement to terminate the Orion Agreements and to enter into certain agreements with the ProStrakan to effect the FARESTON® sale, the Company paid Orion $1,000 in October 2012.

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GTx, Inc.

NOTES TO THE CONDENSED FINANCIAL STATEMENTS

(in thousands, except share and per share data)

(unaudited)

University of Tennessee Research Foundation License Agreements

The Company and the University of Tennessee Research Foundation (UTRF) are parties to a consolidated, amended and restated license agreement (the SARM License Agreement) pursuant to which the Company was granted exclusive worldwide rights in all existing SARM technologies owned or controlled by UTRF, including all improvements thereto, and exclusive rights to future SARM technology that may be developed by certain scientists at the University of Tennessee or subsequently licensed to UTRF under certain existing inter-institutional agreements with The Ohio State University. Under the SARM License Agreement, the Company is obligated to pay UTRF annual license maintenance fees, low single-digit royalties on net sales of products and mid single-digit royalties on sublicense revenues.

Former Ipsen Collaboration and License Agreement

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

In accordance with the terms of the Ipsen Collaboration Agreement, Ipsen paid the Company 23,000 as a license fee and expense reimbursement. Under the Ipsen Collaboration Agreement, the Company recorded deferred revenue of $29,330 related to the Ipsen upfront license fee and expense reimbursement which was being amortized into revenue on a straight-line basis over the estimated ten year development period for toremifene in the European Territory.

In March 2011, the Company reacquired full rights to its toremifene program following the termination by the Company and Ipsen of the collaboration and license agreement, as amended. During the first quarter of 2011, the Company recognized as collaboration revenue all of the remaining $8,066 unamortized revenue. This amount is included in collaboration revenue in the condensed statement of operations for the nine months ended September 30, 2011.

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

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

Forward-Looking Information

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

- the anticipated progress of our research, development and clinical programs, including whether our ongoing or planned clinical trials will achieve similar results to clinical trials that we have previously concluded;
- the timing, scope and anticipated initiation, enrollment and completion of our ongoing and planned clinical trials and any other future clinical trials that we may conduct;
- the timing of regulatory submissions and the timing, scope and anticipated outcome of related regulatory actions;
- our ability to establish and maintain potential new collaborative arrangements for the development and commercialization of our product candidates;
- our ability to obtain and maintain regulatory approvals of our product candidates and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our ability to market, commercialize and achieve market acceptance for our product candidates or products that we may develop;
- our ability to generate additional product candidates for clinical testing;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; and
- our estimates regarding the sufficiency of our cash resources, expenses, capital requirements and needs for additional financing, and our ability to obtain additional financing.

In some cases, you can identify forward-looking statements by terms such as anticipates, believes, could, estimates, expects, intends, ma potential, predicts, projects, should, will, would and similar expressions intended to identify forward-looking statements. Forward-lookin 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.

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Overview

Business Overview

We are a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules for the treatment of cancer, cancer supportive care, and other serious medical conditions.

Business Highlights

We are developing selective androgen receptor modulators, or SARMs, a new class of drugs with the potential to prevent and treat muscle wasting in patients with cancer and other musculoskeletal wasting or muscle loss conditions, including chronic sarcopenia (age related muscle loss). Our lead SARM product candidate, enobosarm (also known as Ostarine® or GTx-024), has to date been evaluated in eight completed clinical trials enrolling approximately 600 subjects, including in a Phase Ib and two Phase II efficacy studies. Enobosarm is the generic name given to the compound by the USAN Council and the World Health Organization and is the first compound to receive the SARM stem in its name, recognizing enobosarm as the first in this new class of compounds.

We are enrolling the POWER 1 and POWER 2 (Prevention and treatment Of muscle Wasting in patients with cancER) pivotal Phase III clinical trials evaluating enobosarm for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer. We are conducting these trials in clinical sites in the United States, Europe, and South America. In each of the placebo-controlled, double-blind clinical trials, approximately 300 patients with Stage III or IV non-small cell lung cancer are being randomized to placebo or enobosarm 3 mg at the time they are to begin first line chemotherapy. The trials are evaluating as co-primary endpoints the effect of enobosarm versus placebo on total lean body mass (muscle) assessed by dual x-ray absorptiometry, or DXA, and on physical function assessed by the Stair Climb Test at three months. Durability of effect is being assessed as a secondary endpoint at five months. In October 2012, after a pre-specified safety review in subjects currently enrolled in these two clinical trials, the independent Data Safety Monitoring Board determined that the trials could continue as planned. We currently expect topline data from these pivotal Phase III clinical trials during the second quarter of 2013. We plan either to build a specialized sales and marketing organization to commercialize enobosarm or consider strategic partnerships or collaborations for the development and commercialization of this product candidate.

Additionally, we are developing Capesaris® (GTx-758), an oral nonsteroidal selective estrogen receptor alpha agonist, for secondary hormonal therapy in men with castration resistant prostate cancer, and, potentially, as a primary treatment for advanced prostate cancer used in combination with androgen deprivation therapy, or ADT. We believe Capesaris® has the potential to reduce testosterone without also causing certain estrogen deficiency side effects, such as bone loss, hot flashes and insulin resistance, which are common with current androgen deprivation therapies for prostate cancer. We also believe that Capesaris® may be effective, in combination with ADT, as a primary treatment of advanced prostate cancer by reducing testosterone to levels lower than what is attainable with ADT alone and potentially reducing the estrogen deficiency side effects caused by the use of ADT.

In May 2012, we announced that the United States Food and Drug Administration, or FDA, had removed its full clinical hold on our Investigational New Drug, or IND, application for Capesaris®. The full clinical hold was placed on our three then-ongoing Phase II clinical trials evaluating Capesaris® to treat men with advanced prostate cancer in February 2012 and resulted in the discontinuation of these trials. The full clinical hold followed our reports to the FDA of venous thromboembolic events (blood clots), or VTEs, in subjects treated with Capesaris® at the doses being studied in those trials (1000 mg and higher per day). Based upon feedback from the FDA in connection with the removal of the full clinical hold, we initiated in the third quarter of 2012 a Phase II clinical trial to evaluate the safety and efficacy of three lower doses of Capesaris® as secondary hormonal therapy in men with metastatic castration resistant prostate cancer.

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Capesaris® has previously demonstrated the ability to increase the production of a protein called sex hormone binding globulin, or SHBG, in men with advanced prostate cancer and reduce serum prostate specific antigen, or PSA, and free testosterone, which can stimulate prostate cancer growth. The primary endpoint of the current Phase II open-label clinical trial is the proportion of subjects with a ³ 50% decline from baseline in serum prostate specific antigen, or PSA, by day 90. Other key cancer endpoints include serum PSA progression, time to progression and progression free survival in the study subjects. In addition, the clinical study will evaluate the ability of Capesaris® to treat certain side effects associated with luteinizing hormone releasing hormone agonists such as hot flashes, bone loss, and insulin resistance. The clinical trial requires subjects to continue receiving their ADT treatment, which will allow us to assess the safety and tolerability of Capesaris® in these subjects, including the incidence of VTEs. The trial design provides for 75 total subjects, with three sequential dosing arms. The first 25 subjects in the Phase II clinical trial are being enrolled in the Capesaris® 125 mg dosing arm. Assuming that an acceptable incidence of VTEs has been observed when the last subject enrolled in the Capesaris® 125 mg dose arm has completed one 30 day cycle of therapy, enrollment of the next 25 subjects will commence in the Capesaris® 250 mg dosing arm. Similarly, the Capesaris® 500 mg dosing arm will commence enrollment of the final 25 subjects when the last subject enrolled in the 250 mg dose arm has completed one 30 day cycle of therapy, assuming an acceptable incidence of VTEs has been observed in both of the lower dosage arms.

Financial Highlights

Effective September 30, 2012, we sold our rights and certain assets related to FARESTON® to Strakan International S.á r.l., an affliliate of ProStrakan Group plc, or ProStrakan, for a purchase price of approximately $21.7 million in cash and recognized a gain on the sale of $18.8 million. Through September 30, 2012, we sold FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of metastatic breast cancer in postmenopausal women, in the United States.

Our net loss for the nine months ended September 30, 2012 was $14.1 million. Our net loss included a gain of $18.8 million on the sale of our rights and certain assets related to FARESTON®. We expect to incur significant net losses in 2012 and for the foreseeable future as we continue our clinical development and research and development activities. Currently, we have no ongoing collaborations for the development and commercialization of our product candidates, and, as a result of the sale of our rights and certain assets related to FARESTON®, we also currently have no source of revenue. Our current product candidates, enobosarm and Capesaris®, will require significant additional clinical development and financial resources to obtain necessary regulatory approvals in order to develop these product candidates into commercially viable products. Accordingly, we do not expect to obtain FDA approval or any other regulatory approvals to market any of our product candidates in the near future, and it is possible that our product candidates will never receive any regulatory approvals.

At September 30, 2012, we had cash, cash equivalents and short-term investments of $47.3 million compared to $74.4 million at December 31, 2011. In October 2012, we increased our cash and short-term investments when we received net cash proceeds of approximately $19 million related to the sale of our rights and certain assets related to FARESTON®. As of the date of this Quarterly Report on Form 10-Q, we estimate that our current cash, cash equivalents, and short-term investments, together with interest thereon, will be sufficient to meet our projected operating requirements for at least the next twelve months. We have based this estimate on our current business plan and assumptions that may prove to be wrong. We could utilize our available capital resources sooner than we currently expect, and we could need additional funding sooner than currently anticipated. In any event, to complete the development of and seek regulatory approval for enobosarm and Capesaris®, we will need to obtain substantial additional funding.

Research and Development

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

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We expect that our research and development expenses for fiscal year 2012 will increase as compared to fiscal year 2011 and to be primarily focused on the following:

- the continued clinical development of enobosarm;
- the continued clinical development of Capesaris®; and
- the continued preclinical development of other potential product candidates.

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

Product Candidates

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

Product Candidate/ Proposed Indication	Program	Clinical Development Phase	Status
Enobosarm (Ostarine®; GTx-024)			
Prevention and treatment of muscle wasting in patients with non-small cell lung cancer	SARM	Phase III	Enrolling the POWER 1 and POWER 2 pivotal Phase III clinical trials for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer.
Capesaris® (GTx-758)			
Secondary hormonal therapy in men with metastatic castration resistant prostate cancer and primary treatment for advanced prostate cancer used in combination with ADT	Selective ER alpha agonist	Phase II	Initiated a Phase II clinical trial in the third quarter of 2012 for secondary hormonal therapy in men with metastatic castration resistant prostate cancer.

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, and investor relations functions. General and administrative expenses also include facility costs, insurance costs, and professional fees for legal, accounting, and public relation services.

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.

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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, 2011 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.

Discontinued Operations

Effective September 30, 2012, we completed the sale of FARESTON® for a total cash purchase price of $21.7 million, including payment for purchased inventory. We have accounted for FARESTON® as a discontinued operation. As a result, revenue, cost of goods sold, and operating expenses relating to FARESTON® have been excluded from their respective captions in the condensed statements of operations and have been included in discontinued operations for the three and nine months ended September 30, 2012. We have also applied retroactive adjustments to the condensed statements of operations for the three and nine months ended September 30, 2011 to reflect the effects of the discontinued operations.

Revenue Recognition

Our revenues consisted of product sales of FARESTON®, which is included in income from discontinued operations before income taxes, and in 2011, also consisted of revenues derived from our former collaboration and license agreements.

Revenue from product sales of FARESTON® was recognized less deductions for estimated sales discounts and sales returns. Revenue from product sales was recognized when persuasive evidence of an arrangement existed, title passed, the price was fixed or determinable, and collectability was reasonably assured. We accounted 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. Although we sold our rights and certain assets related to FARESTON® effective September 30, 2012, we retain the liability for future product returns relating to sales of FARESTON® by us prior to September 30, 2012. Therefore, we estimate an accrual for product returns 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, 2012 and December 31, 2011, our accrual for product returns, was $1.2 million and $1.1 million, respectively.

Collaboration revenue consisted of non-refundable upfront payments, license fees, reimbursements for research and development activities, and milestone payments associated with our former collaboration and license agreements and was based on the performance requirements of the specific agreements. We analyzed our agreements with multiple element arrangements to determine whether the deliverables under the agreement, including license and performance obligations such as joint steering committee participation and research and development activities, could have been separated or whether all of the deliverables must have been accounted for as a single unit of accounting. Performance obligations typically consisted of significant milestones in the development life cycle of the related product candidates and technology, such as initiation of clinical trials, achievement of specified clinical trial endpoints, filing for approval with regulatory agencies and approvals by regulatory agencies.

Research and Development Expenses

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

Research and development expenses for the nine months ended September 30, 2011 included an impairment charge of $1.6 million related to the unamortized portion of capitalized license fees paid to Orion Corporation related to our former toremifene 80 mg program.

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Share-Based Compensation

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

The determination of the fair value of share-based payment awards on the date of grant include the expected life of the award, the expected stock price volatility over the expected life of the awards, 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.

The following table summarizes share-based compensation expense included within the condensed statements of operations for the three and nine months ended September 30, 2012 and 2011:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	(in thousands)			
Research and development expenses	$ 335	$ 503	$ 696	$ 1,410
General and administrative expenses	458	623	1,310	1,909
Total share-based compensation	$ 793	$ 1,126	$ 2,006	$ 3,319

Share-based compensation expense recorded in the condensed statement of operations as general and administrative expense for the three months ended September 30, 2012 and 2011 included share-based compensation expense related to deferred compensation arrangements for our non-employee directors of $40,000 and $45,000, respectively. Share-based compensation expense recorded in the condensed statement of operations as general and administrative expense for the nine months ended September 30, 2012 and 2011 included share-based compensation expense related to deferred compensation arrangements for our non-employee directors of $128,000 and $141,000, respectively. Share-based compensation expense recorded as research and development expenses for the nine months ended September 30, 2012 was offset by the reversal of previously recognized share-based compensation expense for non-vested stock options that were canceled in conjunction with the resignation of an executive officer during the period. At September 30, 2012, the total compensation cost related to non-vested awards not yet recognized was approximately $4.9 million with a weighted average expense recognition period of 2.93 years.

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Results of Operations

Three Months Ended September 30, 2012 and 2011

Research and Development Expenses. Research and development expenses increased 19% to $9.8 million for the three months ended September 30, 2012 from $8.2 million for the three months ended September 30, 2011. The increase in research and development expenses during the three months ended September 30, 2012 compared to the prior year comparable quarter was due primarily to a $2.6 million increase in costs related to the continued enrollment of and operations related to the two pivotal Phase III clinical trials for enobosarm. This increase was partially offset by a $1.1 million decrease in research and development expenses due to the discontinuance in February 2012 of the three Phase II clinical trials of Capesaris® to treat men with advanced prostate cancer that were placed on full clinical hold by the FDA. Other research and development expenses in the table below includes the cost of personnel, supplies, and facilities associated with preclinical and discovery research and development activities. The following table identifies the research and development expenses for each of our clinical product candidates, as well as research and development expenses pertaining to our other research and development efforts, for both of the periods presented. Research and development expenses for past periods may not be indicative of future periods.

Product Candidate/ Proposed Indication	Program	Three Months Ended September 30, 2012	2011	Increase/ (Decrease)
		(in thousands)		
Enobosarm				
Prevention and treatment of muscle wasting in patients with non-small cell lung cancer	**SARM**	$ 6,312	$ 3,702	$ 2,610
Capesaris®				
Secondary hormonal therapy in men with metastatic castration resistant prostate cancer	**Selective ER alpha agonist**	1,729	2,815	(1,086)
Other research and development		1,723	1,664	59
Total research and development expenses		$ 9,764	$ 8,181	$ 1,583

***General and Administrative Expenses*.** General and administrative expenses increased during the three months ended September 30, 2012 to $3.0 million from $2.7 million for the three months ended September 30, 2011. This increase was primarily due to an increase in salaries and benefits of $194,000 and increased legal expenses of $71,000.

Discontinued Operations. Income from discontinued operations before income taxes was $20.2 million for the three months ended September 30, 2012 and consisted of FARESTON® operating income of $1.4 million and the recognition of a gain of $18.8 million on the sale of our rights and certain assets related to FARESTON®.

The components of FARESTON® operating income for the three months ended September 30, 2012 and 2011 were as follows:

	Three Months Ended September 30, 2012	2011	Increase/ (Decrease)
	(in thousands)		
Product sales, net	$ 1,826	$ 2,029	$ (203)
Cost of product sales	263	311	(48)
Operating expenses	180	196	(16)
FARESTON® operating income	$ 1,383	$ 1,522	$ (139)

During the three months ended September 30, 2012, FARESTON® gross product sales increased from the same period of 2011 due to an increase in the sales price of FARESTON® and, to a lesser extent, an increase in sales volume. However, this was offset by an increase in governmental rebates as compared to the prior period.

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Nine Months Ended September 30, 2012 and 2011

Collaboration Revenue. Collaboration revenue was $8.1 million for the nine months ended September 30, 2011. As a result of the termination of our license and collaboration agreement with Ipsen Biopharm Limited in March 2011, we recognized as collaboration revenue all of the remaining $8.1 million of unamortized revenue in the three months ended March 31, 2011. We had no collaboration revenue during the nine months ended September 30, 2012.

Research and Development Expenses. Research and development expenses increased by 25% to $28.8 million for the nine months ended September 30, 2012 from $23.1 million for the nine months ended September 30, 2011. The increase in research and development expenses during the nine months ended September 30, 2012 compared to the prior year comparable period was due primarily to a $10.2 million increase in costs related to the continued enrollment of and operations related to the two pivotal Phase III clinical trials for enobosarm. This increase was partially offset by a $2.5 million decrease in research and development expenses due to the discontinuance in February 2012 of the three Phase II clinical trials of Capesaris® to treat men with advanced prostate cancer that were placed on full clinical hold by the FDA. Other research and development expenses in the table below includes the cost of personnel, supplies, and facilities associated with preclinical and discovery research and development activities. The following table identifies the research and development expenses for each of our clinical product candidates, as well as research and development expenses pertaining to our other research and development efforts, for both of the periods presented.

Product Candidate/ Proposed Indication	**Program**	**Nine Months Ended September 30,**		**Increase/ (Decrease)**
		2012	**2011**	
		(in thousands)		
Enobosarm				
Prevention and treatment of muscle wasting in patients with non-small cell lung cancer	**SARM**	$ 17,420	$ 7,178	$ 10,242
Capesaris®				
Secondary hormonal therapy in men with metastatic castration resistant prostate cancer	**Selective ER alpha agonist**	5,969	8,463	(2,494)
Other research and development [1]		5,447	7,434	(1,987)
Total research and development expenses		$ 28,836	$ 23,075	$ 5,761

[1] Other research and development for the nine months ended September 30, 2011 included research and development expenses of $2.0 million for toremifene 80 mg, which included an impairment charge of $1.6 million, and $434,000 for toremifene 20 mg. We have discontinued our toremifene development programs.

General and Administrative Expenses. General and administrative expenses decreased during the nine months ended September 30, 2012 to $8.0 million from $8.9 million for the nine months ended September 30, 2011. This decrease was primarily due to the discontinuance of our toremifene development programs, which resulted in decreased personnel related costs of $359,000 and decreased legal expenses of $460,000.

Discontinued Operations. Income from discontinued operations before income taxes was $22.8 million for the nine months ended September 30, 2012 and consisted of FARESTON® operating income of $3.9 million and the recognition of a gain of $18.8 million on the sale of rights and certain assets related to FARESTON®.

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The components of FARESTON® operating income for the nine months ended September 30, 2012 and 2011 were as follows:

	Nine Months Ended September 30,		Increase/ (Decrease)
	2012	2011	
	(in thousands)		
Product sales, net	$ 5,294	$ 4,903	$ 391
Cost of product sales	782	780	2
Operating expenses	591	3,172	(2,581)
FARESTON® operating income	$ 3,921	$ 951	$ 2,970

FARESTON® gross product sales increased for the nine months ended September 30, 2012 compared to the same period in 2011 due to an increase in the sales price of FARESTON® and, to a lesser extent, an increase in sales volume, which was partially offset by an increase in governmental rebates as compared to the prior period. FARESTON® operating expenses decreased for the nine month period ended September 30, 2012 as compared to the same period in 2011 due to a reduction in FARESTON® marketing and medical education expenses.

Liquidity and Capital Resources

At September 30, 2012, we had cash, cash equivalents and short-term investments of $47.3 million, compared to $74.4 million at December 31, 2011. In October 2012, we increased our cash and short-term investments when we received net cash proceeds of approximately $19 million related to the sale of our rights and certain assets related to FARESTON®. Net cash used in operating activities was $27.0 million and $24.5 million for the nine months ended September 30, 2012 and 2011, respectively, and resulted primarily from funding our operations for the periods.

Net cash provided by investing activities was $2.0 million for the nine months ended September 30, 2012 and resulted primarily from the maturities of short-term investments of $10.0 million offset by the purchase of short-term investments of $7.8 million. Net cash used in investing activities was $9.3 million for the nine months ended September 30, 2011 due primarily to the purchase of short-term investments of $12.5 million offset by maturities of short-term investments of $3.2 million.

Net cash provided by financing activities of $15,000 for the nine months ended September 30, 2012 reflects proceeds from the exercise of employee stock options partially offset by payments on capital lease and financed equipment obligations. Net cash provided by financing activities was $49.0 million for the nine months ended September 30, 2011 and reflects proceeds from our underwritten public offering of common stock in September 2011 and proceeds from the exercise of employee stock options. These proceeds were reduced by payments on our capital lease and financed equipment obligations.

As of the date of this Quarterly Report on Form 10-Q, we estimate that our current cash, cash equivalents, and short-term investments, together with interest thereon, will be sufficient to meet our projected operating requirements for at least the next twelve months. We have based this estimate on our current business plan and assumptions that may prove to be wrong. We could utilize our available capital resources sooner than we currently expect, and we could need additional funding sooner than currently anticipated. In any event, to complete the development of and seek regulatory approval for enobosarm and Capesaris®, we will need to obtain substantial additional funding.

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

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- the scope, rate of progress and cost of our clinical trials and other research and development activities, including our ongoing and any other future clinical trials of enobosarm and Capesaris®;
- the terms and timing of any potential future collaborative, licensing and other arrangements that we may establish;
- the decision to initiate development of new potential medicines from our research and discovery activities;
- the amount and timing of any license fees, milestone payments and royalty payments from potential future collaborators, if any;
- future clinical trial results;
- the cost and timing of regulatory filings and/or approvals to commercialize our product candidates and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- the cost and timing of establishing medical education, sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we and/or any potential future collaborators may develop;
- the effect of competing technological and market developments;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, and the cost of defending any other litigation claims; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

We do not currently have any commitments for future external funding nor do we currently have any sources of revenue. Until we can generate a sufficient amount of product revenue, which we may never do, we expect to finance future cash needs through public or private equity offerings, debt financings or collaboration and licensing arrangements, or a combination of the above, as well as through interest income earned on the investment of our cash balances and short-term investments. In June 2011, we announced a workforce reduction of approximately 15% in order to reduce our operating expenses relating to our discontinued toremifene development programs. If we are unable to raise additional funds when needed, we may need to further reduce our expenditures, perhaps significantly, to preserve our cash. Cost-cutting measures that we may take in the future may not be sufficient to enable us to meet our cash requirements, and they may negatively affect our business and growth prospects. To the extent we raise additional funds by issuing equity securities, our stockholders may experience dilution, and debt financing, if available, may involve restrictive covenants. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. To the extent we raise additional funds through potential future collaboration and licensing arrangements, it may be necessary to relinquish rights to some of our technologies or product candidates, or grant licenses on terms that are not favorable to us. Our ability to raise additional funds and the terms upon which we are able to raise such funds may be adversely impacted by the outcomes of ongoing and potential future clinical trials of enobosarm and Capesaris®, uncertainty regarding our financial condition and/or current economic conditions, including the effects of, disruptions to and volatility in the credit and financial markets in the United States, the European Union and other regions of the world, including those resulting from or associated with rising government debt levels. As a result of these and other factors, we cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available when we need them, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs, including our SARM and selective ER alpha agonist programs, or conduct additional workforce or other expense reductions, any of which could have a material adverse effect on our

business.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the nine months ended September 30, 2012, 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, 2011.

ITEM 4. CONTROLS AND PROCEDURES

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

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

There were no changes in our internal control over financial reporting during the third quarter of 2012 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 2, 2012. In addition, the risks described under, and the caption entitled, Our only marketed product generating revenue is FARESTON®, which is subject to a number of risks. These risks may cause sales of FARESTON® to decline. included under Part 1, Item 1A Risk Factors in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 8, 2011 have been removed.

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Risks Related to Our Financial Condition and Need for Additional Financing

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

As of September 30, 2012, we had an accumulated deficit of $400.2 million. Our net loss for the nine months ended September 30, 2012 was $14.1 million, which included a gain of $18.8 million on the sale of our rights and certain assets related to FARESTON®. We expect to incur significant net losses for the foreseeable future as we continue our clinical development and research and development activities. These losses, among other things, have had and will continue to have an adverse effect on our stockholders equity and working capital.

Our current product candidates, enobosarm (also known as Ostarine® or GTx-024) and Capesaris® (GTx-758), will require significant additional clinical development and financial resources to obtain necessary regulatory approvals in order to develop these product candidates into commercially viable products. Accordingly, we do not expect to obtain United States Food and Drug Administration, or FDA, approval or any other regulatory approvals to market any of our product candidates in the near future, and it is possible that our product candidates will never receive any regulatory approvals.

Because of the numerous risks and uncertainties associated with developing and commercializing small molecule drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. We have financed our operations and internal growth primarily through public offerings and private placement of our common stock, as well as payments from our former collaborators. We also previously recognized product revenue from the sale of FARESTON®, the rights to which we sold to a third party in the third quarter of 2012. Currently, we have no ongoing collaborations for the development and commercialization of our product candidates, and as a result of the sale of our rights and certain assets related to FARESTON®, we also currently have no sources of revenue. If we and/or any potential future collaborators are unable to develop and commercialize any of our product candidates, if development is further delayed or is eliminated, or if sales revenue from any product candidate that receives marketing approval is insufficient, we may never become profitable and we will not be successful.

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

We will need to raise substantial additional capital to:

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

As of the date of this Quarterly Report on Form 10-Q, we estimate that our current cash, cash equivalents, and short-term investments, together with interest thereon, will be sufficient to meet our projected operating requirements for at least the next twelve months. We have based this estimate on our current business plan and assumptions that may prove to be wrong. We could utilize our available capital resources sooner than we currently expect, and we could need additional funding sooner than currently anticipated. In any event, to complete the development of and seek regulatory approvals for enobosarm and Capesaris®, we will need to obtain substantial additional funding. Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical trials and other research and development activities, including our ongoing, planned and any other future clinical trials of enobosarm and Capesaris®;

the terms and timing of any potential future collaborative, licensing and other arrangements that we may establish;

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- the decision to initiate development of new potential medicines from our research and discovery activities;
- the amount and timing of any licensing fees, milestone payments and royalty payments from potential future collaborators, if any;
- future clinical trial results;
- the cost and timing of regulatory filings and/or approvals to commercialize our product candidates and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- the cost and timing of establishing medical education, sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we and/or any potential future collaborators may develop;
- the effect of competing technological and market developments;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, and the cost of defending any other litigation claims; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

We do not currently have any commitments for future external funding nor do we currently have any sources of revenue. Until we can generate a sufficient amount of product revenue, which we may never do, we expect to finance future cash needs through public or private equity offerings, debt financings or collaboration and licensing arrangements, or a combination of the above, as well as through interest income earned on the investment of our cash balances and short-term investments. In June 2011, we announced a workforce reduction of approximately 15% in order to reduce our operating expenses relating to our discontinued toremifene development programs. If we are unable to raise additional funds when needed, we may need to further reduce our expenditures, perhaps significantly, to preserve our cash. Cost-cutting measures that we may take in the future may not be sufficient to enable us to meet our cash requirements, and they may negatively affect our business and growth prospects.

To the extent we raise additional funds by issuing equity securities, our stockholders may experience dilution, and debt financing, if available, may involve restrictive covenants. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. To the extent we raise additional funds through potential future collaboration and licensing arrangements, it may be necessary to relinquish rights to some of our technologies or product candidates, or grant licenses on terms that are not favorable to us. Our ability to raise additional funds and the terms upon which we are able to raise such funds may be adversely impacted by the outcomes of ongoing and planned clinical trials of enobosarm and Capesaris®, uncertainty regarding our financial condition and/or current economic conditions, including the effects of, disruptions to and volatility in the credit and financial markets in the United States, the European Union and other regions of the world, including those resulting from or associated with rising government debt levels. As a result of these and other factors, we cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available when we need them, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs, including our SARM and selective ER alpha agonist programs, or conduct additional workforce or other expense reductions, any of which could have a material adverse effect on our business.

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Risks Related to Development of Product Candidates

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

Significant additional research and development and financial resources will be required to obtain necessary regulatory approvals for our product candidates and to develop them into commercially viable products. Preclinical and clinical testing is expensive, can take many years to complete and has an uncertain outcome. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. Typically, the failure rate for development candidates is high. If a product candidate fails at any stage of development, we will not have the anticipated revenues from that product candidate to fund our operations, and we will not receive any return on our investment in that product candidate. For example, we announced in May 2010 that toremifene 20 mg failed to meet its primary efficacy endpoint in our Phase III clinical trial of toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia, after we had incurred significant development costs. Even if the results of a clinical trial are positive, the efficacy and/or safety results from the trial may be insufficient to support the submission of a new drug application, or NDA, to the FDA, or if submitted, the approval of the NDA by the FDA. For example, we received a Complete Response Letter in October 2009 from the FDA regarding our NDA for toremifene 80 mg to reduce fractures in men with prostate cancer on androgen deprivation therapy, or ADT, notifying us that the FDA would not approve the NDA. We have since discontinued our toremifene development programs.

Significant delays in clinical testing could materially impact our product development costs. We do not know whether planned or other future clinical trials will begin on time, or whether ongoing or planned clinical trials will need to be restructured or will be completed on schedule, if at all. We or any potential future collaborators may experience numerous unforeseen and/or adverse events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent our or our potential future collaborators ability to commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us or any potential future collaborators to commence a clinical trial or conduct a clinical trial at a prospective trial site, or we may experience substantial delays in obtaining these authorizations;
- preclinical or clinical trials may produce negative or inconclusive results, which may require us or any potential future collaborators to conduct additional preclinical or clinical testing or to abandon projects that we expect to be promising;
- even if preclinical or clinical trial results are positive, the FDA or foreign regulatory authorities could nonetheless require us to conduct unanticipated additional clinical trials;
- registration or enrollment in clinical trials may be slower than we anticipate, resulting in significant delays or study terminations;
- we or any potential future collaborators may suspend or terminate clinical trials if the participating patients are being exposed to unacceptable health risks;
- regulators or institutional review boards may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; and
- our product candidates may not have the desired effects or may include undesirable side effects.

If any of these events were to occur and, as a result, we or any potential future collaborators have significant delays in or termination of clinical trials, our costs could increase and our ability to generate revenue could be impaired, which would materially and adversely impact our business, financial condition and growth prospects.

If we or any potential future collaborators observe serious or other adverse events during the time our product candidates are in development or after our products are approved and on the market, we or any potential future collaborators may be required to perform lengthy additional clinical trials, may be required to cease further development of such product candidates, 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 three Phase II clinical trials of Capesaris®, which were discontinued earlier in the year, we observed venous thromboembolic events, or blood clots, in subjects treated with Capesaris® at the doses being studied in the trials (1000 mg and higher per day) and reported those events to the FDA. There were two deaths in subjects treated with Capesaris® and two deaths in subjects treated with Lupron Depot®. In February 2012, the FDA placed all of our then ongoing clinical studies of Capesaris® on full clinical hold and we suspended further enrollment into these studies and notified clinical sites to discontinue treatment of subjects with Capesaris®. In May 2012, the FDA notified us that it had removed the full clinical hold on Capesaris®. In the third quarter of 2012, we initiated a Phase II clinical trial to evaluate Capesaris®, at doses lower than those which were previously being tested in our discontinued Phase II clinical trials, as secondary hormonal therapy in men with metastatic castration resistant prostate cancer. Although our current Phase II clinical trial is evaluating Capesaris® at doses lower than those which were previously being tested in our discontinued Phase II clinical trials, we cannot be confident that we will not observe an unacceptable incidence of venous thromboembolic events or other adverse events in the current Phase II clinical trial. If an unacceptable incidence of venous thromboembolic events or other adverse events are observed in our current Phase II clinical trial of Capesaris®, we may be required to abandon our development of Capesaris®, in which case, we would not receive any return on our investment in that product candidate.

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In our Phase II clinical trials for enobosarm for the treatment of muscle wasting in patients with cancer and healthy older males and postmenopausal females, we observed mild elevations of hepatic enzymes, which in certain circumstances may lead to liver failure, in a few patients in both the placebo and enobosarm treated groups. Reductions in high-density lipoproteins have also been observed in subjects treated with enobosarm. Lower levels of high-density lipoproteins could lead to increased risk of adverse cardiovascular events.

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

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Any collaborative arrangements that we establish in the future may not be successful or we may otherwise not realize the anticipated benefits from these collaborations. In addition, any future collaboration arrangements may place the development and commercialization of our product candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

We have in the past established and intend to continue to establish collaborations with third parties to develop and commercialize some of our current and future product candidates, and these collaborations may not be successful or we may otherwise not realize the anticipated benefits from these collaborations. For example, in March 2011, we and Ipsen Biopharm Limited, or Ipsen, mutually agreed to terminate our collaboration for the development and commercialization of our toremifene-based product candidate, and, as a result, we will not receive any additional milestone payments from Ipsen on account of our collaboration with Ipsen. As of the date of this report, we have no ongoing collaborations for the development and commercialization of our product candidates. In the future, we may not be able to locate third-party collaborators to develop and market our product candidates, and we may lack the capital and resources necessary to develop our product candidates alone.

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

- we may not be able to control the amount and timing of resources that our potential future collaborators may devote to our product candidates;
- potential future collaborations may experience financial difficulties or changes in business focus;
- we may be required to relinquish important rights such as marketing and distribution rights;
- should a collaborator fail to develop or commercialize one of our compounds or product candidates, we may not receive any future milestone payments and will not receive any royalties for the compound or product candidate;
- business combinations or significant changes in a collaborator s business strategy may also adversely affect a collaborator s willingness or ability to complete its obligations under any arrangement;
- under certain circumstances, a collaborator could move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which could delay the development and may increase the cost of developing our product candidates.

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

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

We rely on third-party vendors for the manufacture of enobosarm drug substance. If our supply of enobosarm becomes unusable or if the contract manufacturers that we are currently utilizing to meet our supply needs for enobosarm or any future SARM product candidates prove incapable or unwilling to continue to meet our supply needs, we could experience a delay in conducting any additional clinical trials of enobosarm or any future SARM product candidates. In addition, we rely on third-party contractors for the manufacture of Capesaris® drug substance. We may not be able to maintain or renew our existing or any other third-party manufacturing arrangements on acceptable terms, if at

all. If our suppliers fail to meet our requirements for Capesaris®, enobosarm or any future product candidates for any reason, we would be required to obtain alternate suppliers. Any inability to obtain alternate suppliers, including an inability to obtain approval from the FDA of an alternate supplier, would delay or prevent the clinical development and commercialization of these product candidates.

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

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

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

If we are not able to obtain adequate supplies of our product candidates, it will be more difficult for us to develop our product candidates and compete effectively. Our product candidates and any products that we and/or our potential future collaborators may develop may compete with other product candidates and products for access to manufacturing facilities.

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

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

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

Risks Related to Our Intellectual Property

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

We have licensed intellectual property rights and technology from UTRF used in a substantial part of our business. This license agreement, under which we were granted rights to SARM compounds and technologies, may be terminated by UTRF if we are in breach of our obligations under, or fail to perform any terms of, the agreement and fail to cure that breach. If this agreement is terminated, then we may lose our rights to utilize the SARM technology and intellectual property covered by that agreement to market, distribute and sell licensed products, including enobosarm, which may prevent us from continuing a substantial part of our business and may result in a serious adverse effect on our financial condition, results of operations and any prospects for growth.

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

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Our commercial success will depend in part on obtaining and maintaining patent and trade secret protection for our product candidates, as well as the methods for treating patients in the product indications using these product candidates. We will be able to protect our product candidates and the methods for treating patients in the product indications using these product candidates from unauthorized use by third parties only to the extent that we or our exclusive licensors own or control such valid and enforceable patents or trade secrets.

Our rights to certain patents and patent applications relating to SARM compounds that we have licensed from UTRF are subject to the terms of UTRF s inter-institutional agreements with The Ohio State University, or OSU, and our rights to future related improvements in some instances are subject to UTRF s exercise of exclusive options under its agreements with OSU for such improvements.

Even if our product candidates and the methods for treating patients for prescribed indications using these product candidates are covered by valid and enforceable patents and have claims with sufficient scope, disclosure and support in the specification, the patents will provide protection only for a limited amount of time. Our and our licensors ability to obtain patents can be highly uncertain and involve complex and in some cases unsettled legal issues and factual questions. Furthermore, different countries have different procedures for obtaining patents, and patents issued in different countries provide different degrees of protection against the use of a patented invention by others. Therefore, if the issuance to us or our licensors, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims in, or the written description or enablement in, a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent defense and enforcement. The regulations and procedures to govern administration of the Leahy-Smith Act, and the substantive and procedural changes to patent law associated with the Leahy-Smith Act are being implemented in stages, beginning from September 16, 2011, and continuing through March 16, 2013. For example, the Leahy-Smith Act has introduced procedures making it easier for third-parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. In addition, the Leahy-Smith Act will change the United States from a first-to-invent jurisdiction to a first-inventor-to-file jurisdiction and will change the definition of what constitutes prior art for an application. Finally, the Leahy-Smith Act contains new statutory provisions that still require the Patent Office to issue new regulations for their implementation and it may take the courts years to interpret the provisions of the new statute. Accordingly, it is too early to determine what effect or impact the Leahy-Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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

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

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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/or might have been the first to file patent applications for these inventions. In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us or our licensors, which may later result in issued patents that cover the production, manufacture, synthesis, commercialization, formulation or use of our product candidates. In addition, the production, manufacture, synthesis, commercialization, formulation or use of our product candidates may infringe existing patents of which we are not aware. Defending ourselves against third-party claims, including litigation in particular, would be costly and time consuming and would divert management s attention from our business, which could lead to delays in our development or commercialization efforts. If third parties are successful in their claims, we might have to pay substantial damages or take other actions that are adverse to our business.

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

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

Risks Related to Regulatory Approval of Our Product Candidates

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

Our product candidates and the activities associated with their development and commercialization are subject to comprehensive regulation by the FDA, other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent us or any potential future collaborator from commercializing the product candidate. We have not received regulatory approval to market any of our product candidates in any jurisdiction, and we do not expect to obtain FDA or any other regulatory approvals to market any of our product candidates in the near future, if at all. The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved.

Changes in the regulatory approval policy during the development period, changes in or the enactment of additional regulations or statutes, or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. For example, on July 9, 2012 Congress enacted the Food and Drug Administration Safety and Innovation Act (FDASIA) that, among other things, reauthorizes the Prescription Drug User Fee Act, or PDUFA, for an additional five years. FDASIA incorporates new FDA performance goals that effectively extend by two months the time period in which the FDA is expected to review and approve certain NDAs. Although the FDA has stated that it expects to meet PDUFA s updated timing goals, it has in the past provided its managers discretion to miss them due to heightened agency workload or understaffing in the review divisions; accordingly, it remains unclear whether and to what extent the FDA will adhere to PDUFA timing goals in the future. If the FDA were to miss a PDUFA timing goal for one of our product candidates, the development and commercialization of the product candidate could be delayed. In addition, the Food and Drug Administration Amendments Act of 2007, or FDAAA, which was enacted in September 2007, expands the FDA s authority to regulate drugs throughout the product life cycle, including enhanced authority to require post-approval studies and clinical trials. Other proposals have been made to impose additional requirements on drug approvals, further expand post-approval requirements and restrict sales and promotional activities. This legislation, and the additional proposals if enacted, may make it more difficult or burdensome for us or our potential future collaborators to obtain approval of our product candidates. Even if the FDA approves a product candidate, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product, and may impose ongoing requirements for post-approval

studies, including additional research and development and clinical trials. The approval may also impose risk evaluation mitigation strategies, or REMS, on a product if the FDA believes there is a reason to monitor the safety of the drug in the market place. REMS may include requirements for additional training for health care professionals, safety communication efforts and limits on channels of distribution, among other things. The sponsor would be required to evaluate and monitor the various REMS activities and adjust them if need be. The FDA also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

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Furthermore, the approval procedure and the time required to obtain approval varies among countries and can involve additional testing beyond that required by the FDA. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions.

The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. For example, in October 2009, we received a Complete Response Letter from the FDA regarding our NDA for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT notifying us that the FDA would not approve our NDA as a result of certain clinical deficiencies identified in the Complete Response Letter. We have since discontinued our toremifene 80 mg development program, as well as our other toremifene-based products and terminated our license and supply agreement with Orion for toremifene products. While we have met with the FDA to discuss the development program and required endpoints to obtain approval of enobosarm, there can be no assurance that the FDA will ultimately determine that data from our current pivotal Phase III clinical trials of enobosarm will be sufficient for approval of this product candidate. Additionally, there can be no assurance that the FDA will determine that the data from our ongoing clinical trial or future clinical trials of Capesaris® will be sufficient for approval of this product candidate in any indication. For example, we may observe an unacceptable incidence of adverse events in our ongoing, planned or potential future clinical trials of enobosarm or Capesaris®, which could require us to abandon the development of the affected product candidate.

In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent regulatory approval of a product candidate. Even if we submit an application to the FDA for marketing approval of a product candidate, it may not result in marketing approval from the FDA.

We do not expect to receive regulatory approval for the commercial sale of any of our product candidates that are in development in the near future, if at all. The inability to obtain FDA approval or approval from comparable authorities in other countries for our product candidates would prevent us or any potential future collaborators from commercializing these product candidates in the United States or other countries. See the section entitled Business Government Regulation under Part 1, Item 1 of our Annual Report on Form 10-K, filed with the SEC on March 2, 2012, for additional information regarding risks associated with marketing approval, as well as risks related to potential post-approval requirements.

Risks Related to Commercialization

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

Any products that we and/or any potential future collaborators may develop may not gain market acceptance among physicians, patients, health care payors and the medical community. If these products do not achieve an adequate level of acceptance, we may not generate material product revenues or receive royalties to the extent we currently anticipate, and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

efficacy and safety results in clinical trials;

the prevalence and severity of any side effects;

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potential advantages over alternative treatments;

whether the products we commercialize remain a preferred course of treatment;

the ability to offer our product candidates for sale at competitive prices;

relative convenience and ease of administration;

the strength of marketing and distribution support; and

sufficient third-party coverage or reimbursement.

If we are unable to establish 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. In the event one of our product candidates is approved, we will need to establish sales and marketing capabilities or establish and maintain agreements with third parties to market and sell our product candidates. We may be unable to build our own sales and marketing capabilities, and there are risks involved with entering into arrangements with third parties to perform these services, which could delay the commercialization of any of our product candidates if approved for commercial sale. In addition, to the extent that we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues are likely to be lower than if we market and sell any products that we develop ourselves.

If we and/or any potential future collaborators are unable to obtain reimbursement or experience a reduction in reimbursement from third-party payors for products we sell, our revenues and prospects for profitability will suffer.*

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

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 established comprehensive Medicare coverage and reimbursement of prescription drugs under Medicare Part D. Product candidates currently in development as oral drug products capable of self-administration by patients would likely be covered by Medicare Part D (if covered by Medicare at all). The prescription drug program established by this legislation may have the effect of reducing the prices that we or any potential future collaborators are able to charge for products we and/or any potential future collaborators develop and sell through the program. In March 2010, the United States Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act. This health care reform legislation will increase the number of individuals who receive health insurance coverage and will close a gap in drug coverage under Medicare Part D as established in 2003. However, the legislation also implements cost containment measures that could adversely affect our revenues. These measures include increased drug rebates under Medicaid for brand name prescription drugs and extension of these rebates to Medicaid managed care, each of which would reduce the amount of net reimbursement for any products that we and/or any potential future collaborators may develop and sell. The legislation also extended 340B discounted pricing on outpatient drugs to children s hospitals, critical access hospitals, and rural health centers, which has reduced the amount of reimbursement received for drugs purchased by these new 340B-covered entities.

Additional provisions of the health care reform legislation may negatively affect our revenues and prospects for profitability in the future. Along with other pharmaceutical manufacturers and importers of brand name prescription drugs, we would be assessed a fee based on our proportionate share of sales of brand name prescription drugs to certain government programs, including Medicare and Medicaid, made in the preceding year if such sales exceed a defined threshold. As part of the health care reform legislation s provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the donut hole), as of January 1, 2011, we would be required to provide a 50% discount on brand name prescription drugs sold to beneficiaries who fall within the donut hole.

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The health care reform legislation has been subject to political and judicial challenge. In 2012, the Supreme Court considered the constitutionality of certain provisions of the law. The court upheld as constitutional the mandate for individuals to obtain health insurance but held that the provision allowing the federal government to withhold certain Medicaid funds to states that do not expand state Medicaid programs was unconstitutional. The impact of the court s ruling remains uncertain. Political and judicial challenges to the law may continue in the wake of the court s ruling.

Economic pressure on state budgets may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for drugs. State Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization for use of drugs where supplemental rebates are not provided. Private health insurers and managed care plans are likely to continue challenging the prices charged for medical products and services, and many of these third-party payors may limit reimbursement for newly-approved health care products. In particular, third-party payors may limit the indications for which they will reimburse patients who use any products that we and/or any potential future collaborators may develop or sell. These cost-control initiatives could decrease the price we might establish for products that we or any potential future collaborators may develop or sell, which would result in lower product revenues or royalties payable to us.

Similar cost containment initiatives exist in countries outside of the United States, particularly in the countries of the European Union, where the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to twelve months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or any potential future collaborators may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our or a potential future collaborators commercialization efforts. Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly-approved health care products. In particular, third-party payors may limit the indications for which they will reimburse patients who use any products that we and/or any potential future collaborators may develop or sell. Cost-control initiatives could decrease the price we might establish for products that we or any potential future collaborators may develop or sell, which would result in lower product revenues or royalties payable to us.

Another development that could affect the pricing of drugs would be if the Secretary of Health and Human Services allowed drug reimportation into the United States. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 gives discretion to the Secretary of Health and Human Services to allow drug reimportation into the United States under some circumstances from foreign countries, including from countries where the drugs are sold at a lower price than in the United States. If the circumstances were met and the Secretary exercised the discretion to allow for the direct reimportation of drugs, it could decrease the price we or any potential future collaborators receive for any products that we and/or any potential future collaborators may develop, negatively affecting our revenues and prospects for profitability.

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

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting health care reform, as evidenced by the enactment in the United States of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act in 2010. It is likely that federal and state legislatures within the United States and foreign governments will continue to consider changes to existing health care legislation. These changes adopted by governments may adversely impact our business by lowering the price of health care products in the United States and elsewhere.

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

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of any products that we may develop.*

We face an inherent risk of product liability exposure related to our prior commercial sales of FARESTON® and the testing of our product candidates in human clinical trials, and we 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:

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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 any commercial products up to a $20 million annual aggregate limit. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost, and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

If our competitors are better able to develop and market products than any products that we and/or any potential future collaborators may develop, our commercial opportunity will be reduced or eliminated.*

We face competition from commercial pharmaceutical and biotechnology enterprises, as well as from academic institutions, government agencies and private and public research institutions. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we and/or any potential future collaborators may develop. Competition could result in reduced sales and pricing pressure on our product candidates, if approved, which in turn would reduce our ability to generate meaningful revenue and have a negative impact on our results of operations. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before us and impair any ability to commercialize our product candidates.

Various products are currently marketed or used off-label for some of the diseases and conditions that we are targeting in our pipeline, and a number of companies are or may be developing new treatments. These product uses, as well as promotional efforts by competitors and/or clinical trial results of competitive products, could significantly diminish any ability to market and sell any products that we and/or any potential future collaborators may develop.

With respect to our SARM program, there are other SARM product candidates in development that may compete with enobosarm and any future SARM product candidates, if approved for commercial sale, including SARMs in development from Ligand Pharmaceuticals Inc., GlaxoSmithKline, and Bristol-Myers Squibb Company. Pfizer Inc., Eli Lilly & Co. and Amgen have myostatin inhibitors in development that may compete with enobosarm if approved for commercial sale. In addition, Cytokinetics, Inc. is developing a troponin activator with a muscle specific mechanism in Phase II studies, with a focus on neurological muscle diseases (amyotrophic lateral sclerosis and myasthenia gravis) and Novartis AG is developing a human monoclonal antibody for various muscle indications. Moreover, there are other categories of drugs in development, including ghrelin receptor agonists, growth hormone, secretagogues, inflammatory modulators and other agents, that may have some muscle activity. Helsinn Group is developing anamorelin, a ghrelin receptor agonist, in Phase III clinical trials for treatment of cancer cachexia in patients with non-small cell lung cancer. Appetite stimulants such as Megace® (megestrol acetate) and dronabinol are used off-label for the treatment of weight loss and the treatment of loss of appetite in patients with cancer.

We are developing Capesaris® for secondary hormonal therapy in men with castration resistant prostate cancer, and, potentially, as a primary treatment for advanced prostate cancer used in combination with androgen deprivation therapy. There are various products approved or under clinical development to treat men with advanced prostate cancer who have castration resistant prostate cancer which may compete with Capesaris®. Dendreon Corporation markets and sells Provenge®, an autologous cellular immunotherapy, for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer. Zytiga®, sold by Johnson & Johnson, has been approved for the treatment of

metastatic castration resistant prostate cancer in patients who have received prior chemotherapy. Medivation, Inc. has received approval for Xtandi®, an oral androgen receptor antagonist, for the treatment of metastatic castration-resistant prostate cancer in men previously treated with docetaxel. Both Medivation, Inc. and Johnson & Johnson continue to develop Xtandi® and Zytiga® for men with castration resistant prostate cancer prior to receiving chemotherapy. Millennium: The Takeda Oncology Company is developing TAK-700 for the treatment of men with metastatic castrate resistant prostate cancer prior to chemotherapy and post docetaxel. Capesaris® is being developed as a treatment for this same patient population prior to the initiation of chemotherapy.

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

Risks Related to Employees and Growth

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

Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. If we are not able to attract and keep senior management and key scientific personnel, particularly Dr. Mitchell S. Steiner, we may not be able to successfully develop or commercialize our product candidates. All of our employees are at-will employees and can terminate their employment at any time. We do not carry key person insurance covering members of senior management, other than $22.5 million of insurance covering Dr. Steiner.

In December 2009, we announced a reduction of approximately 26% of our workforce in order to reduce our operating expenses in connection with the receipt of the Complete Response Letter regarding our NDA for toremifene 80 mg. We also announced a reduction of approximately 15% of our workforce in June 2011 in connection with our decision to discontinue the development of toremifene 80 mg and toremifene 20 mg. These and any future workforce reductions may negatively affect our ability to retain or attract talented employees.

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

In order to commercialize our product candidates in the future, we may need to hire experienced sales and marketing personnel to sell and market those product candidates we decide to commercialize, and we will need to expand the number of our managerial, operational, financial and other employees to support commercialization. Competition exists for qualified personnel in the biotechnology field.

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

Risks Related to Our Common Stock

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

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

- delays in the initiation, enrollment or completion of our ongoing and planned clinical trials of enobosarm and Capesaris®, or negative or inconclusive results reported in any of our ongoing and planned clinical trials of enobosarm and Capesaris®;

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reports of unacceptable incidences of adverse events observed in any of our ongoing and planned clinical trials of enobosarm and Capesaris®;

our ability to enter into new collaborative arrangements with respect to our product candidates;

the terms and timing of any future collaborative, licensing or other arrangements that we may establish;

our ability to raise additional capital to carry through with our clinical development plans and current and future operations and the terms of any related financing arrangements;

the timing of achievement of, or failure to achieve, our and any potential future collaborators clinical, regulatory and other milestones, such as the commencement of clinical development, the completion of a clinical trial or the receipt of regulatory approval;

announcement of FDA approval or non-approval of our product candidates or delays in or adverse events during the FDA review process;

actions taken by regulatory agencies with respect to our product candidates or products, our clinical trials or our sales and marketing activities, including regulatory actions requiring or leading to restrictions, limitations and/or warnings in the label of an approved product candidate;

the commercial success of any product approved by the FDA or its foreign counterparts;

introductions or announcements of technological innovations or new products by us, our potential future collaborators, or our competitors, and the timing of these introductions or announcements;

market conditions for equity investments in general, or the biotechnology or pharmaceutical industries in particular;

regulatory developments in the United States and foreign countries;

changes in the structure or reimbursement policies of health care payment systems;

any intellectual property infringement lawsuit involving us;

actual or anticipated fluctuations in our results of operations;

changes in financial estimates or recommendations by securities analysts;

hedging or arbitrage trading activity that may develop regarding our common stock;

sales of large blocks of our common stock;

sales of our common stock by our executive officers, directors and significant stockholders;

changes in accounting principles; and

the loss of any of our key scientific or management personnel.

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

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

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

As of September 30, 2012, our executive officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 63.3% of our outstanding common stock, and our executive officers and directors alone beneficially owned approximately 38.2% of our outstanding common stock. As a result, these stockholders, acting together, may or will have the ability to control all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders.

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

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

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

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

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

For the 12-month period ended September 30, 2012, the average daily trading volume of our common stock on The NASDAQ Global Market was 316,408 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, 2012, we had 62,816,924 shares of common stock outstanding.

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

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ITEM 5. OTHER INFORMATION

On September 24, 2012, we exercised our option to extend, for a term of two years, the term of that certain sublease agreement, dated October 1, 2009 (the Lease), with the University of Tennessee Research Foundation (successor-in-interest to TriStar Enterprises, Inc.) (Landlord) for the lease of approximately 53,000 square feet of laboratory and office space located at 3 North Dunlap Street, Memphis, TN (the Premises). As a result of exercise of our extension option, the term of the Lease was extended for a period of 24 months expiring on December 31, 2014, unless sooner terminated in accordance with the terms of the Lease. The monthly base rent under the Lease is equal to 98% of the Landlord s actual operating costs in owning, maintaining, operating and repairing the Premises and the building in which the Premises are located (the Landlord Operating Costs). As a result of entering into a Memorandum of Understanding (MOU) with the Landlord concerning the Lease dated April 14, 2011, we agreed to reduce the amount of square feet which we occupy to 31,000 square feet in exchange for a reduction in our monthly base rent to 50% of the Landlord Operating Costs from May 1, 2011 until April 30, 2013. From May 1, 2013 through the end of the extended lease term, we will again lease 53,000 square feet of laboratory and office space at the Premises and our monthly base rent will revert back to 98% of the Landlord Operating Costs unless the parties decide to enter into a new MOU or extend the existing one. Under the terms of the Lease, we are also responsible for maintaining certain insurance policies during the remaining term of the Lease. In the event of a default of certain of our obligations under the Lease, the Landlord would have right to terminate the Lease. The foregoing is only a brief description of the material terms of the Lease and does not purport to be a complete statement of the rights and obligations of the parties under the Lease, and is qualified in its entirety by reference to (i) the Lease that is filed as Exhibit 10.55 to our Annual Report on Form 10-K for the year ended December 31, 2009 and filed with the SEC on March 15, 2010 and (ii) that certain Memorandum of Understanding with the Landlord concerning the Lease dated April 14, 2011 that is filed as an Exhibit 10.59 to our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2011 and filed with the SEC on August 9, 2011.

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 8, 2012

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

Date: November 8, 2012

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

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EXHIBIT INDEX

Number	Description
2.1	Asset Purchase Agreement, dated as of September 28, 2012, by and between the Registrant and Strakan International S.á r.l.[1]
3.1	Restated Certificate of Incorporation of GTx, Inc.[2]
3.2	Certificate of Amendment of Restated Certificate of Incorporation of GTx, Inc. [3]
3.3	Amended and Restated Bylaws of GTx, Inc.[4]
4.1	Reference is made to Exhibits 3.1, 3.2 and 3.3
4.2	Specimen of Common Stock Certificate[5]
4.3	Amended and Restated Registration Rights Agreement between Registrant and Oracle Partners, L.P. dated August 7, 2003[5]
4.4	Amended and Restated Registration Rights Agreement between Registrant and J. R. Hyde, III dated August 7, 2003[5]
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[6]
4.6	Consent, Waiver and Amendment between Registrant and J. R. Hyde, III and Pittco Associates, L.P. dated December 3, 2007[6]
10.55	Sublease Agreement dated October 1, 2009 between the Registrant and the University of Tennessee Research Foundation[7]
10.59	Memorandum of Understanding dated April 14, 2011 between the Registrant and the University of Tennessee Research Foundation[8]
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) [9]
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) [9]
101.INS*	XBRL Instance Document[10]
101.SCH*	XBRL Taxonomy Extension Schema Document[10]
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document[10]
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document[10]
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document[10]
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document[10]

Confidential treatment has been requested with respect to certain portions of this exhibit. This exhibit omits the information subject to this confidentiality request. Omitted portions have been filed separately with the SEC.

* Filed herewith.

(1) 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 October 3, 2012, and incorporated herein by reference.

(2) 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.

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

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

(5) 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.

(6) 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.

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(7) Filed as the like numbered Exhibit to the Registrant s Annual Report on Form 10-K (File No. 000-50549), filed with the SEC on March 15, 2010, and incorporated herein by reference.

(8) Filed as the like numbered Exhibit to the Registrant s Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on August 9, 2011, and incorporated herein by reference.

(9) 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.

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