GTX INC /DE/
Form 10-Q
May 12, 2008

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2008

OR

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

For the transition period from _____ to _____

Commission file number: 000-50549

GTx, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**62-1715807**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

3 N. Dunlap Street
Van Vleet Building
Memphis, Tennessee 38163
(Address of principal executive offices, including 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 o

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

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

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

As of May 9, 2008, 36,239,096 shares of the registrant s Common Stock were outstanding.

GTx, INC.
FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2008
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PART I: FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2008 (unaudited)	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 128,313	$ 100,178
Short-term investments	6,389	9,810
Accounts receivable, net	98	117
Inventory	46	78
Receivable from collaboration partners	2,364	40,719
Prepaid expenses and other current assets	1,945	1,362
Total current assets	139,155	152,264
Property and equipment, net	2,787	2,308
Intangible assets, net	4,346	4,430
Other assets	788	728
Total assets	$ 147,076	$ 159,730
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 3,650	$ 1,614
Accrued expenses	6,678	6,784
Deferred revenue current portion	10,934	10,934
Total current liabilities	21,262	19,332
Deferred revenue, less current portion	58,512	61,245
Other long term liabilities	216	236
Commitments and contingencies		
Stockholders equity:		
Common stock, $0.001 par value: 60,000,000 shares authorized; 36,236,263 shares issued and outstanding at March 31, 2008 and 36,216,263 shares issued and outstanding at December 31, 2007	36	36
Additional paid-in capital	349,931	349,019
Accumulated deficit	(282,881)	(270,138)
Total stockholders equity	67,086	78,917
Total liabilities and stockholders equity	$ 147,076	$ 159,730

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 March 31,	
	2008	**2007**
Revenues:		
Product sales, net	$ 257	$ 192
Collaboration revenue	4,216	1,463
Total revenues	4,473	1,655
Costs and expenses:		
Cost of product sales	135	109
Research and development expenses	13,999	8,007
General and administrative expenses	4,250	3,117
Total costs and expenses	18,384	11,233
Loss from operations	(13,911)	(9,578)
Interest income	1,168	1,454
Net loss	$ (12,743)	$ (8,124)
Net loss per share:		
Basic and diluted	$ (0.35)	$ (0.23)
Weighted average shares used in computing net loss per share:		
Basic and diluted	36,224,834	34,842,160

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)

	Three Months Ended March 31,	
	2008	**2007**
Cash flows from operating activities:		
Net loss	$ (12,743)	$ (8,124)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	302	276
Share-based compensation	730	469
Directors deferred compensation	51	38
Deferred revenue amortization	(2,733)	(1,463)
Foreign currency transaction gain	(218)	(31)
Changes in assets and liabilities:		
Short-term investments	3,421	
Accounts receivable, net	19	(7)
Inventory	32	27
Receivable from collaboration partners	38,509	
Prepaid expenses and other assets	(579)	(873)
Accounts payable	2,036	412
Accrued expenses and other long term liability	(125)	925
Net cash provided by (used in) operating activities	28,702	(8,351)
Cash flows from investing activities:		
Purchase of property and equipment	(697)	(93)
Purchase of intangible assets		(64)
Net cash used in investing activities	(697)	(157)
Cash flows from financing activities:		
Proceeds from exercise of employee stock options	131	390
Payments on capital lease obligation	(1)	(1)
Net cash provided by financing activities	130	389
Net increase (decrease) in cash and cash equivalents	28,135	(8,119)
Cash and cash equivalents, beginning of period	100,178	119,550
Cash and cash equivalents, end of period	$ 128,313	$ 111,431

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

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

1. Business and Basis of Presentation

Business

GTx, Inc. (GTx or the Company), a Delaware corporation incorporated on September 24, 1997 and headquartered in Memphis, Tennessee, is a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules that selectively target hormone pathways to treat cancer, osteoporosis and bone loss, muscle wasting and other serious medical conditions. GTx operates in one business segment.

GTx is developing ACAPODENE® (toremifene citrate), a selective estrogen receptor modulator (SERM) in two separate clinical programs in men: first, a completed pivotal Phase III clinical trial for the treatment of multiple serious side effects of androgen deprivation therapy (ADT) for advanced prostate cancer and second, an ongoing pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia (high grade PIN). GTx has licensed to Ipsen Limited (Ipsen) exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein, and the Commonwealth of Independent States (collectively, the European Territory) to develop and commercialize toremifene in all indications which the Company has licensed from Orion Corporation (Orion). In December 2007, the Company and Merck and Co., Inc. (Merck) entered into a collaboration to discover and develop selective androgen receptor modulators (SARMs), a new class of drugs with the potential to treat age-related muscle loss (a condition generally defined as sarcopenia) as well as other musculoskeletal conditions. The Merck-GTx SARM clinical development program is currently focused on sarcopenia and cancer cachexia (muscle wasting). The Company and Merck are conducting several Phase I and Phase II clinical trials evaluating multiple SARM product candidates including Ostarine (now designated as MK-2866) for sarcopenia. Ostarine is also in a Phase II clinical trial for muscle wasting (cachexia) in patients with cancer.

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, 2007. Operating results for the three months ended March 31, 2008 are not necessarily indicative of the results that may be expected for the entire fiscal year ending December 31, 2008.

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

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GTx, Inc.
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the condensed financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual amounts and results could differ from those estimates.

Revenue Recognition

The Company recognizes net product sales revenue from the sale of FARESTON® less deductions for estimated sales discounts and sales returns. Revenue from product sales is recognized when the goods are shipped and title and risk of loss pass to the customer and the other criteria outlined in Staff Accounting Bulletin (SAB) No. 101, *Revenue Recognition in Financial Statement*s, as amended by SAB No. 104 (together, SAB No. 104) and Statement of Financial Accounting Standards (SFAS) No. 48, *Revenue Recognition When Right of Return Exists,* are satisfied. The Company accounts for rebates to certain governmental agencies as a reduction of product sales. The Company allows customers to return product within a specified time period prior to and subsequent to the product s labeled expiration date. The Company estimates its accrual for product returns, which is recorded as a reduction of product sales, based on factors which include historical product returns and estimated product in the distribution channel which is expected to exceed its expiration date. At March 31, 2008 and December 31, 2007, the Company s accrual for product returns was $243 and $324, respectively. If actual future results are different than the Company s estimates, the Company may need to adjust its estimated accrual for product returns, which could have a material effect on earnings in the period of the adjustment.

Collaboration revenue consists of non-refundable upfront payments, license fees and milestone payments associated with the Company s collaboration and license agreements discussed in Note 4. The Company recognizes this revenue in accordance with SAB No. 104, Emerging Issues Task Force (EITF) Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21) and EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent* (EITF 99-19). Accordingly, revenues from licensing agreements are recognized based on the performance requirements of the agreement. The Company has analyzed its agreements with multiple element arrangements to determine whether the deliverables under the agreement, including license and performance obligations such as joint steering committee participation and research and development activities, can be separated or whether all of the deliverables must be accounted for as a single unit of accounting in accordance with EITF 00-21. For these arrangements, the Company was not able to identify evidence of fair value for the undelivered elements and therefore recognizes any consideration for a single unit of accounting in the same manner as revenue is recognized for the final deliverable, which is ratable over the performance period. The performance period was estimated at the inception of each agreement and is reevaluated at each reporting period. Cost reimbursements for research and development activities are recognized as collaboration revenue if the provisions of EITF 99-19 are met, the amounts are determinable and collection of the related receivable is reasonably assured. Revenues from milestone payments for which the Company has no continuing performance obligations are recognized upon achievement of the performance milestone, as defined in the related agreement, provided the milestone is substantive and a culmination of the earnings process has occurred. Performance obligations typically consist of significant milestones in the development life cycle of the related products and technology, such as initiation of clinical trials, achievement of specified clinical trial end points, filing for approval with regulatory agencies and approvals by regulatory agencies.

Short-term Investments

Short-term investments consist of an investment in Bank of America Corporation s Columbia Strategic Cash Portfolio (the Fund). In December 2007, Columbia Management Group, LLC, the Fund s

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manager, determined that the assets of the Fund had declined in fair value and the Fund would no longer seek to maintain a net asset value (NAV) of $1.00 per share. The Fund ceased accepting orders for new shares and began an orderly distribution of Fund assets for distribution to its shareholders. At December 31, 2007 and March 31, 2008, the Fund s NAV was $0.9874 and $0.9701 per share, respectively. For the three months ended March 31, 2008, the Company recognized a loss on its investment in the Fund of approximately $120. The Company has classified this investment as trading, in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities.* Accordingly, this investment is carried at fair value and all unrealized gains and losses are included in the condensed statement of operations. The fair value of this investment was determined based on quoted market prices and other observable market data, or Level 1 and Level 2 inputs as defined by SFAS No. 157, *Fair Value Measurements* (SFAS No. 157).

Recent Accounting Pronouncements

Effective January 1, 2008, the Company adopted SFAS No. 157, which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosure about fair value measurements. The fair value of the Company s short-term investments is subject to the fair value measurement criteria in SFAS No. 157. Adoption of SFAS No. 157 did not have a significant impact on the Company s financial position or results of operations (see *Short-term Investments* in Note 1).

In November 2007, the Emerging Issues Task Force issued EITF Issue No. 07-01, *Accounting for Collaborative Arrangements* (EITF 07-01). EITF 07-01 concludes that the equity method of accounting cannot be applied to collaborative arrangement activities that are not conducted within a separate legal entity. Instead, the revenues and costs incurred with third parties in connection with the collaborative arrangement should be presented gross or net by the collaborators based on the criteria in EITF 99-19, and other applicable accounting literature. EITF 07-01 is effective for years beginning after December 15, 2008. The Company does not expect the adoption of EITF 07-01 will have a material impact on its financial position or results of operations.

2. Share-Based Compensation

Effective January 1, 2006, the Company adopted SFAS No.123(R), *Share-Based Payment,* and began recognizing compensation expense for its share-based payments based on the fair value of the awards. Share-based payments include stock option grants under the Company s stock option plans and deferred compensation arrangements for the Company s directors. 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, 2007.

Total share-based compensation expense for the three months ended March 31, 2008 was $781, of which $345 and $436 were recorded in the condensed statement of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the three months ended March 31, 2007 was $507, of which $234 and $273 were recorded in the condensed statement of operations as research and development expenses and general and administrative expenses, respectively. Share-based compensation expense for the three months ended March 31, 2008 and 2007 included share-based compensation expense related to deferred compensation arrangements for the Company s directors of $51 and $38, respectively.

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The Company uses the Black-Scholes-Merton option pricing valuation model to value stock options. The expected life is determined by calculating the average of the vesting term and the contractual term of the options, as allowed by SAB 110. 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 Company estimates the forfeiture rate at the time of valuation and reduces expense ratably over the vesting period. The fair value of options granted was estimated using the following assumptions for the periods presented:

	Three Months Ended March 31,	
	2008	**2007**
Expected price volatility	50.5%	50.9%
Risk-free interest rate	3.7%	4.7%
Weighted average expected life in years	7.0 years	7.0 years

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

	Number of Shares	**Weighted Average Exercise Price Per Share**
Options outstanding at December 31, 2007	1,879,652	$ 11.27
Options granted	689,500	14.25
Options forfeited	(12,832)	12.80
Options exercised	(20,000)	6.55
Options outstanding at March 31, 2008	2,536,320	12.11

3. Basic and Diluted Net Loss Per Share

The Company computed net loss per share according to SFAS No. 128, *Earnings per Share,* which requires disclosure of basic and diluted earnings (loss) per share.

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

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

	Three Months Ended March 31,	
	2008	**2007**
Basic and diluted net loss per share		
Numerator:		
Net loss	$ (12,743)	$ (8,124)
Denominator (weighted average shares):		
Common stock outstanding at beginning of period	36,216,263	34,822,362
Exercise of employee stock options	8,571	19,798
Weighted average shares used in computing basic and diluted net loss per share	36,224,834	34,842,160
Basic and diluted net loss per share	$ (0.35)	$ (0.23)

Weighted average options outstanding to purchase shares of common stock of 2,548,435 and 1,760,674 for the three months ended March 31, 2008 and 2007, respectively, were excluded from the calculations of diluted net loss per share as inclusion of the options would have had an anti-dilutive effect on the net loss per share for the periods.

4. Collaboration and License Agreements

Merck & Co., Inc.

On November 5, 2007, GTx and Merck entered into a global Exclusive License and Collaboration Agreement (the Merck Collaboration Agreement) governing the Company s and Merck s joint research, development and commercialization of SARM compounds and related SARM products, including SARMs currently being developed by the Company and Merck and those yet to be discovered, for all potential indications of interest. The Merck Collaboration Agreement became effective on December 18, 2007.

Under the Merck Collaboration Agreement, the Company granted Merck an exclusive worldwide license under its SARM-related patents and know-how. The Company is conducting preclinical research of SARM compounds and products, and Merck is primarily responsible for conducting and funding development and commercialization of products developed under the Merck Collaboration Agreement. Merck paid the Company an upfront licensing fee of $40,000, which was received in January 2008. In addition, Merck has agreed to pay the Company $15,000 in guaranteed cost reimbursements for research and development activities in equal annual installments over a three year period beginning on the first anniversary of the effective date of the Merck Collaboration Agreement. The Company is also eligible to receive under the Merck Collaboration Agreement up to $422,000 in future milestone payments associated with the development and regulatory approval of a lead product candidate, including Ostarine , as defined in the Merck Collaboration Agreement, if multiple indications are developed and

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receive required regulatory approvals, as well as additional milestone payments for the development and regulatory approval of other product candidates developed under the Merck Collaboration Agreement. Merck has also agreed to pay the Company tiered royalties on net sales of products that may be developed under the Merck Collaboration Agreement. The Company is responsible for any payments owed to the University of Tennessee Research Foundation (UTRF) resulting from the Merck Collaboration Agreement.

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

The Company and Merck also entered into a Stock Purchase Agreement on November 5, 2007 pursuant to which the Company sold to Merck at the closing on December 18, 2007, 1,285,347 newly-issued shares of the Company s common stock for an aggregate purchase price of approximately $30,000, or $23.34 per share.

The Company deferred the recognition of the upfront licensing fee of $40,000 and the $10,800 in equity premium received that represents the difference between the purchase price and the closing price of the Company s common stock on the date the stock was purchased by Merck. These payments are being recognized as revenue over the period of the Company s performance obligation, which the Company estimates to be ten years. The Company recognized as collaboration revenue $1,271 for the three months ended March 31, 2008 from the amortization of the Merck deferred revenue. Cost reimbursements for research and development activities will begin to be recognized as collaboration revenue when the amounts are determinable and collection of the related receivable is reasonably assured.

Ipsen Group

In September 2006, the Company entered into a collaboration and license agreement with Ipsen pursuant to which the Company granted Ipsen exclusive rights in the European Territory to develop and commercialize toremifene in all indications which the Company has licensed from Orion, which include all indications in humans except the treatment and prevention of breast cancer outside of the United States. In accordance with the terms of the license agreement, Ipsen has agreed to pay the Company 23,000 as a license fee and expense reimbursement, of which 1,500 is to be paid in equal installments over a three year period from the date of the agreement. In October 2006, the Company received 21,500 (approximately $27,100) from Ipsen as the initial payment for the license fee and expense reimbursement. In September 2007, the Company received 500 (approximately $688) from Ipsen as the first annual installment payment. Pursuant to the agreement, the Company is also entitled to receive from Ipsen up to an aggregate of 39,000 in milestone payments depending on the successful development and launch of toremifene in certain countries of the European Territory for the high grade PIN indication, subject to certain conditions, and the ADT indication. In February 2008, the Company earned a milestone payment of 1,000 (approximately $1,482) with the achievement of the primary end point in the toremifene 80 mg ADT Phase III clinical trial. This amount was recognized as collaboration revenue for the three months ended March 31, 2008. Ipsen has agreed to be responsible for and to pay all clinical development, regulatory and launch activities to

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commercialize toremifene in the European Territory for both the high grade PIN indication and ADT indication. Ipsen has agreed to pay the Company a royalty equal to a graduating percentage of aggregate net sales of products containing toremifene which rates will be dependent on whether such sales are for the high grade PIN indication or the ADT indication. The Company will remain responsible for paying upstream royalties on toremifene to both Orion and UTRF for the PIN indication and to Orion only for the ADT indication. Ipsen will purchase the bulk drug product supply directly from Orion and is responsible for the packaging and labeling of the final product.

The Company recorded deferred revenue of $29,259 related to the Ipsen upfront license fee and expense reimbursement which is expected to be amortized into revenue on a straight-line basis over the estimated five year development period for toremifene in the European Territory. The Company recognized as collaboration revenue $1,463 for each of the three months ended March 31, 2008 and 2007 from the amortization of the Ipsen deferred revenue.

University of Tennessee Research Foundation

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

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

Under the agreements with UTRF, the Company agreed to pay to UTRF a one-time, upfront fee of $290 per agreement as consideration for entering into the agreements. The Company is also obligated to pay UTRF annual license maintenance fees and royalties on sublicense revenues and net sales of products.

5. Commitments and Contingencies

In April 2008, UTRF asserted a claim against the Company for a sublicense royalty fee of $1,500 associated with the purchase in December 2007 of 1,285,347 shares of Company common stock by Merck for $30,000, pursuant to a Stock Purchase Agreement executed between the Company and Merck in November 2007. UTRF claims that Merck s purchase of the Company s stock was conditioned on the parties also signing the Merck Collaboration Agreement granting to Merck rights in the Company s SARM technology, which the Company has licensed from UTRF, and therefore, UTRF contends, the Company is liable to UTRF for a sublicense royalty as the proceeds received by the Company from the stock sale, UTRF contends, represent payments to the Company derived from the licensing of the SARM technology under the Merck Collaboration Agreement. The Company believes that its sale of stock to

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Merck represents an equity transaction and, therefore, did not result in proceeds derived from the licensing of the SARM technology, and that there is no sublicense royalty due to UTRF as a result of the stock sale. The Company believes it has meritorious defenses against the UTRF claim and does not believe that an unfavorable outcome to the Company is probable. Accordingly, the Company has not accrued any amounts related to this matter as of March 31, 2008.

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 which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements include statements about:

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

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

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

Overview

We are a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules that selectively target hormone pathways to treat cancer, osteoporosis and bone loss, muscle wasting and other serious medical conditions. We are developing ACAPODENE® (toremifene citrate), a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: first, a completed pivotal Phase III clinical trial for the treatment of multiple serious side effects of androgen deprivation therapy, or ADT, for advanced prostate cancer, and second, an ongoing pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia, or high grade PIN. In the first quarter of 2008, we announced that the Phase III clinical trial results for toremifene 80 mg for the treatment of multiple serious side effects of ADT showed that toremifene 80 mg reduced new morphometric vertebral fractures, met other key endpoints of bone mineral density, or BMD, lipid profiles and gynecomastia, and also showed that toremifene 80 mg demonstrated a reduction in hot flashes in a subset of patients. We expect to file a New Drug Application, or NDA, for toremifene 80 mg with the U.S. Food and Drug Administration, or FDA, in the summer of 2008. We have licensed to Ipsen Limited, or Ipsen, exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States, which we refer to collectively as the European Territory, to develop and commercialize toremifene in all indications which we have licensed from Orion Corporation, or Orion, which include all indications in humans except the treatment and prevention of breast cancer outside of the United States. In December 2007, we and Merck and Co., Inc., or Merck, entered into a collaboration to discover and develop selective androgen receptor modulators, or SARMs, a new class of drugs with the potential to treat age-related muscle loss (a condition generally defined as sacropenia) as well as other musculoskeletal conditions. Sarcopenia is the loss of skeletal muscle mass resulting in reduced physical strength and ability to perform activities of daily living. The Merck-GTx SARM clinical development program is currently focused on sarcopenia and cancer cachexia (muscle wasting). We and Merck are conducting several Phase I and Phase II clinical trials evaluating multiple SARM product candidates including Ostarine (now designated as MK-2866) for sarcopenia. Ostarine is also in a Phase II clinical trial for muscle wasting (cachexia) in patients with cancer which is due to be completed in the third quarter of 2008. We and Merck are evaluating additional muscle loss indications for potential SARM clinical development.

We also have an extensive preclinical pipeline generated from our own discovery program, including GTx-758, an oral luteinizing hormone, or LH, inhibitor being developed for the treatment of advanced prostate cancer, and GTx-878, an estrogen receptor beta agonist, a new class of drugs being developed for the treatment of benign prostatic hyperplasia, or BPH. We are planning to initiate Phase I clinical testing for GTx-758 by the end of 2008 and for GTx-878 in 2009.

Our most advanced product candidate, toremifene, is being developed to treat multiple serious side effects of ADT and to prevent prostate cancer in high risk men with high grade PIN. ADT is the most common treatment for advanced, recurrent or metastatic prostate cancer, and we believe that it is currently used to treat approximately 700,000 men in the United States. ADT is hormone therapy that works by reducing testosterone and estrogen. The low estrogen levels unintentionally caused by ADT can lead to multiple serious side effects including: severe bone loss, or osteoporosis, resulting in skeletal fractures; hot flashes; lipid profile changes that lead to higher rates of cardiovascular disease; and breast pain and enlargement, or gynecomastia. There are currently no drugs approved by the FDA for the

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treatment of these multiple serious side effects of ADT. We commenced a pivotal Phase III clinical trial of toremifene 80 mg under a Special Protocol Assessment, or SPA, with the FDA for this indication in November 2003. A SPA is designed to facilitate the FDA s review and approval of drug products by allowing the agency to evaluate the proposed design and size of clinical trials that are intended to form the primary basis for determining a drug product s efficacy. The primary endpoint was new morphometric vertebral fractures measured by x-ray, and the secondary endpoints included BMD, lipid profile changes, gynecomastia and hot flashes. In the first quarter of 2008, we announced that the results of the Phase III clinical trial showed that toremifene 80 mg reduced new morphometric vertebral fractures, met other key endpoints of BMD, lipid profiles and gynecomastia and also demonstrated a reduction in hot flashes.

In January 2005, we initiated a pivotal Phase III clinical trial of toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, which is being conducted under a SPA with the FDA. We will evaluate efficacy endpoints for the clinical trial at 36 months after completion of enrollment, and we anticipate conducting a planned efficacy interim analysis after a certain number of cancer events have been recorded among study patients, which we currently expect to occur in the second quarter of 2008. If the efficacy results from the planned interim analysis achieve the statistical outcome specified in the SPA (α spend = 0.001), we plan to file a NDA with the FDA. If we are able to file a NDA based on the results of the efficacy interim analysis, we will continue to collect efficacy data and safety data during the review process to satisfy the FDA s safety requirements set forth in the SPA. If the efficacy results from the planned interim analysis do not satisfy the specified statistical requirements in the SPA, we plan to continue the clinical trial for the full 36 month period and then determine whether the trial results satisfy the efficacy endpoints required by the SPA.

In our third clinical program, Ostarine™, a SARM, is being developed to treat age-related muscle loss, as well as other musculoskeletal conditions. In December 2006, we announced that Ostarine™ met its primary endpoint in a Phase II proof of concept, double blind, randomized, placebo controlled clinical trial in 60 elderly men and 60 postmenopausal women. We initiated a Phase II randomized, double blind, placebo controlled clinical trial evaluating Ostarine for the treatment of cancer cachexia in approximately 150 patients diagnosed with non-small cell lung cancer, colorectal cancer, non-Hodgkin s lymphoma, chronic lymphocytic leukemia or breast cancer. The clinical trial is being conducted at approximately 40 clinical sites in the United States and Argentina. We expect to receive data from this trial during the third quarter of 2008. We and Merck, through our SARM collaboration, will determine the development strategy of Ostarine and other collaboration compounds.

In November 2007, we entered into a license and collaboration agreement with Merck which governs our and Merck s joint research, development and commercialization of SARM compounds and related SARM products, including SARMs currently being developed by us and Merck and those yet to be discovered, for all potential indications of interest. Under the agreement, we are conducting preclinical research of SARM compounds and products, and Merck is primarily responsible for conducting and funding development and commercialization of products developed. We received an upfront licensing fee of $40.0 million in January 2008, of which $1.9 million was due to the University of Tennessee Research Foundation, or UTRF, as sublicense royalty. Merck also agreed to pay us $15.0 million in guaranteed cost reimbursements for research and development activities in equal annual installments over a three year period beginning on the first anniversary of the effective date of the agreement. We are also eligible to receive up to $422.0 million in future milestone payments associated with the development and regulatory approval of a lead product candidate, including Ostarine , as defined in the agreement, if multiple indications are developed and receive required regulatory approvals, as well as additional milestone payments for the development and regulatory approval of other product candidates developed under the agreement, upon the achievement of such development and regulatory approval milestones and assuming the continued effectiveness of the agreement. Merck also has agreed to pay us tiered royalties on net sales of products that may be developed under the agreement. On the date the agreement became

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effective in December 2007, we issued to Merck 1,285,347 newly-issued shares of our common stock for an aggregate purchase price of approximately $30.0 million.

Our net loss for the three months ended March 31, 2008 was $12.7 million. Our net loss included FARESTON® net product sales of $257,000 and the recognition of collaboration revenue of $4.2 million. We have financed our operations and internal growth primarily through public offerings and private placements of our common stock and preferred stock, as well as proceeds from our collaborations. We expect to continue to incur net losses as we continue our clinical development and research and development activities, apply for regulatory approvals, expand our sales and marketing capabilities and grow our operations.

Research and Development

Since our inception in 1997, we have been focused on drug discovery and development programs. Research and development expenses represented 77% of our total operating expenses for the three months ended March 31, 2008. Research and development expenses include our expenses for personnel associated with our research activities, screening and identification of product candidates, formulation and synthesis activities, manufacturing, preclinical studies, toxicology studies, clinical trials, regulatory affairs, medical affairs, quality assurance activities and license and royalty fees.

We expect that research and development expenditures will continue to increase in future years due to:

- obtaining regulatory approval of toremifene 80 mg;
- the continuation of the pivotal Phase III clinical trial of toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN;
- our ongoing SARM research efforts with Merck as a part of our collaboration and the completion of the Phase II clinical trial evaluating Ostarine™ for the treatment of cancer cachexia;
- the continued preclinical development of other product candidates, including GTx-758 and GTx-878; and
- increases in research and development personnel.

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

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Product Candidates

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

Program	Product Candidate/ Proposed Indication	Development Phase	Status
		Clinical	
SERM	**Toremifene 80 mg** Multiple serious side effects of ADT	Pivotal Phase III clinical trial	Phase III clinical trial, which was conducted under a SPA, completed in February 2008; achieved primary endpoint of reduction of new morphometric vertebral fractures; NDA expected to be filed in the summer of 2008
	Toremifene 20 mg Prevention of prostate cancer in high risk men with high grade PIN	Pivotal Phase III clinical trial	Phase III clinical trial ongoing under a SPA; planned efficacy interim analysis in the second quarter of 2008
SARM	**Ostarine™** Cancer cachexia	Phase II clinical trial	Phase II proof of concept clinical trial completed in December 2006; Phase II clinical trial to treat cancer cachexia ongoing; attained enrollment goal and expect data from the trial in the third quarter of 2008
		Preclinical	
LH inhibitor	**GTx-758** Advanced prostate cancer	Preclinical	Phase I clinical testing planned to initiate by the end of 2008
Estrogen receptor beta agonist	**GTx-878** BPH	Preclinical	Phase I clinical testing planned to initiate in 2009

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Sales and Marketing

We currently market FARESTON® (toremifene citrate 60 mg) tablets, which have been approved by the FDA for the treatment of metastatic breast cancer in postmenopausal women in the United States. In January 2005, we acquired from Orion the right to market FARESTON® tablets in the United States for the metastatic breast cancer indication. We also acquired from Orion a license to toremifene for all indications in humans worldwide, except breast cancer outside of the United States. The active pharmaceutical ingredient in FARESTON® is the same as in our toremifene 80 mg and toremifene 20 mg product candidates. We plan to build a specialty sales and marketing infrastructure, which we expect to include 50 to 100 sales representatives, to market toremifene, if approved by the FDA, to the relatively small and concentrated community of urologists and medical oncologists in the United States. We have partnered with Ipsen to commercialize toremifene in Europe. We are currently seeking partners to market toremifene in Asia and other markets outside of the United States and Europe.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries and other related costs for personnel serving executive, finance, legal, human resources, information technology, investor relations and marketing functions. Other costs include facility costs not otherwise included in research and development expense and professional fees for legal, accounting, public relations, and marketing services. General and administrative expenses also include insurance costs and FARESTON® selling and distribution expenses. We expect that our general and administrative expenses will increase in future periods as we add personnel, additional office space and other expenses to support the planned growth of our business. In addition, we plan to expand our sales and marketing efforts which will result in increased sales and marketing expenses in future years.

Critical Accounting Policies and Significant Judgments and Estimates

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

While our significant accounting policies are more fully described in Note 2 to our financial statements appearing in our Annual Report on Form 10-K for the year ended December 31, 2007 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.

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Revenue Recognition

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

We use revenue recognition criteria outlined in Staff Accounting Bulletin (SAB) No. 101, *Revenue Recognition in Financial Statements* as amended by SAB No. 104, (together, SAB 104), Statement of Financial Accounting Standards (SFAS) No. 48, *Revenue Recognition When Right of Return Exists* (SFAS No. 48), Emerging Issues Task Force (EITF) Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21) and EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent* (EITF 99-19). Accordingly, revenues from licensing agreements are recognized based on the performance requirements of the agreement. We have analyzed our agreements with multiple element arrangements to determine whether the deliverables under the agreement, including license and performance obligations such as joint steering committee participation and research and development activities, can be separated or whether all of the deliverables must be accounted for as a single unit of accounting in accordance with EITF 00-21. For these arrangements, we were not able to identify evidence of fair value for the undelivered elements and therefore recognize any consideration for a single unit of accounting in the same manner as the revenue is recognized for the final deliverable, which is ratable over the performance period. The performance period is estimated at the inception of the agreement and is reevaluated at each reporting period. Cost reimbursements for research activities are recognized as collaboration revenue if the provisions of EITF 99-19 are met, the amounts are determinable and collection of the related receivable is reasonably assured. Revenues from milestone payments for which we have no continuing performance obligations are recognized upon achievement of the performance milestone, as defined in the related agreement, provided the milestone is substantive and a culmination of the earnings process has occurred. Performance obligations typically consist of significant milestones in the development life cycle of the related products and technology, such as initiation of clinical trials, filing for approval with regulatory agencies and approvals by regulatory agencies.

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

We recognize net product sales revenue from sales of FARESTON® less deductions for estimated sales discounts and sales returns. We recognize revenue from product sales when the goods are shipped and title and risk of loss pass to the customer and the other criteria of SAB No. 104 and SFAS No. 48 are satisfied. We account for rebates to certain governmental agencies as a reduction of product sales. We allow customers to return product within a specified time period prior to and subsequent to the product s labeled expiration date. As a result, we estimate an accrual for product returns, which is recorded as a reduction of product sales, based on factors which include historical product returns and estimated product in the distribution channel which is expected to exceed its expiration date. We retained substantially the same wholesale customers of, and the distribution channel that was used by, another pharmaceutical company that distributed FARESTON® for six years prior to our obtaining the rights to market FARESTON® in January 2005. We also obtained historical product return trend information that we continue to update with our own product return data. We estimate the amount of product in the distribution channel which is expected to exceed its expiration date and be returned by the customer by

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receiving information from our three largest wholesale customers about the levels of FARESTON® inventory held by these customers. These three largest wholesale customers accounted for 95% of our gross product sales of FARESTON® for the three months ended March 31, 2008. Based on this information, and other factors, we estimate the number of months of product on hand. At March 31, 2008 and December 31, 2007, our accrual for product returns was $243,000 and $324,000, respectively. If actual future results are different than our estimates, we may need to adjust our estimated accrual for product returns, which could have a material effect on our financial results in the period of the adjustment.

Share-Based Compensation

We have stock option plans that provide for the purchase of our common stock by certain of our employees and directors. Effective January 1, 2006, we adopted SFAS 123(R), *Share-Based Payment*, and began recognizing compensation expense for our share-based payments based on the fair value of the awards. Share-based payments include stock option grants under our stock option plans and deferred compensation arrangements for the Company s directors.

The determination of the fair value of share-based payment awards on the date of grant include the expected life of the award, the expected stock price volatility over the expected life of the awards, expected dividend yield, and risk-free interest rate. We estimate the expected life of options by calculating the average of the vesting term and contractual term of the options, as allowed by SAB 110. 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. Forfeitures are estimated at the time of valuation and reduce expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate.

Total share-based compensation expense for the three months ended March 31, 2008 was $781,000, of which $345,000 and $436,000 were recorded in the condensed statements of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the three months ended March 31, 2007 was $507,000, of which $234,000 and $273,000 were recorded in the condensed statements of operations as research and development expenses and general and administrative expenses, respectively. Included in share-based compensation expense for the three months ended March 31, 2008 and 2007 is share-based compensation expense related to deferred compensation arrangements for our directors of $51,000 and $38,000, respectively. At March 31, 2008, the total compensation cost related to non-vested awards not yet recognized was approximately $8.2 million with a weighted average expense recognition period of 2.58 years.

Recent Accounting Pronouncements

Effective January 1, 2008, we adopted SFAS No. 157, *Fair Value Measurements* (SFAS No. 157), which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosure about fair value measurements. The fair value of our short-term investments is subject to the fair value measurement criteria in SFAS No. 157. Adoption of SFAS No. 157 did not have a significant impact on our financial position or results of operations.

In November 2007, the Emerging Issues Task Force issued EITF Issue No. 07-01, *Accounting for Collaborative Arrangements* (EITF 07-01). EITF 07-01 concludes that the equity method of accounting cannot be applied to collaborative arrangement activities that are not conducted within a

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separate legal entity. Instead, the revenues and costs incurred with third parties in connection with the collaborative arrangement should be presented gross or net by the collaborators based on the criteria in EITF 99-19, and other applicable accounting literature. EITF 07-01 is effective for years beginning after December 15, 2008. We do not expect the adoption of EITF 07-01 will have a material impact on our financial position or results of operations.

Results of Operations

Three Months Ended March 31, 2008 and 2007

Revenues. Revenues for the three months ended March 31, 2008 were $4.5 million, as compared to $1.7 million for the same period of 2007. Revenues include net sales of FARESTON® marketed for the treatment of metastatic breast cancer and collaboration revenue from Ipsen and Merck. During the three months ended March 31, 2008 and 2007, FARESTON® net sales were $257,000 and $192,000, respectively, while costs of products sales were $135,000 and $109,000, respectively. Product sales revenue increased due to a 10% higher sales price and a 19% increase in sales volume for the three months ended March 31, 2008 compared to the same period of the prior year. We expect FARESTON® sales to decline in future periods, particularly as a result of aromatase inhibitors continuing to capture breast cancer market share from SERMs, including FARESTON®. Collaboration revenue was $4.2 million for the three months ended March 31, 2008, and $1.5 million for the three months ended March 31, 2007. Collaboration revenue for the three months ended March 31, 2008 consisted of approximately $1.5 million and approximately $1.3 million from the amortization of deferred revenue from Ipsen and Merck, respectively, and approximately $1.5 million from an earned milestone from Ipsen with the achievement of the primary end point in the toremifene 80 mg ADT Phase III clinical trial. Collaboration revenue for the three months ended March 31, 2007 consisted of approximately $1.5 million from the amortization of deferred revenue from Ipsen.

Research and Development Expenses. Research and development expenses increased 75% to $14.0 million for the three months ended March 31, 2008 from $8.0 million for the three months ended March 31, 2007. The following table identifies the research and development expenses for certain of our product candidates, as well as research and development expenses pertaining to our other research and development efforts, for each of the periods presented.

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Program	Product Candidate/ Proposed Indication	Three Months Ended March 31, 2008	2007	Increase
			(in thousands)	
SERM	**Toremifene 80 mg** Multiple serious side effects of ADT	$ 5,394	$2,312	$3,082
	Toremifene 20 mg Prevention of prostate cancer in high risk men with high grade PIN	2,639	2,333	306
SARM	**Ostarine™** Cancer cachexia	2,256	1,304	952
LH inhibitor	**GTx-758** Advanced prostate cancer	541	_	541
Estrogen receptor beta agonist	**GTx-878** BPH	246	_	246
Other research and development		2,923	2,058	865
Total research and development expenses		$13,999	$8,007	$5,992

General and Administrative Expenses. General and administrative expenses increased during the three months ended March 31, 2008 to $4.3 million from $3.1 million for the three months ended March 31, 2007. This increase was primarily the result of increased personnel related expenses of $642,000 and marketing and promotional expenses of $458,000.

Interest Income. Interest income decreased to $1.2 million for the three months ended March 31, 2008 from $1.5 million for the three months ended March 31, 2007. The decrease was primarily attributable to lower average interest rates during the three months ended March 31, 2008, as compared to the same period in 2007.

Liquidity and Capital Resources

At March 31, 2008, we had cash, cash equivalents and short-term investments of $134.7 million, compared to $110.0 million at December 31, 2007. Net cash provided by operating activities was $28.7 million and $8.4 million was used in operating activities for the three months ended March 31, 2008 and 2007, respectively. The cash provided by operating activities for the three months ended March 31, 2008 consisted primarily of the receipt of $40.0 million from Merck in conjunction with our exclusive license and collaboration agreement, offset by funding our net loss for the period. The use of cash for the three months ended March 31, 2007 resulted primarily from funding our net loss. Net cash used in investing activities was $697,000 and $157,000 for the three months ended March 31, 2008 and 2007, respectively.

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Net cash used in investing activities for both periods was primarily for the purchase of research and development equipment, software, information technology equipment, furniture and fixtures and leasehold improvements. We currently expect to make capital expenditures of approximately $2.8 million for the remainder of 2008.

Net cash provided by financing activities was $130,000 for the three month period ended March 31, 2008 and included proceeds from the exercise of employee stock options of $131,000, offset by principal payments under a capital lease obligation of $1,000. Net cash provided by financing activities was $389,000 for the three month period ended March 31, 2007 and included proceeds from the exercise of employee stock options of $390,000, offset by principal payments under a capital lease obligation of $1,000.

We estimate that our current cash balances and short-term investments, interest on these funds and product revenue from the sale of FARESTON® will be sufficient to meet our projected operating requirements through at least the next twelve months. This estimate does not include funding from future milestone payments that we may receive under our existing collaborations with Merck and Ipsen, nor does it include any funding that we may receive under potential future collaboration arrangements with other pharmaceutical companies or potential issuances and sales of our securities.

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

- the scope, rate of progress and cost of our and/or our collaborators clinical trials and other research and development activities;
- future clinical trial results;
- the achievement of certain milestone events under, and other matters related to, our collaborative arrangements with Merck and Ipsen;
- the terms and timing of any future collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory filings and/or approvals;
- potential future licensing fees, milestone payments and royalty payments, including any milestone payments or royalty payments that we may receive under our collaborative arrangements with Merck and Ipsen;
- the cost and timing of establishing sales, marketing and distribution capabilities;

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the cost of establishing clinical and commercial supplies of our product candidates and any products that we and/or our collaborators may develop;

the effect of competing technological and market developments;

the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and

the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Until we can generate a sufficient amount of product revenue, we expect to finance future cash needs through public or private equity offerings, debt financings or collaboration and licensing arrangements, such as our arrangements with Merck and Ipsen, as well as through interest income earned on the investment of our cash balances and short-term investments and revenues from the sale of FARESTON®. With the exception of payments that we may receive under our collaborations with Merck and Ipsen, we do not currently have any commitments for future external funding. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, such as our arrangements with Merck and Ipsen, it may be necessary to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or to obtain funds through collaborations with others that are on unfavorable terms or that may require us to relinquish rights to some of our technologies or product candidates that we would otherwise seek to develop on our own.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the three months ended March 31, 2008, 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, 2007.

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 our disclosure controls and procedures (as defined in Rules13a-15(e) and 15d-15(e) of the Exchange Act as of the end of the period covered by this report. Based on the evaluation of these disclosure controls

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and procedures, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective.

There were no changes in our internal control over financial reporting during the first quarter of 2008 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 11, 2008.

Risks Related to Our Financial Results and Need for Additional Financing

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

We have a limited operating history. As of March 31, 2008, we had an accumulated deficit of $282.9 million, of which $96.3 million related to non-cash dividends and adjustments to the preferred stock redemption value. We have incurred losses in each year since our inception in 1997. Net losses were $12.7 million for the three months ended March 31, 2008, $40.4 million in 2007, $35.5 million in 2006, and $36.8 million in 2005. We expect to continue to incur significant and increasing operating losses for the foreseeable future. These losses have had and will continue to have an adverse effect on our stockholders equity and working capital.

Because of the numerous risks and uncertainties associated with developing small molecule drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. We have primarily financed our operations and internal growth through sales of common stock and preferred stock, including $30.0 million in proceeds from the sale of our common stock to Merck & Co., Inc., or Merck, pursuant to a stock purchase agreement we entered into with Merck in November 2007. In addition, we have received upfront license fees and milestone and other payments pursuant to our collaborative arrangements with third parties, including $40.0 million in upfront license fees from Merck received in January 2008 and the $1.5 million milestone payment from Ipsen received in April 2008. FARESTON® is currently our only commercial product and, we expect, will account for all of our product revenue for the foreseeable future. For the three months ended March 31, 2008, we recognized $257,000 in net revenues from the sale of FARESTON®.

We expect our research and development expenses to increase in connection with our ongoing clinical trials and our increasing SARM research efforts with Merck as a part of our collaboration. In addition,

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subject to regulatory approval of any of our product candidates, we expect to incur additional sales and marketing expenses and increased manufacturing expenses.

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

We will need to raise additional capital to:

fund our operations and clinical trials;

continue our research and development; and

commercialize our product candidates, if any such product candidates receive regulatory approval for commercial sale.

We estimate that our current cash resources, interest on these funds and product revenue from the sale of FARESTON®, will be sufficient to meet our projected operating requirements through at least the next twelve months. This estimate does not include funding from milestone payments that we may receive under our existing collaborations with Merck and Ipsen, nor does it include any funding that we may receive under potential future collaboration arrangements with other pharmaceutical companies or potential future issuances and sales of our securities. Our future funding requirements will depend on many factors, including:

the scope, rate of progress and cost of our and/or our collaborators clinical trials and other research and development activities;

future clinical trial results;

the achievement of certain milestone events under, and other matters related to, our collaborative arrangements with Merck and Ipsen;

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

the cost and timing of regulatory filings and/or approvals;

potential future licensing fees, milestone payments and royalty payments, including any milestone payments or royalty payments that we may receive under our collaborative arrangements with Merck and Ipsen;

the cost and timing of establishing sales, marketing and distribution capabilities;

the cost of establishing clinical and commercial supplies of our product candidates and any products that we and/or our collaborators may develop;

the effect of competing technological and market developments;

the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and

the 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.

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Until we can generate a sufficient amount of product revenue, we expect to finance future cash needs through public or private equity offerings, debt financings or collaboration and licensing arrangements, as well as through interest income earned on our cash balances and short-term investments, and revenues from the sale of FARESTON®.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, may involve restrictive covenants. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and/or licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or product candidates, or we may be required to grant licenses on terms not favorable to us.

Risks Related to Development of Product Candidates

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

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

In clinical studies the efficacy and/or safety results from the trial may be insufficient to support the filing or approval of a new drug application, or NDA, with the U.S. Food and Drug Administration, or FDA.

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

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

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

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

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

In our Phase III clinical trial for toremifene 20 mg for the for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia, or high grade PIN, some patients have experienced venous thromboembolic events, or VTEs, such as deep vein thromboses and pulmonary embolisms, as well as myocardial infarctions, or heart attacks, which have been considered by investigators as possibly related to treatment with toremifene 20 mg. Because this trial is blinded, we cannot establish whether these patients received placebo or toremifene 20 mg in this trial. In addition, although the results from our Phase III clinical trial for toremifene 80 mg for the treatment of multiple serious side effects of androgen deprivation therapy, or ADT, showed that the drug had a favorable safety profile and was well tolerated, there were a higher number of VTEs in the toremifene 80 mg treatment group 17 (2.4%) versus 7 (1.02%) in the placebo group. Even though the majority of VTEs occurred in men who were at high risk for a VTE (including: age greater than 80 years, history of VTEs, recent surgical procedure and immobilization) and our results showed that the number of VTE s in men without major risk factors for VTEs was 3 in the toremifene 80 mg treatment group versus 2 in the placebo group, the FDA will consider the overall safety profile when making its determination to grant approval and the requirement of any potential warnings in the label if approval is granted.

There have been no drug-related serious adverse events related to our other product candidates. In addition, in our Phase II clinical trial for Ostarine™, we observed mild elevations of hepatic enzymes in a few patients, and in our preclinical studies for Ostarine™, only at the highest doses, we observed expected selective effects on the reproductive and other target organs in the male population consistent with the stimulating and inhibiting effects on the androgen receptor which is located in these organs.

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

- we or our collaborators may be required to conduct additional preclinical or clinical trials, make changes in labeling of any such approved products, reformulate any such products, or implement changes to or obtain new approvals of our contractors manufacturing facilities;

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regulatory authorities may be unwilling to approve our product candidates or may withdraw approval of our products;

we may experience a significant drop in the sales of the affected products;

our reputation in the marketplace may suffer; and

we may become the target of lawsuits, including class action suits.

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

Risks Related to Our Dependence on Third Parties

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

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

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

In the event that Orion terminates our license and supply agreement due to our uncured material breach or bankruptcy, we would not be able to manufacture toremifene until the expiration of Orion s patents with respect to the composition of matter of toremifene. Although Orion s composition of matter patents within the European Territory have expired, and as such, would not prevent Ipsen from manufacturing toremifene within the European Territory, there is no obligation on the part of Orion to transfer its manufacturing technology to Ipsen or to assist Ipsen in developing manufacturing capabilities to meet Ipsen s supply needs if Ipsen is in material breach of its supply agreement with Orion. Although we and Ipsen have agreed to collaborate with each other in the event either of our supply rights are terminated by Orion for any reason, a disruption in the supply of toremifene could delay the development of and impair our and Ipsen s ability to commercialize toremifene. In addition, Orion may terminate its obligation to supply us and Ipsen with toremifene if Orion ceases its manufacture of toremifene permanently, or Orion may terminate its obligation to supply us with toremifene if toremifene is not approved for commercial sale in the United States prior to December 31, 2009. If such termination occurs because Orion is no longer manufacturing toremifene, or because such regulatory approval is not obtained prior to the specified date, we and Ipsen will have the right to manufacture toremifene, but any arrangements we make for an alternative supply would still have to be made with a qualified alternative supplier with appropriate FDA approval in order for us to obtain our supply requirements for toremifene. We and Ipsen have mutually agreed to cooperate in the manufacture of toremifene in the event Orion ceases manufacture of toremifene for any of the above-mentioned reasons.

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

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

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

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

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party because of factors beyond our control;
- the possible termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us;
- drug product supplies not meeting the requisite requirements for clinical trial use; and
- the possible exercise by Orion of its right to terminate its obligation to supply us with toremifene:
  - if it permanently ceases manufacture of toremifene or if we do not obtain regulatory approval of toremifene in the United States prior to December 31, 2009; or
  - if Orion terminates due to our uncured material breach or bankruptcy.

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

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access to manufacturing facilities. For example, the active pharmaceutical ingredient in our toremifene 80 mg and toremifene 20 mg product candidates is also the active pharmaceutical ingredient in FARESTON®. Further, Orion has agreed to supply toremifene tablets to Ipsen for clinical trials and commercial supply in the European Territory. Orion also manufactures toremifene for third parties for sale outside the United States for the treatment of advanced breast cancer in postmenopausal women.

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

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

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

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

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

- we are not able to control either the amount and timing of resources that Ipsen devotes to toremifene or the amount of timing and resources that Merck devotes to SARM compounds and products developed under our collaboration with Merck;

- we may not be able to control the amount and timing of resources that our potential future partners may devote to our product candidates;

- our partners may experience financial difficulties or changes in business focus;

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we may be required to relinquish important rights such as marketing and distribution rights;

under certain circumstances, Ipsen may not be required to commercialize toremifene in certain countries of the European Territory if Ipsen determines that it is not commercially reasonable for it to do so;

pricing reimbursement constraints within the European Territory may diminish the prospects of our receiving royalty payments from Ipsen on aggregate net sales of toremifene in some or all of the countries within the European Territory;

should a collaborator fail to develop or commercialize one of our compounds or product candidates, we may not receive any future milestone payments and will not receive any royalties for the compound or product candidate;

business combinations or significant changes in a collaborator s business strategy may also adversely affect a collaborator s willingness or ability to complete its obligations under any arrangement;

under certain circumstances, a collaborator could move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and

collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our product candidates.

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

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

Under our agreement with Ipsen, we and Ipsen have agreed that neither party will seek to commercialize, promote, market or sell certain products within the European Territory for an agreed period of time subsequent to the time of the first commercial launch of toremifene within the European Territory. We and Ipsen have also agreed to grant to the other a right of first negotiation with respect to the development, marketing, sale and distribution of any new SERM-based products for the field of the prevention and treatment of prostate cancer or related side effects, or any other indication the parties agree on. However, we cannot assure you that we will be able to reach an agreement with Ipsen on reasonable terms, or at all, for any new SERM-based products.

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Under our agreement with Merck, we and Merck have agreed that neither party will engage in the development and commercialization of SARMs with any third party for an agreed upon period of time. However, we cannot assure you that we and Merck will be able to successfully develop new SARM products or identify new indications for existing and/or future SARM products under our collaboration with Merck. Additionally, Merck has the right to terminate our agreement with Merck for any reason after a specified period of time with prior written notice, and Ipsen has the right to terminate our agreement with Ipsen with 12 months prior written notice for any reason and with 30 days prior written notice as a result of legitimate and documented safety concerns. Both Ipsen and Merck may terminate their agreements with us following our uncured material breach or bankruptcy. If our agreements with Ipsen and Merck are terminated, the anticipated future benefits to us from these agreements would be eliminated, the development and commercialization of toremifene in the European Territory and the development and commercialization of our SARM product candidates could be delayed, and our costs of development would increase. For example, Merck s obligation to pay us $15.0 million in guaranteed cost reimbursements for research funding over a three year period is subject to our exclusive license and collaboration agreement with Merck not being terminated for cause and there not occurring certain change of control events involving us during such three-year period. In any such or similar events, we may not realize the anticipated benefits from our collaborative arrangements with Ipsen and Merck.

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

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

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

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

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Furthermore, we and our affiliates are prohibited from marketing or selling products containing toremifene or related SERM compounds for human use in the United States and other major countries located outside the European Union during the term of Orion s patents covering toremifene in such countries, which in the United States expire in September 2009. The binding effect of this noncompetition provision on us and our affiliates may make it more difficult for us to be acquired by some potential buyers during the relevant time periods even if we determine that a sale of the company would be in the best interests of our stockholders.

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

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

Our rights to certain patent applications relating to SARM compounds that we have licensed from the University of Tennessee Research Foundation, or 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, which UTRF is required to do at our request. In addition, under the terms of our agreements with the diagnostic companies to which we provided clinical samples from our Phase IIb and Phase III clinical trials of toremifene, we will not obtain any intellectual property rights in any of their developments, including any test developed to detect high grade PIN or prostate cancer.

Even if our product candidates and the methods for treating patients for prescribed indications using these product candidates are covered by valid and enforceable patents and have claims with sufficient scope and support in the specification, the patents will provide protection only for a limited amount of time. For example, the patent that we have licensed from Orion covering the composition of matter of toremifene expires in the United States in September 2009. Foreign counterparts of this patent have either already expired or will expire in Australia, Italy, Sweden and Switzerland in 2008, that is, before we or Ipsen will receive regulatory approval to commercialize toremifene. As a result, outside the United States and in the United States after 2009, we will need to rely primarily on the protection afforded by method of use patents relating to the use of toremifene for the relevant product indications that have been issued or may be issued from our owned or licensed patent applications. Also, within the European Union, Ipsen may need to rely primarily on the protection afforded by marketing and data exclusivity for the toremifene products to be sold within the countries comprising the European Union. To date, most of our applications for method of use patents filed for toremifene outside of the United States are still pending and have not yielded issued patents. Loss of marketing and data exclusivity for the toremifene products to be commercialized within the European Union could adversely affect its ability to successfully commercialize these products. We are not eligible for any such exclusivity or further extension of the composition of matter patent of toremifene licensed to us by Orion in the United States.

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

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

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

If we lose our licenses from Orion and UTRF, we may be unable to continue our business.

We have licensed intellectual property rights and technology from Orion and UTRF under our license agreements with each of them. Each of these license agreements may be terminated by the other party if we are in breach of our obligations under, or fail to perform any terms of, the agreement and fail to cure that breach. If any of these agreements were terminated, then we may lose our rights to utilize the technology and intellectual property covered by that agreement to market, distribute and sell our licensed products, which may prevent us from continuing our business. Additionally, the termination of our UTRF license related to SARM technology could lead to a termination of our exclusive license and collaboration agreement with Merck, which would terminate our rights to any potential milestone or royalty payments from Merck. In addition, the termination of our UTRF license for chemoprevention of prostate cancer could lead to a termination of our license and collaboration agreement with Ipsen, which would terminate our rights to any potential milestone or royalty payments from Ipsen.

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

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

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

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

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

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or commercialization efforts. If third parties are successful in their claims, we might have to pay substantial damages or take other actions that are adverse to our business.

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

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

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

Risks Related to Regulatory Approval of Our Product Candidates

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

Our product candidates and the activities associated with their development and commercialization are subject to comprehensive regulation by the FDA, other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent us or our collaborators from commercializing the product candidate. We have not received regulatory approval to market any of our product candidates in any jurisdiction and have only limited experience in preparing and filing the applications necessary to gain regulatory approvals. In addition, we will not receive a substantial majority of the milestone payments provided under our collaboration and license agreement with Ipsen or any royalty payments if Ipsen is unable to obtain the necessary regulatory approvals to commercialize toremifene within the European Territory. Likewise, we may not receive a majority of the milestone payments or any royalty payments provided for under our exclusive license and collaboration agreement with Merck if Merck is not able to obtain the necessary regulatory approvals to commercialize any SARM products, including Ostarine™, developed under the collaboration. The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved.

Changes in the regulatory approval policy during the development period, changes in or the enactment of additional regulations or statutes, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. For example, the Food and Drug Administration Amendments Act of 2007, or the FDA Amendments Act, which was enacted in September 2007, expands the FDA s authority to regulate drugs throughout the product life cycle, including enhanced authority to require post-approval studies and clinical trials. Other proposals have been made to impose additional requirements on drug approvals, further expand post-approval requirements and restrict sales and promotional activities. This new legislation, and the additional proposals if enacted, may make it more difficult or burdensome for us or our collaborators to obtain approval of our product candidates. Even if the FDA approves a product candidate, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product, and may impose ongoing requirements for post-approval

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

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

The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. For example, we completed our Phase III clinical trial of toremifene to treat multiple side effects of androgen deprivation therapy and are conducting our Phase III clinical trial of toremifene for the prevention of prostate cancer in high risk men with high grade PIN, under Special Protocol Assessments, or SPAs, from the FDA. A SPA is designed to facilitate the FDA s review and approval of drug products by allowing the FDA to evaluate the proposed design and size of clinical trials that are intended to form the primary basis for determining a drug product s efficacy. If agreement is reached with the FDA, a SPA documents the terms and conditions under which the design of the subject trial will be adequate for submission of the efficacy and human safety portion of a NDA. However, there are circumstances under which we may not receive the benefits of a SPA, notably if the FDA subsequently identifies a substantial scientific issue essential to determining the product s safety or efficacy. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Furthermore, even if we file an application with the FDA for marketing approval of a product candidate, it may not result in marketing approval from the FDA.

We may not receive regulatory approval for the commercial sale of any of our product candidates that are in development for at least another year, if ever. Similarly, it is not anticipated that Ipsen will receive the appropriate regulatory approvals to market toremifene within the European Territory any sooner than we will achieve regulatory approval in the United States, and it may be thereafter. The inability to obtain FDA approval or approval from comparable authorities in other countries for our product candidates would prevent us or our collaborators from commercializing these product candidates in the United States or other countries. See the section entitled Business Government Regulation under Part I, Item 1 of our Annual Report on Form 10-K for the year ended December 31, 2007 for additional information regarding risks associated with marketing approval, as well as risks related to post-approval requirements.

Risks Related to Commercialization

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

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

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efficacy and safety results in clinical trials;

the prevalence and severity of any side effects;

potential advantages over alternative treatments;

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

relative convenience and ease of administration;

the strength of marketing and distribution support; and

sufficient third-party coverage or reimbursement.

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

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

the loss of the availability of Orion s website to market FARESTON®, which is an important source of advertising;

the loss of one or more of our three largest wholesale drug distributors, which together accounted for approximately 95% of our gross product sales of FARESTON® for the three months ended March 31, 2008;

the continued success of competing products, including aromatase inhibitors;

the loss of coverage or reimbursement for FARESTON® from Medicare and Medicaid, private health insurers or other third-party payors;

exposure to product liability claims related to the commercial sale of FARESTON®, which may exceed our product liability insurance;

the failure of Orion to maintain regulatory filings or comply with applicable FDA requirements with respect to FARESTON®;

the ability of third parties to market and sell generic toremifene products that will compete with FARESTON for the treatment of breast cancer after the composition of matter patents that we license from Orion expire in the United States in September 2009;

the loss of Orion, upon which we rely as a single source, as our supplier of FARESTON®; and

our inability to manufacture FARESTON® until Orion s patents with respect to the composition of matter of toremifene expire if Orion terminates our license and supply agreement due to our uncured material breach or bankruptcy.

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

We have limited experience as a company in the sales, marketing and distribution of pharmaceutical products. There are risks involved with building our own sales and marketing capabilities, as well as entering into arrangements with third parties to perform these services. For example, building a sales force is expensive and time-consuming and could delay any launch of a product candidate. We are relying on Ipsen to market and distribute our toremifene product candidates through Ipsen s established sales and marketing network within the European Territory. If our collaboration and license agreement with Ipsen is terminated for any reason, our ability to sell our toremifene product candidates in the European Territory would be adversely affected, and we may be unable to develop or engage an effective sales force to successfully market and sell our toremifene product candidates in the European Territory. Currently, we do not have a partner outside of the European Territory and our success in regions other than the European Territory may be dependent on our ability to find suitable partners in other regions of the world. Similarly, we are relying on Merck for the commercialization of any SARM products developed under our collaboration with Merck and if our exclusive license and collaboration agreement with Merck is terminated for any reason, our ability to successfully market and sell any of our SARM product candidates would be adversely affected, and we may be unable to develop or engage an effective sales force to successfully market and sell any SARM products that we may develop, including Ostarine™. In addition, to the extent that we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues are likely to be lower than if we market and sell any products that we develop ourselves.

If we or our collaborators are unable to obtain adequate coverage and reimbursement from third-party payors for products we sell at acceptable prices, our revenues and prospects for profitability will suffer.

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

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

A primary trend in the United States health care industry is toward cost containment. In addition, in some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory marketing

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approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our or our collaborators commercialization efforts. Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly-approved health care products. In particular, third-party payors may limit the indications for which they will reimburse patients who use any products that we and/or our collaborators may develop or sell. Cost-control initiatives could decrease the price we might establish for products that we or our collaborators may develop or sell, which would result in lower product revenues or royalties payable to us.

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

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

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

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

We have product liability insurance that covers our clinical trials and commercial products up to a $25.0 million annual aggregate limit. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

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

We face competition from commercial pharmaceutical and biotechnology enterprises, as well as from academic institutions, government agencies and private and public research institutions. Our commercial

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opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we and/or our collaborators may develop. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before us and impair our or our collaborators ability to commercialize our product candidates.

Various products are currently marketed or used off-label for some of the diseases and conditions that we are targeting, and a number of companies are or may be developing new treatments. These product uses, as well as promotional efforts by competitors and/or clinical trial results of competitive products, could significantly diminish our or our collaborators ability to market and sell any products that we and/or our collaborators may develop. For example, although there are no products that have been approved by the FDA to treat multiple side effects of androgen deprivation therapy, we are aware of a number of drugs marketed by Eli Lilly (Evista®), Merck (Fosamax®), Sanofi-Aventis and Procter & Gamble (Actonel®), Wyeth Pharmaceuticals (Effexor®), Boehringer Ingelheim (Catapres®), Novartis (Zometa®) and Bristol Myers Squibb (Megace®) that are prescribed to treat single side effects of androgen deprivation therapy; that external beam radiation and tamoxifen are used to treat breast pain and enlargement, or gynecomastia; and that Amgen is developing a product candidate for the treatment of osteoporosis in prostate cancer patients. While we have the only pharmaceutical product in clinical development to prevent prostate cancer in high risk men with high grade PIN, GlaxoSmithKline is conducting a Phase III study for Avodart® on prostate cancer prevention in men with elevated prostate specific antigen. In addition, there are nutritional supplement studies (for example, selenium) investigating prostate cancer prevention in men with high grade PIN. Similarly, while there are no drugs that have been approved by the FDA for the treatment of muscle wasting from cancer, there are drugs marketed by Steris Laboratories and Savient Pharmaceuticals that are being prescribed off-label for the treatment of some types of muscle wasting from cancer. Testosterone and other anabolic agents are used to treat involuntary weight loss in patients who have acute muscle wasting. There are other SARM product candidates in development that may compete with our product candidates. Wyeth and Amgen have myostatin inhibitors in development which may compete for similar patients as Ostarine™. This could result in reduced sales and pricing pressure on our product candidates, if approved, which in turn would reduce our ability to generate revenue and have a negative impact on our results of operations.

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

Risks Related to Employees and Growth

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

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

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

In order to continue our clinical trials and commercialize our product candidates, we will need to expand the number of our managerial, operational, financial and other employees. We currently anticipate that we will need between 150 and 250 additional employees by the time toremifene is initially commercialized, including 50 to 100 sales representatives. The competition for qualified personnel in the biotechnology field is intense.

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

Risks Related to Our Common Stock

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

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

adverse results or delays in our clinical trials;

the timing of achievement of our and our collaborators clinical, regulatory and other milestones, such as the commencement of clinical development, the completion of a clinical trial or the receipt of regulatory approval;

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

actions taken by regulatory agencies with respect to our product candidates or products, our clinical trials or our sales and marketing activities;

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

developments with respect to our collaborations with Ipsen and Merck;

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

regulatory developments in the United States and foreign countries;

changes in the structure of health care payment systems;

any intellectual property infringement lawsuit involving us;

announcements of technological innovations or new products by us or our competitors;

market conditions for the biotechnology or pharmaceutical industries in general;

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actual or anticipated fluctuations in our results of operations;

changes in financial estimates or recommendations by securities analysts;

sales of large blocks of our common stock;

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

changes in accounting principles; and

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

The stock markets in general, and the markets for biotechnology stocks in particular, have experienced significant volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock. In the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs, which would hurt our financial condition and results of operations and divert management s attention and resources, which could result in delays of our clinical trials or commercialization efforts.

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

As of March 31, 2008, our officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 68.3% of our outstanding common stock and our officers and directors alone beneficially owned approximately 47.5% of our outstanding common stock. As a result, these stockholders, acting together, will be able to control all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders.

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

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

a classified Board of Directors;

a prohibition on actions by our stockholders by written consent;

the ability of our Board of Directors to issue preferred stock without stockholder approval, which could be used to institute a poison pill that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board of Directors; and

limitations on the removal of directors.

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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.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well. *

For the 12-month period ended March 31, 2008, the average daily trading volume of our common stock on the NASDAQ Global Market was approximately 453,061 shares. As a result, future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the then-prevailing market price of our common stock. As of March 31, 2008, we had 36,236,263 shares of common stock outstanding.

Moreover, J.R. Hyde, III, and Oracle Partners, L.P., two of our largest stockholders, and their affiliates, have rights, subject to some conditions, to require us to file registration statements covering the approximately 10.8 million shares of common stock they hold in the aggregate which are subject to registration rights or to include these shares in registration statements that we may file for ourselves or other stockholders. In addition, we filed a registration statement covering the 1,285,347 shares of common stock that we issued to Merck in December 2007. Finally, all shares of common stock that we may issue under our employee benefit plans can be freely sold in the public market upon issuance.

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.

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SIGNATURES

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

GTx, Inc.

Date: May 12, 2008

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

Date: May 12, 2008

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

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EXHIBIT INDEX

Number	Description
3.1	Restated Certificate of Incorporation of GTx, Inc.(1)
3.2	Amended and Restated Bylaws of GTx, Inc.(2)
4.1	Reference is made to Exhibits 3.1 and 3.2
4.2	Specimen of Common Stock Certificate(3)
4.3	Amended and Restated Registration Rights Agreement between Registrant and Oracle Partners, L.P. dated August 7, 2003(3)
4.4	Amended and Restated Registration Rights Agreement between Registrant and J. R. Hyde, III dated August 7, 2003(3)
4.5	Consent, Waiver and Amendment between the Registrant and Oracle Partners, L.P., Oracle Investment Management, Inc. and Oracle Institutional Partners, L.P. dated November 29, 2007(4)
4.6	Consent, Waiver and Amendment between Registrant and J. R. Hyde, III and Pittco Associates, L.P. dated December 3, 2007(4)
4.7	Registration Rights Agreement between Registrant and Merck & Co., Inc. dated December 18, 2007(5)
10.44	2008 Compensation Information for Registrant s Executive Officers(6)
12.1*	Statement of Computation of Deficiency of Earnings Available to Cover Fixed Charges
31.1*	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a)
31.2*	Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a)
32.1*	Certification of Chief Executive Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350) (7)
32.2*	Certification of Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350) (7)

* Filed herewith.

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

(2) Filed as the like numbered Exhibit to the Registrant s Current Report on Form 8-K (File No. 000-50549),

filed with the SEC on July 26, 2007, as amended, and incorporated herein by reference.

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

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

(5) Filed as the like numbered Exhibit to the Registrant s Current Report on Form 8-K (File No. 000-50549), filed with the Securities and Exchange Commission on December 18, 2007, and incorporated herein by reference.

(6) Filed as the like numbered Exhibit to the Registrant s Annual Report on Form 10-K (File No. 000-50549), filed with the Securities and Exchange Commission on March 11, 2008, and incorporated herein by reference.

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