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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2005

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 ☑ No o

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

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

As of November 4, 2005, 30,992,550 shares of the Registrant's Common Stock were outstanding.

GTx, INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2005
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PART I: FINANCIAL INFORMATION

ITEM 1 FINANCIAL STATEMENTS

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

	September 30, 2005 (unaudited)	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 37,808	$ 64,528
Inventory	175	448
Prepaid expenses and other current assets	2,497	1,176
Total current assets	40,480	66,152
Property and equipment, net	1,865	1,537
Purchased intangible assets, net	5,037	4,943
Other assets	312	450
Total assets	$ 47,694	$ 73,082
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,955	$ 900
Accrued expenses	5,585	2,617
Deferred revenue — current portion	1,337	1,337
Total current liabilities	8,877	4,854
Deferred revenue, less current portion	3,292	4,295
Capital lease obligation	20	24
Stockholders' equity:		
Common stock, $0.001 par value: 60,000,000 shares authorized; 24,666,133 shares issued and outstanding at September 30, 2005 and 24,664,716 shares issued and outstanding at December 31, 2004	25	25
Deferred stock compensation	(1,884)	(2,701)
Additional paid-in capital	223,837	224,015
Accumulated deficit	(186,473)	(157,430)
Total stockholders' equity	35,505	63,909
Total liabilities and stockholders' equity	$ 47,694	$ 73,082

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Revenues:				
Product sales, net	$ 288	$ —	$ 2,133	$ —
Collaboration revenue	334	335	1,003	721
Reimbursement of development costs	—	42	—	802
Total revenue	622	377	3,136	1,523
Costs and expenses:				
Costs of goods sold	185	—	1,350	—
Research and development expenses	8,454	3,971	24,419	12,606
General and administrative expenses	2,271	1,801	7,433	5,014
Total costs and expenses	10,910	5,772	33,202	17,620
Loss from operations	(10,288)	(5,395)	(30,066)	(16,097)
Interest income	345	270	1,023	632
Net loss	(9,943)	(5,125)	(29,043)	(15,465)
Accrued preferred stock dividends	—	—	—	(455)
Adjustments to preferred stock redemption value	—	—	—	17,125
Net (loss) income attributable to common stockholders	$ (9,943)	$ (5,125)	$ (29,043)	$ 1,205
Net (loss) income per share attributable to common stockholders:				
Basic	$ (0.40)	$ (0.21)	$ (1.18)	$ 0.05
Diluted	$ (0.40)	$ (0.21)	$ (1.18)	$ (0.65)
Weighted average shares used in computing net (loss) income per share attributable to common stockholders:				
Basic	24,664,950	24,656,923	24,664,794	22,433,716
Diluted	24,664,950	24,656,923	24,664,794	23,883,264

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

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

	Nine Months Ended September 30,	
	2005	2004
Cash flows from operating activities:		
Net loss	$ (29,043)	$ (15,465)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	749	320
Stock-based compensation expense	480	619
Directors' deferred compensation expense	95	55
Deferred revenue amortization	(1,003)	(721)
Changes in assets and liabilities:		
Inventory	273	88
Prepaid expenses and other current assets	(1,321)	(1,022)
Other assets	138	(348)
Accounts payable	1,055	732
Accrued expenses	3,023	6
Deferred revenue	—	6,687
Net cash used in operating activities	(25,554)	(9,049)
Cash flows from investing activities:		
Purchases of property and equipment	(799)	(1,028)
Purchases of intangible assets	(372)	—
Net cash used in investing activities	(1,171)	(1,028)
Cash flows from financing activities:		
Proceeds from initial public offering	—	71,403
Proceeds from exercise of employee stock options	9	—
Payments on capital lease obligation	(4)	—
Net cash provided by financing activities	5	71,403
Net (decrease) increase in cash and cash equivalents	(26,720)	61,326
Cash and cash equivalents, beginning of period	64,528	14,769
Cash and cash equivalents, end of period	$ 37,808	$ 76,095
Supplemental schedule of non-cash investing and financing activities:		
Preferred stock dividends	$ —	$ 455
Preferred stock adjustment to redemption value	$ —	$ (17,125)
Deferred initial public offering costs reclassified to additional paid-in capital	$ —	$ 1,471

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

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

1. BUSINESS AND BASIS OF PRESENTATION

Business

GTx, Inc. ("GTx," "the Company," "our," "us," or "we") is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for cancer and serious conditions related to men's health. Our lead drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens, two essential classes of hormones. We have four clinical programs. We are developing ACAPODENE® (toremifene citrate), a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: (1) a pivotal Phase III clinical trial for the treatment of serious side effects of androgen deprivation therapy, or ADT, for advanced prostate cancer and (2) a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with the precancerous prostate lesion called high grade prostatic intraepithelial neoplasia, or PIN. In our third clinical program, we are initially developing ostarine, a selective androgen receptor modulator, or SARM, for the treatment of acute muscle wasting conditions, such as burns. We plan to initiate a Phase II clinical trial for ostarine for this indication in the fourth quarter of 2005. We are also evaluating clinical development of ostarine for the treatment of chronic muscle wasting conditions, such as testosterone deficiency in aging men, or andropause. In our fourth clinical program, we and our partner, Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, are developing andarine, another one of our SARMs, for the treatment of weight loss from various types of cancer, which is known as cancer cachexia. We are working with Ortho Biotech to plan a Phase II clinical trial of andarine.

We plan to build a specialized sales and marketing capability to market our product candidates directly to the relatively small and concentrated community of urologists and medical oncologists in the United States and to seek partners to commercialize our product candidates outside the United States and to broader target physician markets. We currently market FARESTON® (toremifene citrate 60 mg) tablets, which have been approved by the U.S. Food and Drug Administration, or FDA, for the treatment of metastatic breast cancer in post-menopausal women in the United States. The active pharmaceutical ingredient in FARESTON is the same as in ACAPODENE, but at a different dose.

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 statements. These interim 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, 2004, as amended. Operating results for the nine months ended September 30, 2005 are not necessarily indicative of the results that may be expected for the entire fiscal year ending December 31, 2005.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

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

Cash and Cash Equivalents

The Company considers all highly-liquid investments with an original maturity of three months or less when purchased to be cash equivalents.

Property and Equipment

Property and equipment is stated at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the assets which range from three to five years. Amortization of leasehold improvements is recognized over the shorter of the estimated useful life of the leasehold improvement or the lease term.

Impairment of Long-Lived Assets

The Company accounts for long-lived assets in accordance with Statement of Financial Accounting Standards ("SFAS") No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets and for Long-Lived Assets to be Disposed of*, which requires that companies consider whether events or changes in facts and circumstances, both internally and externally, may indicate that an impairment of long-lived assets held for use are present. Management periodically evaluates the carrying value of long-lived assets and has determined that there was no impairment as of September 30, 2005. Should there be impairment in the future, the Company would recognize the amount of the impairment based on the expected future cash flows from the impaired assets. The cash flow estimates would be based on management's best estimates, using appropriate and customary assumptions and projections at the time.

Purchased Intangible Assets

The Company accounts for its purchased intangible assets in accordance with SFAS No. 142, *Goodwill and Other Intangible Assets*, which requires that purchased intangible assets with finite lives be amortized over their estimated economic lives. The Company's purchased intangible asset, a license fee, represents the value of a license and supply agreement purchased by the Company from Orion Corporation in connection with entering into an Amended and Restated License and Supply Agreement. The license fee is being amortized on a straight-line basis over the term of the agreement, which the Company estimates to be 16 years. Other purchased intangible assets represent the costs incurred to acquire software used by the Company. The Company amortizes the cost of purchased software on a straight-line basis over the estimated useful lives of the software, generally three years.

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, which include cash and cash equivalents, accounts payable and capital lease obligation approximate their fair value.

Income Taxes

The Company accounts for deferred taxes by recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and the tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. At September 30, 2005 and December 31, 2004, net of the valuation allowance, the net deferred tax assets were reduced to zero.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. The Company has established guidelines relating to diversification and maturities that allow the Company to manage risk. The Company's cash equivalents consist primarily of money market funds. Bank deposits may at times be in excess of FDIC insurance limits.

Revenue Recognition

Revenues associated with the Company's collaboration and license agreement consist of non-refundable, up-front license fees and reimbursement of development expenses.

Revenues from collaboration and license agreements are recognized based on the performance requirements of the agreement. Non-refundable, up-front fees, where the Company has an ongoing involvement or performance obligation, are generally recorded as deferred revenue in the balance sheet and amortized into collaboration revenue in the statement of operations over the term of the performance obligation.

Revenues derived from reimbursements of costs associated with the development of andarine are recorded in compliance with Emerging Issues Task Force ("EITF") EITF Issue 99-19, *"Reporting Revenue Gross as a Principal Versus Net as an Agent"* ("EITF 99-19"). According to the criteria established by EITF 99-19, in transactions where the Company acts as a principal, has discretion to choose suppliers, bears credit risk and performs part of the services required in the transaction, the Company has met the criteria to record revenue for the gross amount of the reimbursements.

Net product sales revenue represents gross revenue from the sale of FARESTON less deductions for estimated sales rebates, sales discounts and sales returns.

Research and Development Costs

The Company expenses research and development costs in the period in which they are incurred. These costs consist of direct and indirect costs associated with specific projects as well as fees paid to various entities that perform research and clinical trial studies on behalf of the Company.

Patent Costs

The Company expenses patent costs, including legal expenses, in the period in which they are incurred. Patent expenses are included in general and administrative expenses in the Company's condensed statements of operations.

Stock Compensation

Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB No. 25"), and its related interpretations are applied to measure compensation expense for stock-based compensation plans. The Company complies with the disclosure provisions of SFAS No. 123, *Accounting for Stock-Based Compensation (*"SFAS No. 123"), as amended by SFAS No. 148, *Accounting for Stock-Based Compensation, Transition and Disclosure*. Under APB No. 25, unearned stock compensation is based on the difference, if any, on the date of grant, between the fair value of the Company's common stock and the exercise price of the related option.

SFAS No. 123 requires pro forma disclosure of net loss attributable to common stockholders, assuming all stock options were valued on the date of grant using the minimum value option pricing model for stock options granted prior to the Company's initial public offering (IPO) in February 2004 and using the Black-Scholes option-pricing model for stock options granted after the IPO.

The following is a table of the weighted average assumptions used in the valuation of the options granted in 2005 and 2004:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Risk free interest rate	4.2%	4.0%	4.0%	4.0%
Expected volatility	66.5%	60.6%	60.5%	60.6%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected option life	6.0 years	6.0 years	5.7 years	6.0 years

If compensation cost for stock-based compensation plans had been determined under SFAS No. 123, the Company's net (loss) income attributable to common stockholders would have been the pro forma amounts indicated as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Net (loss) income attributable to common stockholders, as reported	$ (9,943)	$ (5,125)	$ (29,043)	$ 1,205
Add: Deferred compensation amortization expense included in reported net (loss) income	136	185	480	619
Deduct: Stock-based employee compensation determined under fair value based method for all awards	(580)	(359)	(1,405)	(955)
Pro forma net (loss) income attributable to common stockholders	$ (10,387)	$ (5,299)	$ (29,968)	$ 869
Pro forma SFAS No. 123 disclosure:				
Net (loss) income per share attributable to common stockholders as reported:				
Basic	$ (0.40)	$ (0.21)	$ (1.18)	$ 0.05
Diluted	$ (0.40)	$ (0.21)	$ (1.18)	$ (0.65)
Net (loss) income per share attributable to common stockholders pro forma:				
Basic	$ (0.42)	$ (0.21)	$ (1.22)	$ 0.04
Diluted	$ (0.42)	$ (0.21)	$ (1.22)	$ (0.66)

Deferred Stock Compensation

In anticipation of the Company's IPO on February 6, 2004, the Company determined that for financial reporting purposes the estimated value of its common stock was in excess of the exercise price for stock options issued to employees from June 30, 2003 to December 31, 2003. Accordingly, the Company recorded non-cash deferred stock-based compensation expense of $4,055 in 2003, and is amortizing the related expense over the service period, which is generally five years. Deferred stock compensation for options granted to employees has been determined as the difference between the deemed fair value of the Company's common stock for financial reporting purposes on the date such options were granted and the applicable exercise price. Such amount is included as a reduction of stockholders' equity and is being amortized on the straight-line basis. The Company recorded amortization of deferred stock compensation expense of approximately $136 and $185 for the three months ended September 30, 2005 and 2004, respectively. Of these amounts, $114 and $133 for the respective periods were included in research and development expenses and $22 and $52, respectively, were included in general and administrative expenses in the condensed statements of operations. The Company recorded amortization of deferred stock compensation of approximately $480 and $619 for the nine months ended September 30, 2005 and 2004, respectively. Of these amounts, $354 and $397 were included in research and development expenses and $126 and $222 were included in general and administrative expenses in the condensed statements of operations.

Comprehensive Loss

The Company has adopted the provisions of SFAS No. 130, *Comprehensive Income* ("SFAS No. 130"). SFAS No. 130 establishes standards for the reporting and display of comprehensive loss and its

components for general purpose financial statements. For all periods presented, there were no differences between net loss and comprehensive loss.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123 (revised 2004), *Share-Based Payment* ("SFAS 123R"), which replaces SFAS No. 123, *Accounting for Stock-Based Compensation* ("SFAS 123"), and supercedes APB Opinion No. 25, *Accounting for Stock Issued to Employees.* SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. The pro forma disclosures previously permitted under SFAS 123 no longer will be an alternative to financial statement recognition. The Company is required to adopt SFAS 123R in the first quarter of fiscal 2006, beginning January 1, 2006. Under SFAS 123R, the Company must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. The transition methods include the modified prospective and retroactive adoption options. Under the retroactive option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The modified prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS 123R, while the retroactive methods would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated. The Company is evaluating the requirements of SFAS 123R. The Company anticipates using the modified prospective method of adopting SFAS 123R and does not expect that the adoption will result in amounts that are materially different from the current pro forma disclosures under SFAS 123.

3. ADJUSTMENT TO PREFERRED STOCK REDEMPTION VALUE

The Company's preferred stock was recorded at its redemption value. The per share redemption price was equal to the greater of liquidation value, which included accrued dividends, or the fair value calculated on an as-if converted to common stock basis. At December 31, 2003, the per share redemption value was determined based on the estimated projected midpoint of the range of the Company's initial public offering price per common share of approximately $14.50 per share. At February 6, 2004, the date of the closing of the Company's IPO and automatic conversion of all outstanding preferred stock, and accrued dividends thereon, into common stock, the market price for the Company's common stock was $12.90 per share. Prior to conversion into common stock, the carrying value of the preferred stock and accrued dividends was adjusted to reflect the per share redemption value on the date of conversion resulting in a decrease in the carrying value of preferred stock of $17,125 and an offsetting increase in stockholders' equity. The changes in redemption value affect the net (loss) income attributable to common stockholders.

4. COLLABORATION, LICENSE AND CO-PROMOTION AGREEMENT

In March 2004, we entered into a joint collaboration and license agreement with Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, for andarine for indications related to men's health and other licensed SARM compounds meeting specified criteria which Ortho Biotech may ultimately choose to develop instead of, or in addition to, andarine. We retain the right to independently develop specific SARM compounds which are excluded from the collaboration, including ostarine. Under the terms of the agreement, we received an up-front licensing fee and reimbursement of certain andarine development expenses totaling approximately $6,687, which is being amortized into revenue over five years. We are entitled to receive additional licensing fees and milestone payments prior to product launch of (1) up to an aggregate of $76,000 for licensed products containing andarine or any replacement compound, and (2) up to $45,000 for each licensed product containing any other compound developed

under the agreement, upon achievement of specific clinical development milestones or receipt of regulatory approvals. Johnson & Johnson Pharmaceutical Research & Development, an affiliate of Ortho Biotech, is responsible for further clinical development and related expenses for andarine and other licensed SARM compounds. If a licensed product containing andarine or any other SARM compound is approved for commercial sale, Ortho Biotech will have full and exclusive decision-making authority for marketing such product in the United States and in markets outside the United States. Under the agreement, we have the option, subject to meeting specified conditions, to co-promote andarine and other licensed products to urologists in the United States for indications specifically related to men's health. Ortho Biotech is obligated to pay us up to double digit royalties on worldwide net sales of andarine and other licensed products, and an additional royalty in excess of 20% on all co-promoted net sales to urologists in the United States. Ortho Biotech may terminate the development or commercialization of andarine or any other licensed SARM compound under the agreement upon 90 days' notice, or 30 days' notice if there are safety issues, or may terminate the agreement for our uncured material breach.

The up-front licensing fee and reimbursement of expenses recorded as deferred revenue in the condensed balance sheets are expected to be amortized into collaboration revenue on a straight-line basis through March 2009. The Company recognized collaboration revenue of $334 and $335 for the three months ended September 30, 2005 and 2004, respectively, and $1,003 and $721 for the nine months ended September 30, 2005 and 2004, respectively, from the amortization of the deferred revenue. Additionally, the Company recognized $42 in the third quarter of 2004 and $802 in the first nine months of 2004 from the reimbursement of andarine development costs from Ortho Biotech Products, L.P.

5. BASIC AND DILUTED NET (LOSS) INCOME PER SHARE

The Company computed net (loss) income per common share according to Statement of Financial Accounting Standards No. 128, *"Earnings per Share,"* which requires disclosure of basic and diluted earnings (loss) per share.

The following table sets forth the computation of the Company's basic and diluted net (loss) income per common share attributable to common stockholders:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Basic net (loss) income per share				
Numerator:				
Net (loss) income attributable to common stockholders	$ (9,943)	$ (5,125)	$ (29,043)	$ 1,205
Denominator (weighted average shares):				
Common stock outstanding at beginning of period	24,664,716	24,656,923	24,664,716	7,735,848
Conversion of preferred stock to common stock	—	—	—	10,007,357
Issuance of common stock in initial public offering	—	—	—	4,690,511
Issuance of common stock from the exercise of employee stock options	234	—	78	—
Weighted average shares used in computing basic net (loss) income per share	24,664,950	24,656,923	24,664,794	22,433,716
Basic net (loss) income per share attributable to common stockholders	$ (0.40)	$ (0.21)	$ (1.18)	$ 0.05

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Diluted net loss per share				
Numerator:				
Net loss	$ (9,943)	$ (5,125)	$ (29,043)	$ (15,465)
Denominator (weighted average shares):				
Common stock outstanding at beginning of period	24,664,716	24,656,923	24,664,716	7,735,848
Conversion of preferred stock to common stock	—	—	—	11,456,905
Issuance of common stock in initial public offering	—	—	—	4,690,511
Issuance of common stock from the exercise of employee stock options	234	—	78	—
Weighted average shares used in computing diluted net loss per share	24,664,950	24,656,923	24,664,794	23,883,264
Diluted net loss per share attributable to common stockholders	$ (0.40)	$ (0.21)	$ (1.18)	$ (0.65)

Weighted average options outstanding to purchase shares of common stock of 1,269,756 and 1,230,595 were excluded from the calculation of diluted net loss per share attributable to common stockholders for the three months and nine months ended September 30, 2005, respectively, as inclusion of the options would have an anti-dilutive effect on the net loss for the periods.

6. DIRECTORS' DEFERRED COMPENSATION PLAN

In accordance with the Company's Directors' Deferred Compensation Plan, the directors have the option to defer receipt of all or a portion of their annual director fee and elect to receive part or all of his or her deferred compensation in the form of cash or common stock to be credited to a cash and/or stock account which will be payable to them upon their retirement from the Board of Directors. The Company recorded board of director fees expense of $37 and $100 for the three and nine months ended September 30, 2005, respectively, of which $31 and $95, respectively, was deferred and will be paid in common stock. Director fees expense for the three and nine months ended September 30, 2004 was $26 and $67, respectively, of which $24 and $55, respectively was deferred and will be paid in common stock.

7. SUBSEQUENT EVENT

On October 17, 2005, the Company completed an underwritten public offering of 6,325,000 shares of its common stock including the exercise of the over-allotment option by the underwriters, at a price to the public of $7.80 per share. Net cash proceeds from this offering were approximately $45,764 after deducting underwriting discounts and other offering expenses.

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 is Subject to Risk and Uncertainty

This Quarterly Report on Form 10-Q contains forward-looking statements, including, without limitation, statements related to product sales, potential future licensing fees and milestone and royalty payments and our current and anticipated marketed products, clinical trials and research and development programs. These forward-looking statements are based upon our current expectations. Forward-looking statements involve risks and uncertainties. Our actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of several factors, which include, without limitation, those set forth below under "Additional Factors That May Affect Future Results" and elsewhere in this Quarterly Report on Form 10-Q. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

OVERVIEW

We are a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for cancer and serious conditions related to men's health. Our lead drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens, two essential classes of hormones. We have four clinical programs. We are developing ACAPODENE® (toremifene citrate), a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: (1) a pivotal Phase III clinical trial for the treatment of serious side effects of androgen deprivation therapy, or ADT, for advanced prostate cancer and (2) a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with the precancerous lesion called high grade prostatic intraepithelial neoplasia, or PIN. In our third clinical program, we are initially developing ostarine, a selective androgen receptor modulator, or SARM, for the treatment of acute muscle wasting conditions, such as burns. We plan to initiate a Phase II clinical trial for ostarine for this indication in the fourth quarter of 2005. We are also evaluating clinical development of ostarine for the treatment of chronic muscle wasting conditions, such as testosterone deficiency in aging men, or andropause. In our fourth clinical program, we and our partner, Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, are developing andarine, another one of our SARMs, for the treatment of weight loss from various types of cancer, which is known as cancer cachexia. We are working with Ortho Biotech to plan a Phase II clinical trial of andarine.

We plan to build a specialized sales and marketing capability to market our product candidates directly to the relatively small and concentrated community of urologists and medical oncologists in the United States and to seek partners to commercialize our product candidates outside the United States and to broader target physician markets.

We currently market FARESTON (toremifene citrate 60 mg) tablets, which have been approved by the U.S. Food and Drug Administration, or FDA, for the treatment of metastatic breast cancer in post-menopausal women in the United States. The active pharmaceutical ingredient in FARESTON is the

same as in ACAPODENE, but at a different dose. In January 2005, we acquired from Orion Corporation the right to market FARESTON tablets in the United States for the prevention and treatment of breast cancer. We also acquired a license to toremifene, the active pharmaceutical ingredient in FARESTON and ACAPODENE, for all indications worldwide, except breast cancer outside of the United States.

In addition, we have an extensive preclinical pipeline generated from our own discovery program, which includes the specific product candidate prostarine, a SARM for benign prostatic hyperplasia (BPH), and andromustine, an anticancer drug candidate, for the treatment of hormone refractory prostate cancer.

In November 2003, we initiated a randomized, double-blind, placebo-controlled pivotal Phase III clinical trial of orally-administered ACAPODENE in patients undergoing androgen deprivation therapy for advanced, recurrent or metastatic prostate cancer under a Special Protocol Assessment, or SPA, with the FDA that provides that this clinical trial should serve as an adequate basis for the submission of the effectiveness portion of a New Drug Application, or NDA. An 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. If agreement is reached with the FDA, an SPA documents the terms and conditions under which the design of the subject trial will be adequate for submission of the effectiveness portion of an NDA. In this clinical trial, approximately 1,300 patients with advanced, recurrent or metastatic prostate cancer who have been receiving androgen deprivation therapy for at least six months and who either have significant existing bone loss or are greater than 70 years of age have been randomized to receive for 24 months either a daily dose of 80 mg of ACAPODENE or placebo. The primary endpoint is the incidence of vertebral skeletal fractures measured by x-ray. The secondary endpoints include bone mineral density, hot flashes, gynecomastia and lipid changes. Over 100 clinical sites across the United States and Mexico are participating in this clinical trial. We reached our patient enrollment goal, and in the fourth quarter of 2005, we plan to conduct an interim analysis of the measurement of bone mineral density, a secondary endpoint, in approximately the first 200 patients to complete one year of this clinical trial. We expect that the last patient will complete this clinical trial in the second half of 2007.

In January 2005, we initiated a randomized, double-blind, placebo-controlled pivotal Phase III clinical trial of orally administered ACAPODENE for the prevention of prostate cancer in men with high grade PIN. Over 100 clinical sites across the United States and Canada are participating in this clinical trial. Approximately 1,260 patients with high grade PIN are being randomized to receive either a daily dose of 20 mg of ACAPODENE or placebo. Only patients who have confirmed high grade PIN and a prostate biopsy that excludes cancer in the past six months are eligible to participate. The primary endpoint is the incidence of prostate cancer. We expect to complete patient enrollment in the first quarter of 2006.

In September 2005, we received a Special Protocol Assessment from the FDA for the PIN trial. The timing of analysis of efficacy endpoints for this trial is event driven. We anticipate conducting an efficacy analysis within 24 months of completion of enrollment. Once we have achieved the efficacy endpoint, we plan to file a New Drug Application. We anticipate that we will collect sufficient safety data required under the SPA during the application review process. Enrollment in the trial is on schedule for completion during the first quarter of 2006.

During 2004 and 2005, we entered into separate agreements with diagnostic companies, Hybritech, Inc., diaDexus, Inc., Tessara, Inc., and MacroArray, Inc., to provide clinical samples to each party from our clinical trials of ACAPODENE. We believe that the opportunity now exists to develop a test for high grade PIN and/or prostate cancer. By continuing to collaborate with leading diagnostic labs, we hope to have a urine or blood test developed to detect high grade PIN in the millions of American men who unknowingly harbor this precancerous prostate lesion.

In the third quarter, we completed a second Phase I clinical trial for ostarine and are now able to select doses to advance into Phase II clinical studies. We expect to initiate Phase II clinical testing of ostarine for the treatment of acute muscle wasting associated with burns in the fourth quarter of 2005. We are also evaluating clinical development of ostarine for the treatment of chronic muscle wasting in aging men, known as andropause.

In March 2004, we entered into a joint collaboration and license agreement with Ortho Biotech for andarine for indications related to men's health and other licensed SARM compounds meeting specified criteria which Ortho Biotech may ultimately choose to develop instead of, or in addition to, andarine. We retain the right to independently develop specific SARM compounds which are excluded from the collaboration, including ostarine. Under the terms of the agreement, we received an up-front licensing fee and reimbursement of certain andarine development expenses totaling approximately $6,687, which is being amortized into revenue over five years. We are entitled to receive additional licensing fees and milestone payments prior to product launch of (1) up to an aggregate of $76,000 for licensed products containing andarine or any replacement compound, and (2) up to $45,000 for each licensed product containing any other compound developed under the agreement, upon achievement of specific clinical development milestones or receipt of regulatory approvals. Johnson & Johnson Pharmaceutical Research & Development, an affiliate of Ortho Biotech, is responsible for further clinical development and related expenses for andarine and other licensed SARM compounds. If a licensed product containing andarine or any other SARM compound is approved for commercial sale, Ortho Biotech will have full and exclusive decision-making authority for marketing such product in the United States and in markets outside the United States. Under the agreement, we have the option, subject to meeting specified conditions, to co-promote andarine and other licensed products to urologists in the United States for indications specifically related to men's health. Ortho Biotech is obligated to pay us up to double digit royalties on worldwide net sales of andarine and other licensed products, and an additional royalty in excess of 20% on all co-promoted net sales to urologists in the United States.

Our net loss for the nine month period ended September 30, 2005 was $29,043. Our net loss included FARESTON net product sales of $2,133 and the recognition of collaboration revenue of $1,003 for the nine months ended September 30, 2005. We have financed our operations and internal growth almost exclusively through private placements of preferred stock and our initial public offering. We recently completed an underwritten public offering of 6,325,000 shares of our common stock and received net cash proceeds of approximately $45,764. We expect to continue to incur net losses over the next several years as we continue our clinical development and research and development activities, apply for regulatory approvals, establish sales and marketing capabilities and expand our operations.

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 nine months ended September 30, 2005. 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, and quality assurance activities.

We expect that research and development expenditures will continue to increase during the remainder of the year and in subsequent years due to (1) the continuation of the pivotal Phase III clinical trial of ACAPODENE for the treatment of serious side effects of androgen deprivation therapy for advanced prostate cancer, (2) the continuation of the pivotal Phase III clinical trial of ACAPODENE for the prevention of prostate cancer in high risk men, (3) the continued clinical development of ostarine, (4) the continued development of other product candidates in the Company's SARM program that are not included in our collaboration with Ortho Biotech, including prostarine, (5) the continued preclinical

development of other drug candidates including andromustine, an anticancer drug, for hormone refractory prostate cancer and other research development efforts, and (6) the increase in research and development personnel. Under the terms of our collaboration with Ortho Biotech, Johnson & Johnson Pharmaceutical Research and Development will be responsible for future clinical development and expenses of andarine. We expect to expand the scope of our drug discovery and development programs in future periods, which may result in substantial increases in research and development expenses.

General and administrative expenses consist primarily of salaries and other related costs for personnel serving executive, finance, accounting, legal, human resources, information technology, public relations and marketing functions. Other costs include facility costs not otherwise included in research and development expense, travel expenses, insurance costs, marketing expenses, patent costs and professional fees for accounting and public relations services. We expect that our general and administrative expenses will increase as we add personnel, facilities and infrastructures to support the planned growth of our business as well as additional expenses associated with operating as a public company.

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 for interim financial information. 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 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, 2004 filed with the SEC, we believe that the following accounting policies are most critical to aid you in fully understanding and evaluating our reported financial results.

Revenue Recognition

We use revenue recognition criteria outlined in Staff Accounting Bulletin No. 101, *"Revenue Recognition in Financial Statements"* and EITF Issue 00-21, *"Revenue Arrangements with Multiple Deliverables"*. Accordingly, revenues from licensing agreements are recognized based on the performance requirements of the agreement. Non-refundable up-front fees, where we have an ongoing involvement or performance obligation, are generally recorded as deferred revenue in the balance sheet and amortized into collaboration revenue in the statement of operations over the term of the performance obligation. We estimated the performance obligation period to be five years for the development of andarine. 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 continue to monitor these factors for indications of appropriate revisions.

Revenues derived from reimbursements of costs associated with the development of andarine are recorded in compliance with EITF Issue 99-19, *"Reporting Revenue Gross as a Principal Versus Net as an Agent"* ("EITF 99-19"). According to the criteria established by EITF 99-19, in transactions where we act as a principal, have discretion to choose suppliers, bear credit risk and perform part of the services required in the transaction, we have met the criteria to record revenue for the gross amount of the reimbursements.

Net product sales revenue represents gross revenue from the sale of FARESTON less deductions for estimated sales rebates, sales discounts and sales returns.

Research and Development Costs

We expense research and development costs in the period in which they are incurred. These costs consist of direct and indirect costs associated with specific projects as well as fees paid to various entities that perform research and clinical trial studies on our behalf.

Patent Costs

We expense patent costs, including legal expenses, in the period in which they are incurred. Patent expenses are included in general and administrative expenses in our condensed statements of operations.

Stock Compensation

Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB No. 25"), and its related interpretations are applied to measure compensation expense for stock-based compensation plans. We comply with the disclosure provisions of Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation (*"SFAS No. 123"), as amended by SFAS No. 148, *Accounting for Stock-Based Compensation, Transition and Disclosure*. Under APB No. 25, unearned stock compensation is based on the difference, if any, on the date of grant, between the fair value of our common stock and the exercise price of the related option.

Deferred Stock Compensation

In anticipation of our initial public offering on February 6, 2004, we determined that, for financial reporting purposes, the estimated value of our common stock was in excess of the exercise price for stock options issued to employees from June 30, 2003 to December 31, 2003. Accordingly, we recorded non-cash deferred stock-based compensation expense of $4,055 in 2003, and are amortizing the related expense over the service period, which is generally five years. Deferred stock compensation for options granted to employees has been determined as the difference between the deemed fair value of our common stock for financial reporting purposes on the date such options were granted and the applicable exercise price. Such amount is included as a reduction of stockholders' equity and is being amortized on a straight-line basis.

Purchased Intangible Assets

We account for our purchased intangible assets in accordance with Statement of Financial Accounting Standards ("SFAS") No. 142, *Goodwill and Other Intangible Assets*, which requires that purchased intangible assets with finite lives be amortized over their estimated economic lives. Our purchased intangible asset, a license fee, represents a license fee paid to Orion in connection with entering into an Amended and Restated License and Supply Agreement. The license fee is being amortized on a

straight-line basis over the term of the agreement which we estimate to be 16 years. Other purchased intangible assets represent the costs incurred to acquire software used by us. We amortize the cost of purchased software on a straight-line basis over the estimated useful lives of the software, generally three years. We use a discounted cash flow model to value our license fee. The discounted cash flow model requires assumptions about the timing and amount of future cash inflows and outflows, risk, and the cost of capital. Each of these factors can significantly affect the value of the license fee. We review our license fee for impairment on a periodic basis using an undiscounted net cash flows approach. If the undiscounted cash flows of our license fee are less than its carrying value, it is written down to the discounted cash flow value. If we are unsuccessful in obtaining regulatory approval for ACAPODENE, we may not be able to recover the carrying amount of our license fee.

Results of Operations

Three Months Ended September 30, 2005 and 2004

Revenues

Revenues for the three months ended September 30, 2005 were $622 as compared to $377 for the same period of 2004. Revenues for the three months ended September 30, 2005 included net sales of FARESTON marketed for the treatment of metastatic breast cancer. During the three months ended September 30, 2005, FARESTON net sales were $288 while cost of goods sold was $185. Revenues also included collaboration income of $334 and $335 for the three months ended September 30, 2005 and 2004, respectively, from our partner Ortho Biotech for andarine, one of our proprietary SARM compounds. Revenues for the third quarter of 2004 also included $42 related to the reimbursement of andarine development costs received from Ortho Biotech.

Research and Development Expenses

Research and development expenses increased by $4,483 to $8,454 for the three months ended September 30, 2005 from $3,971 for the same period of 2004. The net increase in research and development expenses by program were as follows:

Program	Product Candidate/ Indication	Development Phase	Status	Increase (Decrease) (in thousands)
SERM	**ACAPODENE** Side effects of androgen deprivation therapy	Pivotal Phase III clinical trial	Phase III clinical trial, ongoing	$ 2,341
	ACAPODENE Prevention of prostate cancer in high risk men with precancerous prostate lesions	Pivotal Phase III clinical trial	Phase III clinical trial, ongoing	1,659
SARM	**Ostarine**			

Program	Product Candidate/ Indication	Development Phase	Status	Increase (Decrease) (in thousands)
	Muscle wasting associated with burns and andropause	Planning Phase II clinical trial	Phase I clinical trials completed; initial Phase II proof of concept and dose finding clinical trial planned for the fourth quarter of 2005	(801)
	Andarine			
	Cachexia from various types of cancer	Planning Phase II clinical trial	Four Phase I clinical trials completed	(11)
Other research and development		Preclinical	Preclinical studies, ongoing	1,295
Total increase in research and development expenses				$ 4,483

General and Administrative Expenses

General and administrative expenses increased during the three months ended September 30, 2005 to $2,271 from $1,801 for the three months ended September 30, 2004. The increase of $470 was primarily the result of increased personnel costs, insurance costs, patent costs, professional fees and other administrative costs to support our planned growth.

Interest Income

Interest income increased to $345 for the three months ended September 30, 2005 from $270 for the three months ended September 30, 2004. The increase was attributable to higher average interest rates and was partially offset by lower average cash and cash equivalents balances during the three months ended September 30, 2005, as compared to the same period in 2004.

Nine Months Ended September 30, 2005 and 2004

Revenues

Revenues for the nine months ended September 30, 2005 were $3,136 as compared to $1,523 for the same period of 2004. Revenues for the nine months ended September 30, 2005 included net sales of FARESTON marketed for the treatment of metastatic breast cancer. During the nine months ended September 30, 2005, FARESTON net sales were $2,133 while cost of goods sold was $1,350. Revenues also included collaboration income of $1,003 and $721 for the nine months ended September 30, 2005 and 2004, respectively, from our partner, Ortho Biotech for andarine, one of our proprietary SARM compounds. Revenues for the first nine months of 2004 also included $802 from the reimbursement of andarine development costs received from Ortho Biotech.

Research and Development Expenses

Research and development expenses increased by $11,813 to $24,419 for the nine months ended September 30, 2005 from $12,606 for the same period of 2004. The net increase in research and development expenses by program were as follows:

Program	Product Candidate/ Indication	Development Phase	Status	Increase (Decrease) (in thousands)
SERM	**ACAPODENE** Side effects of androgen deprivation therapy	Pivotal Phase III clinical trial	Phase III clinical trial, ongoing	$ 5,447
	ACAPODENE Prevention of prostate cancer in high risk men with precancerous prostate lesions	Pivotal Phase III clinical trial	Phase III clinical trial, ongoing	3,484
SARM	**Ostarine** Muscle wasting associated with burns and Andropause	Planning Phase II clinical trial	Phase I clinical trials completed; initial Phase II proof of concept and dose finding clinical trial planned for the fourth quarter of 2005	1,319
	Andarine Cachexia from various types of cancer	Planning Phase II clinical trial	Four Phase I clinical trials completed	(2,034)
Other research and development		Preclinical	Preclinical studies, ongoing	3,597
Total increase in research and development expenses				$ 11,813

General and Administrative Expenses

General and administrative expenses increased during the nine months ended September 30, 2005 to $7,433 from $5,014 for the nine months ended September 30, 2004. The increase of $2,419 was primarily the result of increased personnel costs, insurance costs, patent costs, medical education costs, professional fees and other administrative costs to support the Company’s planned growth, as well as additional expenses associated with operating as a public company.

Interest Income

Interest income increased to $1,023 for the nine months ended September 30, 2005 from $632 for the nine months ended September 30, 2004. The increase was primarily attributable to higher average interest rates and was partially offset by lower average cash and cash equivalents balances during the nine months ended September 30, 2005, as compared to the same period in 2004.

Adjustment to Preferred Stock Redemption Value

Our preferred stock was recorded at its redemption value. The per share redemption price was equal to the greater of liquidation value, which included accrued dividends, or the fair value calculated on an as-if converted to common stock basis. At December 31, 2003, the per share redemption value was determined based on the estimated projected midpoint of the range of our initial public offering price per common share of approximately $14.50 per share. At February 6, 2004, the date of the closing of the Company's IPO and automatic conversion of all outstanding preferred stock, and accrued dividends thereon, into common stock, the market price for our common stock was $12.90 per share. Prior to conversion into common stock, the carrying value of the preferred stock and accrued dividends was adjusted to reflect the per share redemption value on the date of conversion resulting in a decrease in the carrying value of preferred stock of $17,125 and an offsetting increase in net income attributable to common stockholders.

Liquidity and Capital Resources

At September 30, 2005, we had cash and cash equivalents of $37,808, compared to $64,528 at December 31, 2004. Net cash used in operating activities was $25,554 and $9,049 for the nine months ended September 30, 2005 and 2004, respectively. The use of cash in both periods resulted primarily from funding our net losses. The net cash used in operating activities for the nine months ended September 30, 2004 was partially offset by the up-front licensing fee and reimbursement of development expenses received from Ortho Biotech. Net cash used in investing activities was $1,171 and $1,028 for the nine months ended September 30, 2005 and 2004, respectively. Net cash used in investing activities for the nine months ended September 30, 2005 was primarily for the purchase of research and development equipment, computer equipment, software, furniture and fixtures and leasehold improvements. Net cash used in investing activities for the nine months ended September 30, 2004 related primarily to the purchase of research and development equipment, computer equipment and software. We currently expect to make expenditures for capital equipment, software and leasehold improvements of approximately $300 for the remaining three months of 2005.

Net cash provided by financing activities was $5 for the nine month period ended September 30, 2005 and related to proceeds from the exercise of employee stock options offset by principal payments under a capital lease obligation. Net cash provided by financing activities for the nine months ended September 30, 2004 was $71,403 which represented the proceeds net of underwriting discounts and offering expenses from our initial public offering, which closed in February 2004.

On October 17, 2005, we sold 6,325,000 shares of our common stock in an underwritten public offering resulting in proceeds net of underwriting discounts and offering expenses of approximately $45,764. All of the shares were sold pursuant to our effective shelf registration statement filed with the Securities and Exchange Commission on August 4, 2005.

We estimate that our current cash resources, including the net proceeds from the sale of 6,325,000 shares of our common stock in our recent public offering, interest on these funds, and product revenue from the sale of FARESTON will be sufficient to meet our projected operating requirements through the first half of 2007. This estimate includes a milestone payment that we anticipate receiving from Ortho Biotech upon initiation of our Phase II clinical trial for andarine but does not include funding from other milestone payments that we may receive under our existing collaboration, potential future collaboration agreements with pharmaceutical companies, or the potential future issuance and sale 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 below

under the heading “Additional Factors That May Affect Future Results.” 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 product sales, 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 clinical trials and other research and development activities;
- future clinical trial results;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- potential future licensing fees, milestone payments and royalty payments;
- the cost and timing of expanding sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we 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 financing or corporate collaboration and licensing arrangements, such as our arrangement with Ortho Biotech, as well as through interest income earned on cash balances. With the exception of payments that we may receive under our collaboration with Ortho Biotech, 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 arrangement with Ortho Biotech, 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.

Additional Factors That May Affect Future Results

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.

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 September 30, 2005, we had an accumulated deficit of $186,473, of which $96,281 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 $22,348 in 2004, $14,194 in 2003 and $11,866 in 2002. For the nine months ended September 30, 2005, net losses were $29,043 . 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 financed our operations and internal growth almost exclusively through sales of common stock and preferred stock. In addition, we received an upfront license fee from Ortho Biotech in March 2004 for our joint collaboration for the development and commercialization of andarine and other licensed SARM compounds that Ortho Biotech may choose to develop. FARESTON is currently our only commercial product and, we expect, will account for all of our product revenue for the foreseeable future. For the nine months ended September 30, 2005, we recognized approximately $2,133 in net revenues from the sale of FARESTON.

We expect our research and development expenses to increase in connection with our conduct of clinical trials. In addition, 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 the first half of 2007. This estimate includes a milestone payment we will receive from Ortho Biotech upon initiation of our Phase II clinical trial for andarine but does not include funding from other milestone payments that we may receive under our existing collaboration, potential future collaboration agreements with pharmaceutical companies, or the potential future issuance and sale of our securities.

Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- future clinical trial results;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- potential future licensing fees, milestone payments and royalty payments;
- 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 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 corporate collaboration and licensing arrangements, such as our collaboration with Ortho Biotech, as well as through interest income earned on cash balances.

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 or licensing arrangements with third parties, it will be necessary to relinquish some rights to our technologies or our product candidates, or we may be required to grant licenses on terms that may not be 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 our 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. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent our ability to commercialize our product candidates, including:

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

If any of these events were to occur and, as a result, we 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.

Risks Related to Our Dependence on Third Parties

If third parties do not manufacture our product candidates in sufficient quantities 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 our worldwide requirements of toremifene, the active pharmaceutical ingredient in ACAPODENE, in finished tablet form at specified transfer prices under a license and supply agreement. We rely on Orion as a single source supplier for ACAPODENE. In the event that Orion terminates the agreement due to our uncured material breach or bankruptcy, we would not be able to manufacture ACAPODENE until Orion's patents with respect to the composition of matter of toremifene, the active pharmaceutical ingredient in ACAPODENE, expire. This could delay the development of and impair our ability to commercialize ACAPODENE. In addition, Orion may terminate its obligation to supply us with toremifene if Orion ceases its manufacture of toremifene permanently, or if ACAPODENE is not approved for commercial sale in the United States by 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 will have the right to manufacture ACAPODENE, but we would be required to make arrangements with a qualified alternative supplier and obtain FDA approval of such supplier to do so.

We also rely on Orion to cooperate with us in the filing and maintenance of regulatory filings with

respect to the manufacture of ACAPODENE. Orion may terminate its obligation to assist us in obtaining and maintaining regulatory approval of ACAPODENE if we do not receive regulatory approval for ACAPODENE by 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 ACAPODENE.

We have not entered into an agreement for supply of andarine or ostarine. Under our joint collaboration and license agreement with Ortho Biotech, Ortho Biotech is responsible for the manufacture, packaging and supply of andarine for both clinical trials and commercialization. We previously relied on EaglePicher Pharmaceutical Services, a division of EaglePicher Technologies, LLC, which has filed for protection under the bankruptcy code, as our single supplier of ostarine for clinical use. We are seeking to transfer the manufacturing process for ostarine from EaglePicher to a new contract manufacturer, which is expected to occur by the first half of 2006. Metrics, Inc. packaged and supplied ostarine to our Phase I clinical trial sites and will also supply our planned Phase II trials. In the event that our current supply of ostarine is not sufficient to complete our planned Phase II clinical trials, or if we are unsuccessful in identifying a contract manufacturer or negotiating a manufacturing agreement on a timely basis or at all, we could experience a delay in receiving an adequate supply of ostarine for use in our clinical trials.

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 ACAPODENE and EaglePicher or Ortho Biotech for andarine, or to do so at an acceptable cost, or if these or other suppliers fail to meet our requirements for these product candidates or for ostarine for any reason, we would be required to obtain alternate suppliers. However, we may not be permitted to obtain alternate suppliers for ACAPODENE under our license agreement with Orion if Orion terminates its supply of ACAPODENE due to our uncured material breach or bankruptcy. Any inability to obtain alternate suppliers, including an inability to obtain approval of an alternate supplier from the FDA, 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;
- 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 ACAPODENE prior to December 31, 2009; and
- 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 may develop may compete with other product candidates and products for access to manufacturing facilities. For example, the active pharmaceutical ingredient in ACAPODENE is also the active pharmaceutical ingredient in FARESTON. Orion also manufactures toremifene for third parties for sale outside the United States for the treatment of advanced breast cancer in post-menopausal 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.

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 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.

We are dependent on our collaborative arrangement with Ortho Biotech to develop and commercialize andarine, and we may 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 of our product candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

Any loss of Ortho Biotech as a collaborator in the development or commercialization of andarine, dispute over the terms of the collaboration or other adverse development in our relationship with Ortho Biotech could materially harm our business and might accelerate our need for additional capital.

We may not be successful in entering into additional collaborative arrangements with 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 product candidates and could increase our costs of development and commercialization.

Dependence on collaborative arrangements, including our arrangement with Ortho Biotech for the development of andarine, subjects us to a number of risks, including:

- we may not be able to control the amount and timing of resources that our partners may devote to the product candidates;
- our partners may experience financial difficulties;
- we may be required to relinquish important rights such as marketing and distribution rights;

- should a collaborator fail to develop or commercialize one of our compounds or product candidates, we may not receive any future milestone payments and will not receive any royalties for this 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;
- a collaborator could move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- the collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing 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 ACAPODENE for human uses of toremifene outside the United States.

Our exclusive license 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 to modify our final ACAPODENE 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 development plans adversely affect these activities, any future modifications to our plans imposed by Orion may limit our ability to maximize the commercial potential of ACAPODENE.

Furthermore, we and our affiliates are prohibited from marketing or selling products containing toremifene or related SERM compounds for human use (1) 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 and (2) in major countries in the European Union through October 2006, other than in the dosage forms or formulations which are, or may in the future be, manufactured by Orion under our agreement with Orion. 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 estopped 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. Our rights to specified 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 license with The Ohio State University, or OSU, and our rights to future related improvements are subject to UTRF's exercise of an exclusive option under its agreement with OSU for such improvements, which UTRF can exercise at no additional cost to it. In addition, under the terms of our agreements with the diagnostic companies to which we provide clinical samples from our Phase IIb clinical trial of ACAPODENE, 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 in the product 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 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 commercialize ACAPODENE. 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 ACAPODENE for the relevant product indications that have been issued or may be issued from our owned or licensed patent applications. To date, most of our applications for method of use patents filed for ACAPODENE outside of the United States are still pending and have not yielded issued patents. Although we intend to apply, if appropriate, for regulatory market exclusivity and extensions of patent term under applicable European and United States laws, we might not be able to secure any such regulatory exclusivity or extension of patent term. We are not eligible for any such exclusivity or further extension of the composition of matter patent of toremifene in the United States.

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 noninfringing versions of a patented product in order to facilitate the approval of abbreviated new drug applications for generic substitutes. These same types of incentives encourage competitors to submit new drug applications that rely on literature and clinical data not prepared for or by the drug sponsor, providing another less burdensome pathway to approval.

We also rely on trade secrets to protect our technology, especially where we do not believe that patent

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

Off-label sale or use of toremifene products could decrease our sales of ACAPODENE 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 are developing ACAPODENE.

In all countries in which we hold or have licensed rights to patents or patent applications related to ACAPODENE, 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 ACAPODENE from the risk of off-label sale or use of other toremifene products in place of ACAPODENE. 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 ability to generate revenue from the sale of ACAPODENE, 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 toremifene products would not have been approved for those uses, and in most cases the competitor would not be liable for infringing 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 ACAPODENE for the indications for which we 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 ACAPODENE, 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 ACAPODENE for the indications covered by our pending method of use patent applications.

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 and development 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, commercialization, formulation or use of our product candidates. In addition, the production, manufacture, commercialization, formulation or use of our product candidates may infringe existing patents of which we are not aware. Defending ourselves against third-party claims, including litigation in particular, would be costly and time consuming and would divert management's attention from our business, which could lead to delays in our development or commercialization efforts. If third parties are successful in their claims, we might have to pay substantial damages or take other actions that are adverse to our business.

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

- be prohibited from selling or licensing any product that we 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.

Risk Related to Regulatory Approval of Our Product Candidates

If we are not able to obtain required regulatory approvals, we 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, and 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 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. 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. Even if the FDA approves a product candidate, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product, and may impose ongoing requirements for post-approval studies, including additional research and development and clinical trials. The 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 believe that if the results of our ongoing Phase III clinical trial of ACAPODENE for the reduction in the incidence of prostate cancer in men with high grade PIN are sufficiently positive, that trial will be sufficient to serve as a single pivotal Phase III clinical trial for this indication. In September 2005, we received a Special Protocol Assessment from the FDA. An 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. If agreement is reached with the FDA, an SPA documents the terms and conditions under which the design of the subject trial will be adequate for submission of the effectiveness portion of an NDA. However, there are circumstances under which we may not receive the benefits of the SPA, notably including 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 do not expect to receive regulatory approval for the commercial sale of any of our product candidates that are in development for the next few years. The inability to obtain FDA approval or approval from comparable authorities in other countries for such candidates would prevent us from commercializing our product candidates in the United States or other countries. See the section entitled "Business — Government Regulation" in our Annual Report on Form 10-K, as amended, filed with the Securities and Exchange Commission, for additional information regarding risks associated with approval, as well as risks related to post-approval requirements.

Risks Related to Commercialization

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

Any products that we 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, 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:

- 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. FARESTON is subject to a number of risks that may cause sales of FARESTON to continue to decline.

FARESTON is currently our only marketed product generating sales. Sales of FARESTON in the United States have been declining. Continued sales of FARESTON could be impacted by many factors. The occurrence of one or more of the following risks may cause sales of FARESTON to decline:

- 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 accounted for approximately 95% of our revenue generated from the sale of FARESTON for the nine months ended September 30, 2005;
- 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 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.

If we are unable to expand our sales and marketing capabilities or enter into 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. 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 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 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 may develop, our revenues and prospects for profitability may suffer. In December 2003, the President of the United States signed into law the Medicare Prescription Drug, Improvement and Modernization Act of 2003, legislation creating a prescription drug benefit program for Medicare recipients. The prescription drug program established by the legislation may have the effect of reducing the prices that we are able to charge for products we develop and sell through the program. This prescription drug 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 may develop or to lower the amount that they pay.

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 approval for a product. To obtain reimbursement or pricing approval in some countries, we 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 commercialization. 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 may develop or products we sell. Cost-control initiatives could decrease the price we might establish for products that we may develop or that we sell, which would result in lower product revenues 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 receive for any products that we may develop, negatively affecting our revenues and prospects for profitability.

If product liability lawsuits are brought against us, we will 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 approvals.

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

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

We face competition from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we 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 ability to commercialize our product candidates.

Various products are currently marketed or sold and 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. The occurrence of such off-label uses could significantly reduce our ability to market and sell any products that we may develop. For example, although there are no products that have been approved by the FDA to treat multiple side effects of advanced prostate cancer therapy, we are aware of a number of drugs marketed by Eli Lilly, Merck, Aventis, Proctor & Gamble, Wyeth Pharmaceuticals, Boehringer and Bristol Myers Squibb that are prescribed off-label to treat single side effects of this therapy, that external beam radiation is used to treat breast pain and enlargement and that Amgen Inc. may be developing a product candidate for the treatment of bone loss in post-cancer patients. Similarly, while there are no drugs that have been approved by the FDA for the treatment of muscle wasting weight loss 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 weight loss from cancer. Testosterone and other anabolic agents are used to treat involuntary weight loss in patients who have acute muscle wasting. In addition, there may be product candidates of which we are not aware at an earlier stage of development that may compete with our product candidates. If any are successfully developed and approved, they could compete directly with our product candidates. 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 $15 million of insurance covering Dr. Steiner.

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

In order to continue our clinical trials and commercialize our product candidates, we will need to expand the number of our managerial, operational, financial and other employees. We currently anticipate that we will need between 150 and 250 additional employees by the time that ACAPODENE or ostarine is initially commercialized, including 50 to 80 sales representatives. While to date we have not experienced difficulties in recruiting and hiring qualified individuals, 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 highly volatile 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 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;
- 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;
- actual or anticipated fluctuations in our results of operation;
- 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 will maintain the ability to control all matters submitted to stockholders for approval.

As of September 30, 2005, our officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 79% of our outstanding common stock. As a result, these stockholders, acting together, will be able to control all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders.

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

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

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

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

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 October 31, 2005, the average daily trading volume of our common stock on the Nasdaq National Market was less than 46,579 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 November 4, 2005, we had 30,992,550 shares of common stock outstanding.

In connection with our recent underwritten public offering, all of our executive officers and directors and their affiliated entities have entered into lock-up agreements with the underwriters of the offering. As a result of these lock-up agreements, approximately 18.4 million shares are subject to contractual restriction on resale through January 9, 2006.

The market price for shares of our common stock may drop significantly if stockholders subject to the lock-up agreements sell a substantial number of shares when the restrictions on resale lapse, or if the underwriters waive the lock-up agreements and allow the stockholders to sell some or all of their shares. Based on information currently available to us, all of the shares of our common stock currently outstanding will be eligible for sale in the public market following expiration of the lock-up agreements described above, subject in some cases to volume and other limitations under federal securities laws.

Moreover, J.R. Hyde, III, Oracle Partners, L.P. and Memphis Biomed Ventures I, L.P., three of our largest stockholders, and their affiliates, have rights, subject to some conditions, to require us to file registration statements covering the approximately 11.1 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. Additionally, 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 3 QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk for changes in interest rates relates to our cash equivalents on deposit in highly liquid money market funds. The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. We do not use derivative financial instruments in our investment portfolio. Our cash and investments policy emphasizes liquidity and preservation of principal over other portfolio considerations. Due to the short-term nature of our investments, we believe that there is no material exposure to interest rate risk.

We operate primarily in the United States. Through September 30, 2005, we have not had any material exposure to foreign currency rate fluctuations. Our exposure to foreign currency rate fluctuations results from our obligation to pay Orion Corporation, our supplier of ACAPODENE and FARESTON, in Euros. We do not currently use derivative financial instruments to mitigate this exposure. However, we do not expect fluctuations in foreign currency rates to have a material impact on our financial condition or results of operations.

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 that are designed to ensure that information required to be disclosed

in the reports that we file or submit under the Securities and Exchange Act of 1934 is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosures.

We have carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934) as of the end of the period covered by this report. Based on the evaluation of these disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective.

There were no significant changes to our internal control over financial reporting during the third quarter of 2005 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system are met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of future events. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

As indicated on the cover page of this report, we are not currently an "accelerated filer" within the meaning of Rule 12b-2 under the Securities and Exchange Act of 1934. However, based on our market capitalization as of June 30, 2005, we will be required, beginning with our Annual Report on Form 10-K for the year ending December 31, 2005, to provide annual management assessments of the effectiveness of our internal control over financial reporting and a report by our independent registered public accounting firm attesting to and reporting on these assessments in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 and the rules and regulations of the SEC. If we determine that we do not have adequate internal control over financial reporting, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404. If we cannot favorably assess, or our independent registered public accountants are unable to provide an unqualified attestation report on management's assessment of, and on, the effectiveness of our internal control over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on our stock price.

PART II: OTHER INFORMATION

ITEM 2 UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Our common stock began trading on The Nasdaq National Market under the trading symbol “GTXI” on February 3, 2004. We sold 5,400,000 shares of common stock in our initial public offering at $14.50 per share. Our Registration Statement on Form S-1 (333-109700) was declared effective by the SEC on February 2, 2004. The offering terminated after the sale of all of the securities registered on the registration statement and the expiration of the underwriters’ over-allotment option. After deducting the underwriting discounts and the offering expenses, the Company received net proceeds of $70,365. From the time of receipt through September 30, 2005, we had invested the available net proceeds in short-term securities. In addition, approximately $39,960 of the proceeds were used to fund our operations through September 30, 2005 and approximately $2,319 of the proceeds were used for capital expenditures and $4,826 of the proceeds were used to acquire a license from Orion Corporation. We plan to use the balance of the proceeds to fund our clinical trials and other research and development activities and for general corporate purposes. In addition, we may use a portion of the proceeds to acquire products, technologies or businesses, although we currently have no binding commitments or agreements relating to any of these types of transactions.

ITEM 6. EXHIBITS

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

SIGNATURES

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

GTx, Inc.

Date: November 4, 2005

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

Date: November 4, 2005

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

EXHIBIT INDEX

Number	Description
3.1	Restated Certificate of Incorporation of GTx, Inc.(1)
3.2	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	Amended and Restated Registration Rights Agreement between Registrant and Memphis Biomed Ventures dated August 7, 2003(3)
10.29	Compensation Information for Named Executive Officers, effective as of July 1, 2005(4)
10.30	Employment Agreement dated August 26, 2005, between Registrant and K. Gary Barnette(5)
10.31	Employment Agreement dated August 26, 2005, between Registrant and Gregory A. Deener(6)
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 Exhibit 3.4 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.

(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 Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 000-50549), filed with the SEC on August 12, 2005, and incorporated herein by reference.

(5) Filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 000-50549), filed with the SEC on September 8, 2005, and incorporated herein by reference.

(6) Filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 000-50549), filed with the SEC on September 8, 2005, and incorporated herein by reference.

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

EXHIBIT 31.1

Chief Executive Officer Certification

I, Mitchell S. Steiner, certify that:

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

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

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

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

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

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

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

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

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

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

Dated: November 4, 2005

/s/ Mitchell S. Steiner

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

EXHIBIT 31.2

Chief Financial Officer Certification

I, Mark E. Mosteller, certify that:

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

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

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

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

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

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

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

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

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

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

Dated: November 4, 2005

/s/ Mark E. Mosteller

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

EXHIBIT 32.1

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

In connection with the Quarterly Report of GTx, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2005, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mitchell S. Steiner, Chief Executive Officer of the Company certify, pursuant to Rule 13a-14(b) or Rule 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

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

November 4, 2005

EXHIBIT 32.2

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

In connection with the Quarterly Report of GTx, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2005, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mark E. Mosteller, Chief Financial Officer of the Company certify, pursuant to Rule 13a-14(b) or Rule 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

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

November 4, 2005