

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, 2007

OR

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

For the transition period from _____ to _____

Commission file number: 000-50549

GTx, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

62-1715807

(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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer.

Large accelerated filer Accelerated filer Non-accelerated filer

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

As of November 8, 2007, 34,922,124 shares of the registrant's Common Stock were outstanding.

GTx, INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2007
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PART I: FINANCIAL INFORMATION**ITEM 1. FINANCIAL STATEMENTS**

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

	September 30, 2007 (unaudited)	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 90,944	\$ 119,550
Accounts receivable, net	124	61
Inventory	109	207
Prepaid expenses and other current assets	2,557	1,882
Total current assets	93,734	121,700
Property and equipment, net	1,506	1,448
Intangible assets, net	4,697	4,714
Other assets	710	1,393
Total assets	<u>\$ 100,647</u>	<u>\$ 129,255</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,312	\$ 1,336
Accrued expenses	4,196	3,149
Deferred revenue — current portion	5,852	5,852
Total current liabilities	11,360	10,337
Deferred revenue, less current portion	17,165	21,554
Capital lease obligation	11	15
Other long term liability	244	300
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 60,000,000 shares authorized; 34,922,124 shares issued and outstanding at September 30, 2007 and 34,822,362 shares issued and outstanding at December 31, 2006	35	35
Additional paid-in capital	329,180	326,793
Accumulated deficit	(257,348)	(229,779)
Total stockholders' equity	71,867	97,049
Total liabilities and stockholders' equity	<u>\$ 100,647</u>	<u>\$ 129,255</u>

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,	
	2007	2006	2007	2006
Revenues:				
Product sales, net	\$ 268	\$ 348	\$ 820	\$ 1,512
Collaboration revenue	1,463	724	4,389	1,393
Total revenue	<u>1,731</u>	<u>1,072</u>	<u>5,209</u>	<u>2,905</u>
Costs and expenses:				
Cost of product sales	148	118	463	755
Research and development expenses	9,881	9,614	26,463	26,499
General and administrative expenses	3,182	2,867	9,908	8,509
Total costs and expenses	<u>13,211</u>	<u>12,599</u>	<u>36,834</u>	<u>35,763</u>
Loss from operations	(11,480)	(11,527)	(31,625)	(32,858)
Interest income	1,238	638	4,056	2,061
Net loss	<u>\$ (10,242)</u>	<u>\$ (10,889)</u>	<u>\$ (27,569)</u>	<u>\$ (30,797)</u>
Net loss per share:				
Basic	<u>\$ (0.29)</u>	<u>\$ (0.35)</u>	<u>\$ (0.79)</u>	<u>\$ (0.99)</u>
Diluted	<u>\$ (0.29)</u>	<u>\$ (0.35)</u>	<u>\$ (0.79)</u>	<u>\$ (0.99)</u>
Weighted average shares used in computing net loss per share:				
Basic	<u>34,910,121</u>	<u>31,005,717</u>	<u>34,879,413</u>	<u>31,001,292</u>
Diluted	<u>34,910,121</u>	<u>31,005,717</u>	<u>34,879,413</u>	<u>31,001,292</u>

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,	
	2007	2006
Cash flows from operating activities:		
Net loss	\$ (27,569)	\$ (30,797)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	855	874
Share-based compensation	1,488	948
Directors' deferred compensation	128	105
Deferred revenue amortization	(4,389)	(1,393)
Foreign currency transaction (gain) loss	(102)	175
Changes in assets and liabilities:		
Accounts receivable, net	(63)	32
Inventory	98	(101)
Receivable from collaboration partner	660	(29,262)
Prepaid expenses and other assets	(550)	418
Accounts payable	(24)	(63)
Accrued expenses and other long term liability	991	796
Deferred revenue	—	29,259
Net cash used in operating activities	<u>(28,477)</u>	<u>(29,009)</u>
Cash flows from investing activities:		
Purchase of property and equipment	(518)	(308)
Purchase of intangible assets	(378)	(208)
Net cash used in investing activities	<u>(896)</u>	<u>(516)</u>
Cash flows from financing activities:		
Proceeds from exercise of employee stock options	771	66
Payments on capital lease obligation	(4)	(4)
Net cash provided by financing activities	<u>767</u>	<u>62</u>
Net decrease in cash and cash equivalents	(28,606)	(29,463)
Cash and cash equivalents, beginning of period	119,550	74,014
Cash and cash equivalents, end of period	<u>\$ 90,944</u>	<u>\$ 44,551</u>

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

GTx is developing ACAPODENE® (toremifene citrate), a selective estrogen receptor modulator (“SERM”) in two separate clinical programs in men: first, a pivotal Phase III clinical trial for the treatment of multiple serious side effects of androgen deprivation therapy (“ADT”) for advanced prostate cancer and second, a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia (“high grade PIN”). GTx has licensed to Ipsen Limited (“Ipsen”) exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein, and the Commonwealth of Independent States (collectively, the “European Territory”) to develop and commercialize ACAPODENE® and other products containing toremifene for all indications which we have licensed from Orion Corporation (“Orion”). GTx is also developing Ostarine™, a selective androgen receptor modulator (“SARM”) initially for the treatment of cancer wasting, which is known as cancer cachexia, and is conducting a Phase IIb clinical trial evaluating Ostarine™ for the treatment of cancer cachexia.

Basis of Presentation

The accompanying unaudited condensed financial statements reflect, in the opinion of management, all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation of GTx’s financial position, results of operations and cash flows for each period presented in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted from the accompanying condensed financial statements. These interim condensed financial statements should be read in conjunction with the audited financial statements and related notes thereto, which are included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2006. Operating results for the three and nine months ended September 30, 2007 are not necessarily indicative of the results that may be expected for the entire fiscal year ending December 31, 2007.

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

Use of Estimates

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

Revenue Recognition

The Company recognizes net product sales revenue from the sale of FARESTON® less deductions for estimated sales discounts and sales returns. Revenue from product sales is recognized when the goods are shipped and title and risk of loss pass to the customer and the other criteria outlined in Staff Accounting Bulletin (“SAB”) No. 101, *Revenue Recognition in Financial Statements* as amended by SAB No. 104 (together, “SAB No. 104”) and Statement of Financial Accounting Standards (“SFAS”) No. 48, *Revenue Recognition When Right of Return Exists* are satisfied. The Company accounts for rebates to certain governmental agencies as a reduction of product sales. The Company allows customers to return product within a specified time period prior to and subsequent to the product’s labeled expiration date. The Company estimates its accrual for product returns, which is recorded as a reduction of product sales, based on factors which include historical product returns and estimated product in the distribution channel which is expected to exceed its expiration date. At September 30, 2007 and December 31, 2006, the Company’s accrual for product returns was \$321 and \$415, respectively. If actual future results are different than the Company’s estimates, the Company may need to adjust its estimated accrual for product returns, which could have a material effect on revenues in the period of the adjustment.

Collaboration revenue consists of non-refundable up-front payments and license fees associated with the Company’s collaboration and license agreements discussed in Note 4. The Company recognizes revenue in accordance with SAB No. 104 and Emerging Issues Task Force 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 the Company has an ongoing involvement or performance obligation, are recorded as deferred revenue in the balance sheet and amortized as collaboration revenue in the condensed statements of operations over the term of the performance obligation.

Recent Accounting Pronouncements

In July 2006, the Financial Accounting Standards Board (“FASB”) issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes-an interpretation of FASB Statement No. 109* (“FIN 48”), which clarifies the accounting for uncertainty in tax positions. FIN 48 requires the recognition of the impact of a tax position in the condensed financial statements if that position is more likely than not of being sustained on audit based on the technical merits of the position. The provisions of FIN 48 were effective as of January 1, 2007. The adoption of the standard had no effect on the Company’s financial condition or results of operations.

GTx, Inc.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(in thousands, except share and per share data)
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In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ("SFAS 157"), which defines fair value, establishes a framework for measuring fair value under GAAP and expands disclosures about fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. The Company does not expect the adoption of SFAS 157 to have a material impact on its financial position or results of operations.

In June 2007, the Emerging Issues Task Force issued EITF Issue 07-03, *Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development* ("EITF 07-03"). EITF 07-03 concludes that nonrefundable advance payments for future research and development activities should be deferred and capitalized and recognized as expense as the related goods are delivered or the related services are performed. EITF 07-03 is effective for fiscal years beginning after December 15, 2007. The Company does not expect the adoption of EITF 07-03 to have a material impact on its financial position or results of operations.

2. Share-Based Compensation

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

Total share-based compensation expense for the three months ended September 30, 2007 was \$666, of which \$337 and \$329 were recorded in the condensed statements of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the nine months ended September 30, 2007 was \$1,616, of which \$763 and \$853 were recorded in the condensed statements of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the three months ended September 30, 2006 was \$362, of which \$131 and \$231 were recorded in the condensed statements of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the nine months ended September 30, 2006 was \$1,053, of which \$408 and \$645 were recorded in the condensed statements of operations as research and development expenses and general and administrative expenses, respectively. Included in share-based compensation expense for all periods presented is share-based compensation expense related to deferred compensation arrangements for the Company's directors which was \$53 and \$35 for the three months ended September 30, 2007 and 2006, respectively, and \$128 and \$105 for the nine months ended September 30, 2007 and 2006, respectively.

GTx, Inc.
NOTES TO CONDENSED FINANCIAL STATEMENTS
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The Company grants options to purchase common stock to certain employees and directors under various plans at prices equal to the market value of the stock on the dates the options are granted. The options have a term of ten years from the grant date and vest three years from the grant date for director options and in periods of up to five years from the grant date for employee options. Employees have 90 days after the employment relationship ends to exercise all vested options except in the case of retirement, permanent disability or death, where exercise periods are generally longer. The Company issues new shares of common stock upon the exercise of options. The fair value of each option grant is separately estimated for each vesting date. The fair value of each option is amortized into compensation expense on a straight-line basis between the grant date for the award and each vesting date. The Company estimates the fair value of certain stock option awards as of the date of the grant by applying the Black-Scholes-Merton option pricing valuation model. The application of this valuation model involves assumptions that are judgmental and highly sensitive in the determination of compensation expense. The weighted average for key assumptions used in determining the fair value of options granted for the periods presented and a summary of the methodology applied to develop each assumption are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Expected price volatility	50.2%	79.1%	50.6%	70.2%
Risk-free interest rate	5.0%	4.9%	4.7%	4.6%
Weighted average expected life in years	7.0	6.0	6.9	6.0
Dividend yield	0.0%	0.0%	0.0%	0.0%
Forfeiture rate	12.0%	12.0%	12.0%	12.0%

Expected Price Volatility — This is a measure of the amount by which a price has fluctuated or is expected to fluctuate. For the three and nine months ended September 30, 2007, the Company based its determination of expected volatility on its historical stock price volatility. For the three and nine months ended September 30, 2006, the Company used an average expected price volatility of other publicly traded biopharmaceutical companies because the Company believed that it was the best indicator of future volatility, since the Company had less than two years of its own historical stock price volatility. This change in estimate did not have a material effect on the Company's results from operations for the three and nine months ended September 30, 2007. An increase in the expected price volatility will increase compensation expense.

Risk-Free Interest Rate — This is the U.S. Treasury rate for the week of grant having a term approximating the expected life of the option. An increase in the risk-free interest rate will increase compensation expense.

Expected Life — This is the period of time over which the options granted are expected to remain outstanding and is determined by calculating the average of the vesting term and the contractual term of the options, as allowed by SAB No. 107. Options granted have a maximum term of ten years. An increase in the expected life will increase compensation expense.

GTx, Inc.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(in thousands, except share and per share data)
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Dividend Yield — The Company has not made any dividend payments nor does it have plans to pay dividends in the foreseeable future. An increase in the dividend yield will decrease compensation expense.

Forfeiture Rate — This is the estimated percentage of options granted that are expected to be forfeited or canceled before becoming fully vested. This estimate is based on historical experience. An increase in the forfeiture rate will decrease compensation expense.

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

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price Per Share</u>
Options outstanding at December 31, 2006	1,458,289	\$ 8.33
Options granted	547,167	18.32
Options forfeited	(36,500)	12.70
Options exercised	(99,762)	7.73
Options outstanding at September 30, 2007	<u>1,869,194</u>	11.20

3. Basic and Diluted Net Loss Per Share

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

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

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Basic net loss per share				
Numerator:				
Net loss	\$ (10,242)	\$ (10,889)	\$ (27,569)	\$ (30,797)
Denominator (weighted average shares):				
Common stock outstanding at beginning of period	34,890,371	31,005,717	34,822,362	30,993,967
Exercise of employee stock options	19,750	—	57,051	7,325
Weighted average shares used in computing basic net loss per share	34,910,121	31,005,717	34,879,413	31,001,292
Basic net loss per share	\$ (0.29)	\$ (0.35)	\$ (0.79)	\$ (0.99)
Diluted net loss per share				
Numerator:				
Net loss	\$ (10,242)	\$ (10,889)	\$ (27,569)	\$ (30,797)
Denominator (weighted average shares):				
Common stock outstanding at beginning of period	34,890,371	31,005,717	34,822,362	30,993,967
Exercise of employee stock options	19,750	—	57,051	7,325
Weighted average shares used in computing diluted net loss per share	34,910,121	31,005,717	34,879,413	31,001,292
Diluted net loss per share	\$ (0.29)	\$ (0.35)	\$ (0.79)	\$ (0.99)

Weighted average options outstanding to purchase shares of common stock of 1,876,943 and 1,468,589 for the three months ended September 30, 2007 and 2006, respectively, and 1,823,023 and 1,461,301 for the nine months ended September 30, 2007 and 2006, respectively, were excluded from the calculations of diluted net loss per share as inclusion of the options would have had an anti-dilutive effect on the net loss per share for the periods.

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

4. Collaboration and License Agreements

Ipsen Collaboration and License Agreement

In September 2006, the Company entered into a collaboration and license agreement with Ipsen pursuant to which the Company granted Ipsen exclusive rights in the European Territory to develop and commercialize ACAPODENE® and other products containing toremifene in all indications which the Company has licensed from Orion, which include all indications in humans except the treatment and prevention of breast cancer outside of the United States. In accordance with the terms of the license agreement, Ipsen agreed to pay the Company €23,000 as a license fee and expense reimbursement, of which €1,500 is to be paid in equal installments over a three year period from the date of the agreement. In October 2006, the Company received €21,500 (approximately \$27,100) from Ipsen as the initial payment for the license fee and expense reimbursement. In September 2007, the Company received €500 (approximately \$688) from Ipsen as the first annual installment payment. Pursuant to the agreement, GTx is also entitled to receive from Ipsen up to an aggregate of €39,000 in milestone payments depending on the successful development and launch of ACAPODENE® in certain countries of the European Territory for the high grade PIN indication, subject to certain conditions, and the ADT indication. Ipsen has agreed to be responsible for and to pay all clinical development, regulatory and launch activities to commercialize ACAPODENE® in the European Territory for both the high grade PIN indication and ADT indication. Ipsen has agreed to pay the Company a royalty equal to a graduating percentage of aggregate net sales of products containing toremifene (including ACAPODENE®) which rates will be dependent on whether such sales are for the high grade PIN indication or the ADT indication. The Company will remain responsible for paying upstream royalties on ACAPODENE® to both Orion and the University of Tennessee Research Foundation (“UTRF”) for the PIN indication and to Orion only for the ADT indication. Ipsen will purchase the bulk drug product supply directly from Orion and is responsible for the packaging and labeling of the final product.

The Company recorded deferred revenue of \$29,259 related to the Ipsen up-front license fee and expense reimbursement which is expected to be amortized into revenue on a straight-line basis over the estimated five year development period for ACAPODENE® in the European Territory. The Company recognized collaboration revenue of \$1,463 and \$4,389 for the three and nine months ended September 30, 2007, respectively, from the amortization of the Ipsen deferred revenue. The Company recognized \$390 of collaboration revenue for the three and nine months ended September 30, 2006 from the amortization of the Ipsen deferred revenue.

Ortho Biotech Collaboration and License Agreement

In March 2004, the Company entered into a joint collaboration and license agreement with Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson (“Ortho Biotech”) for andarine and specified backup SARM compounds. Under the terms of the agreement, the Company received in April 2004 an up-front licensing fee and expense reimbursement totaling \$6,687. The up-front licensing fee and expense reimbursement were deferred and amortized into revenue on a straight-line basis over the estimated five year andarine development period. The Company recognized revenue of \$334 and \$1,003 for the three and nine months ended September 30, 2006, respectively, from the amortization of the up-front license fee and expense reimbursement. In December 2006, the Company reacquired full rights to develop and commercialize andarine and all backup compounds previously licensed to Ortho Biotech and

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

the joint collaboration and license agreement was terminated by mutual agreement of the parties. In connection with the termination of the Ortho Biotech agreement, the Company recognized the associated \$3,100 balance of deferred revenue as additional collaboration revenue for the year ended December 31, 2006. Accordingly, the Company did not recognize any collaboration revenue for the three and nine months ended September 30, 2007 with respect to the Ortho Biotech deferred revenue.

5. Subsequent Events

Merck Collaboration and License Agreement

On November 5, 2007, GTx and Merck & Co., Inc. (“Merck”) entered into a global Exclusive License and Collaboration Agreement (the “Collaboration Agreement”) governing the Company’s and Merck’s joint research, development and commercialization of SARM compounds and related SARM products, including SARMS currently being developed by the Company and Merck and those yet to be discovered, for all potential indications of interest. The Collaboration Agreement will become effective upon the satisfaction of certain conditions, including the expiration or earlier termination of all waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1974, as amended. The closing of the transactions contemplated by the Stock Purchase Agreement described below is also a condition to the effectiveness of the Collaboration Agreement.

Under the Collaboration Agreement, the Company will grant Merck an exclusive worldwide license under its SARM-related patents and know-how. Following the effectiveness of the Collaboration Agreement, the Company will conduct preclinical research of SARM compounds and products, and Merck will be responsible for conducting and funding development and commercialization of products developed under the Collaboration Agreement. Merck has agreed to pay the Company an upfront licensing fee of \$40,000 and \$15,000 in guaranteed three-year cost reimbursements for research funding. The Company is also eligible to receive under the Collaboration Agreement up to \$422,000 in future milestone payments associated with the development and regulatory approval of a lead product candidate, including Ostarine™, as defined in the Collaboration Agreement, if multiple indications are developed and receive required regulatory approvals, as well as additional milestone payments for the development and regulatory approval of other product candidates developed under the Collaboration Agreement. Merck has also agreed to pay the Company tiered royalties on net sales of products that may be developed under the Collaboration Agreement.

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

Merck Stock Purchase Agreement

On November 5, 2007, the Company and Merck entered into a Stock Purchase Agreement pursuant to which the Company agreed to sell and Merck agreed to purchase at the closing thereunder, 1,285,347

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newly-issued shares of the Company's common stock (the "Shares") for an aggregate purchase price of approximately \$30,000, or \$23.34 per Share. The per Share price of \$23.34 represents 140% of the average of the last reported sales prices of the Company's common stock for the 30 consecutive trading days ended November 2, 2007. The closing of the purchase and sale of the Shares is subject to the Collaboration Agreement becoming effective as well as other customary closing conditions. In connection with the closing of the purchase and sale of the Shares, the Company and Merck have agreed to enter into a Registration Rights Agreement pursuant to which, among other things, the Company will agree to prepare and file, as soon as reasonably practicable following the closing of the purchase and sale of the Shares, a registration statement under the Securities Act of 1933, as amended, registering the resale of the Shares from time to time under the registration statement.

As indicated above, the completion of the transactions contemplated by the Collaboration Agreement and the Stock Purchase Agreement is subject to customary closing conditions, including the expiration or earlier termination of all waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1974, as amended, the continued accuracy of certain representation and warranties of the parties, the absence of any injunction, rule, order or the like prohibiting the completion of the transactions with Merck, and the receipt of all necessary governmental and other third-party authorizations, consents, waivers and approvals. The Company is currently evaluating the accounting impact of this proposed transaction.

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 I, Item 1 of this Quarterly Report on Form 10-Q.

Forward-Looking Information

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

- the anticipated progress of our research, development and clinical programs, including whether future clinical trials will achieve similar results to clinical trials that we have successfully concluded;
- potential future licensing fees, milestone payments, and royalty payments that we may receive under our collaboration and license agreement with Ipsen Limited ("Ipsen");
- our proposed collaboration with Merck & Co., Inc. ("Merck"), including statements related to potential future licensing fees, cost reimbursements for research funding, milestone payments and royalty payments under our exclusive license and collaboration agreement with Merck, as well as our receipt of proceeds from the sale of our common stock to Merck;
- our and our collaborator's ability to market, commercialize and achieve market acceptance for our product candidates or products that we may develop;

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- our ability to generate additional product candidates for clinical testing;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; and
- our estimates regarding the sufficiency of our cash resources.

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

Overview

We are a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules that selectively target hormone pathways to treat cancer, osteoporosis and bone loss, muscle wasting and other serious medical conditions. We are developing ACAPODENE® (toremifene citrate), a selective estrogen receptor modulator (“SERM”) in two separate clinical programs in men: first, a pivotal Phase III clinical trial for the treatment of multiple serious side effects of androgen deprivation therapy (“ADT”), for advanced prostate cancer, and second, a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia (“high grade PIN”). We have licensed to Ipsen exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States to develop and commercialize ACAPODENE® and other products containing toremifene in all indications which we have licensed from Orion Corporation (“Orion”), which include all indications in humans except the treatment and prevention of breast cancer outside of the United States. We are also developing Ostarine™, a selective androgen receptor modulator (“SARM”), initially for the treatment of cancer wasting, which is known as cancer cachexia, and we are conducting a Phase IIb clinical trial evaluating Ostarine™ for the treatment of cancer cachexia. In addition, we are developing GTx-838, another of our SARMS, for the treatment of sarcopenia. We have entered into an exclusive license and collaboration agreement with Merck governing our and Merck’s joint research, development and global commercialization of SARMS with the potential to treat a variety of indications associated with muscle wasting and bone loss, including sarcopenia and osteoporosis, cancer cachexia, and chronic kidney disease (“CKD”) muscle wasting. We are evolving into a selective nuclear hormone receptor modulator company that develops small molecules to target hormone pathways to address a myriad of unmet medical needs in men and women.

We also have an extensive preclinical pipeline generated from our own discovery program, including GTx-878, an estrogen receptor beta agonist, a new class of drugs for the treatment of benign prostatic

hyperplasia and chronic prostatitis. We are planning to initiate human clinical studies for GTx-878 in 2009.

We commenced a pivotal Phase III clinical trial of ACAPODENE® 80 mg under a Special Protocol Assessment (“SPA”) with the United States Food and Drug Administration (“FDA”) for the treatment of multiple serious side effects of ADT in November 2003. We reached our enrollment goal in the fall of 2005 and randomized 1,389 patients into the trial. The last patient is expected to complete the ADT clinical trial in November 2007, and we anticipate announcing top-line results from the trial in the latter part of the first quarter of 2008, with a New Drug Application (“NDA”) filing expected later that year if the results are favorable.

In January 2005, we initiated a pivotal Phase III clinical trial of ACAPODENE® 20 mg for the prevention of prostate cancer in high risk men with high grade PIN. The trial is being conducted under an SPA with the FDA. We have randomized 1,590 patients into the trial, of which 330 are also participating in bone and ocular substudies requested by the FDA under the SPA. We will evaluate efficacy endpoints for the clinical trial at 36 months after completion of enrollment, and we anticipate conducting a planned interim efficacy analysis after a certain number of cancer events have been recorded among study patients, which we currently expect to occur in the latter part of the first quarter of 2008. If the efficacy results from the planned interim analysis achieve the statistical outcome specified in the SPA (alpha \leq 0.001), we plan to file an NDA with the FDA. If we are able to file an NDA based on the results of the interim efficacy analysis, we will continue to collect efficacy data and safety data during the review process to satisfy the FDA’s safety requirements set forth in the SPA. If the efficacy results from the planned interim analysis do not satisfy the specified statistical requirements in the SPA, we plan to continue the clinical trial for the full 36 month period and then determine whether the trial results satisfy the efficacy endpoints required by the SPA.

In our third clinical program, Ostarine™, a SARM, is being developed to treat a variety of medical conditions relating to muscle wasting and/or bone loss. In December 2006, we announced that Ostarine™ met its primary endpoint in a Phase II proof of concept, double blind, randomized, placebo controlled clinical trial in 60 elderly men and 60 postmenopausal women. The trial was designed to evaluate the activity of Ostarine™ on building muscle as well as to assess safety in both elderly men and postmenopausal women. In 2006, we conducted discussions with various divisions of the FDA to investigate the required regulatory pathways for several indications under consideration for the ongoing clinical development of Ostarine™, and selected cancer cachexia and CKD muscle wasting as the initial indications for Ostarine™ development. We initiated a Phase IIb randomized, double blind, placebo controlled clinical trial evaluating Ostarine™ for the treatment of cancer cachexia in 150 patients diagnosed with non-small cell lung cancer, colorectal cancer, non-Hodgkin’s lymphoma, or chronic lymphocytic leukemia. The clinical trial is being conducted at approximately 60 clinical sites in the United States and Argentina, and we expect to receive data from this trial during the summer of 2008. We and Merck, through our proposed SARM collaboration, will determine the development strategy of Ostarine™ for CKD muscle wasting and GTx-838 for the treatment of sarcopenia.

On November 5, 2007, we entered into a global Exclusive License and Collaboration Agreement (the “Collaboration Agreement”) with Merck governing our and Merck’s joint research, development and commercialization of SARM compounds and related SARM products, including SARMS currently being developed by us and Merck and those yet to be discovered, for all potential indications of interest. Under the Collaboration Agreement, we will grant Merck an exclusive worldwide license under our SARM-related patents and know-how. Following the effectiveness of the Collaboration Agreement, we will conduct preclinical research of SARM compounds and products, and Merck will be responsible for conducting and funding development and commercialization of products developed under the Collaboration Agreement. Merck has agreed to pay us an upfront licensing fee of \$40.0 million and \$15.0

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million in guaranteed three-year cost reimbursements for research funding. We are also eligible to receive under the Collaboration Agreement up to \$422.0 million in future milestone payments associated with the development and regulatory approval of a lead product candidate, including Ostarine™, as defined in the Collaboration Agreement, if multiple indications are developed and receive required regulatory approvals, as well as additional milestone payments for the development and regulatory approval of other product candidates developed under the Collaboration Agreement, in all cases assuming the achievement of such development and regulatory approval milestones and assuming the continued effectiveness of the Collaboration Agreement. Merck also has agreed to pay us tiered royalties on net sales of products that may be developed under the Collaboration Agreement. The Collaboration Agreement will become effective upon the satisfaction of certain conditions, including the expiration or earlier termination of all waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1974, as amended, and the closing of the purchase and sale of approximately \$30.0 million of shares of our common stock pursuant to a Stock Purchase Agreement that we entered into with Merck on November 5, 2007. There can be no assurance that our proposed collaboration with Merck will become effective in a timely manner, or at all, or that we will receive all or any portion of the anticipated proceeds of our proposed collaboration with Merck, including from the sale of our common stock to Merck. For more information on these and other risks and uncertainties related to our proposed collaboration with Merck, see the discussion under “Item 1A. Risk Factors—Risks Related to our Proposed Collaboration with Merck.”

On July 24, 2007, we and the University of Tennessee Research Foundation (“UTRF”) entered into a Consolidated, Amended, and Restated License Agreement (“Consolidated SARM License”) to consolidate and replace our two previously existing SARM license agreements with UTRF and to modify and expand certain rights and obligations of each of the parties under both license agreements. Pursuant to the Consolidated SARM License, we were granted exclusive worldwide rights in all existing SARM technologies owned or controlled by UTRF, including all improvements thereto, and exclusive rights to future SARM technology that may be developed by certain scientists at the University of Tennessee or subsequently licensed to UTRF under certain existing inter-institutional agreements with The Ohio State University. On September 24, 2007, we and UTRF entered into an Amended and Restated License Agreement (“SERM License”) to replace our previously existing exclusive worldwide license agreement for ACAPODENE®. Pursuant to the SERM License, we were granted exclusive worldwide rights to UTRF’s method of use patents relating to SERMs, including ACAPODENE® for chemoprevention of prostate cancer as well as future related SERM technologies that may be developed by certain scientists at the University of Tennessee. Under both the Consolidated SARM License and the SERM License, we agreed to pay to UTRF a one-time, upfront fee of \$290,000 per license. We also are obligated to pay annual license maintenance fees during the term of each such license agreement, which fees will be creditable against any royalties due to UTRF on sublicense revenues and net sales of products during the year in which the annual maintenance fees were paid. We also expect to enter into revised and restated license agreements with UTRF for other preclinical technology with terms and provisions similar to those in the Consolidated SARM License and SERM License for which we expect to pay minimal amounts as consideration for those license agreements.

Our net loss for the nine months ended September 30, 2007 was \$27.6 million. Our net loss included FARESTON® net product sales of \$820,000 and the recognition of collaboration revenue of \$4.4 million. We have financed our operations and internal growth primarily through private placements of preferred stock and public offerings. 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, expand our sales and marketing capabilities and grow our operations.

Research and Development

Since our inception in 1997, we have been focused on drug discovery and development programs. Research and development expenses represented 73% of our total operating expenses for the nine months ended September 30, 2007. Research and development expenses included our expenses for personnel associated with our research activities, including screening and identification of product candidates, preclinical studies, toxicology studies, formulation and synthesis activities, product development and manufacturing, clinical trials, regulatory affairs, and quality assurance activities.

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

- the continuation of the pivotal Phase III clinical trial of ACAPODENE® 80 mg for the treatment of multiple serious side effects of ADT for advanced prostate cancer;
- the continuation of the pivotal Phase III clinical trial of ACAPODENE® 20 mg for the prevention of prostate cancer in high risk men with high grade PIN;
- the continuation of the Phase IIb clinical trial of Ostarine™ for the treatment of cancer cachexia;
- the continued preclinical development of other potential product candidates, including GTx-878; and
- increases in research and development personnel.

In addition, if our proposed collaboration with Merck does not become effective in a timely manner, or at all, we expect that our research and development expenditures will also increase as a result of our being required to independently fund the development of our SARM product candidates and clinical trial activities, including our planned clinical trial activities evaluating Ostarine™ for the treatment of CKD muscle wasting and GTx-838 for the treatment of sarcopenia.

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

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

<u>Program</u>	<u>Product Candidate/ Indication</u>	<u>Development Phase</u>	<u>Status</u>
SERM	ACAPODENE® 80 mg Multiple serious side effects of ADT	Pivotal Phase III clinical trial	Phase III clinical trial ongoing under an SPA; attained enrollment goal; obtained statistically significant results from a planned BMD interim analysis in fourth quarter of 2005 and from a lipid interim analysis in second quarter of 2006
	ACAPODENE® 20 mg Prevention of prostate cancer in high risk men with high grade PIN	Pivotal Phase III clinical trial	Phase III clinical trial ongoing under an SPA; attained enrollment goal
SARM	Ostarine™ Cancer cachexia	Phase IIb clinical trial	Phase II proof of concept clinical trial completed December 2006; Phase IIb trial to treat cancer cachexia ongoing
	GTx-838 Sarcopenia	Preclinical	GTx and Merck, through our proposed SARM collaboration, will determine the clinical development strategy of GTx-838

Sales and Marketing

We currently market FARESTON® (toremifene citrate 60 mg) tablets, which have been approved by the FDA, for the treatment of metastatic breast cancer in postmenopausal women in the United States. In January 2005, we acquired from Orion the right to market FARESTON® tablets in the United States for the metastatic breast cancer indication. We also acquired from Orion a license to toremifene for all indications in humans worldwide, except breast cancer outside of the United States. The active pharmaceutical ingredient in FARESTON® is the same as in ACAPODENE®, but in a different dose. We plan to build specialized sales and marketing capabilities to promote our product candidates to urologists and medical oncologists in the United States and to seek partners to commercialize our product candidates in broader markets in the United States and in the rest of the world.

General and Administrative Expenses

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

Critical Accounting Policies and Significant Judgments and Estimates

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

While our significant accounting policies are more fully described in Note 2 to our financial statements appearing in our Annual Report on Form 10-K for the year ended December 31, 2006 filed with the SEC, we believe that the following accounting policies are most critical to aid you in fully understanding and evaluating our reported financial results.

Revenue Recognition

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

We use revenue recognition criteria outlined in Staff Accounting Bulletin ("SAB") No. 101, *Revenue Recognition in Financial Statements* as amended by SAB No. 104, (together, "SAB 104") and Statement of Financial Accounting Standards ("SFAS") No. 48, *Revenue Recognition When Right of Return Exists* ("SFAS No. 48") and Emerging Issues Task Force Issue 00-21, *Revenue Arrangements with Multiple Deliverables*. Accordingly, revenues from licensing and collaboration 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 as collaboration revenue in the condensed statements of operations over the term of the performance obligation. We estimate the performance obligation period to be five years for the development of ACAPODENE® for both the high grade PIN and ADT indications in the European Territory with Ipsen. The factors that drive the actual development period of a pharmaceutical product are inherently uncertain and include determining the timing and expected costs to complete the project, projecting regulatory approvals and anticipating potential delays. We use all of these factors in initially

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estimating the economic useful lives of our performance obligations, and we also continually monitor these factors for indications of appropriate revisions.

We recognize net product sales revenue from sales of FARESTON® less deductions for estimated sales discounts and sales returns. We recognize revenue from product sales when the goods are shipped and title and risk of loss pass to the customer and the other criteria of SAB No. 104 and SFAS No. 48 are satisfied. We account for rebates to certain governmental agencies as a reduction of product sales. We allow customers to return product within a specified time period prior to and subsequent to the product's labeled expiration date. As a result, we estimate an accrual for product returns, which is recorded as a reduction of product sales, based on factors which include historical product returns and estimated product in the distribution channel which is expected to exceed its expiration date. We retained substantially the same wholesale customers of, and the distribution channel that was used by, another pharmaceutical company that distributed FARESTON® for six years prior to our obtaining the rights to market FARESTON® in January 2005. We also obtained historical product return trend information that we continue to update with our own product return data. We estimate the amount of product in the distribution channel which is expected to exceed its expiration date and be returned by the customer by receiving information from our three largest wholesale customers about the levels of FARESTON® inventory held by these customers. These three largest wholesale customers accounted for 93% of the total sales of FARESTON® for the nine months ended September 30, 2007. Based on this information, and other factors, we estimate the number of months of product on hand. At September 30, 2007 and December 31, 2006, our accrual for product returns was \$321,000 and \$415,000, respectively. If actual future results are different than our estimates, we may need to adjust our estimated accrual for product returns, which could have a material effect on earnings in the period of the adjustment.

Research and Development Expenses

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, development and clinical trial studies on our behalf.

Patent Costs

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

Share-Based Compensation

We have stock option plans that provide for the purchase of our common stock by certain of our employees and directors. Effective January 1, 2006, we adopted SFAS No. 123(R), *Share-Based Payment* ("SFAS 123R") and began recognizing compensation expense for our share-based payments based on the fair value of the awards. Share-based payments include stock option grants under our stock option plans. Under SFAS 123R, forfeitures are estimated at the time of valuation and reduce expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate.

Total share-based compensation expense for the three months ended September 30, 2007 was \$666,000, of which \$337,000 and \$329,000 were recorded in the statements of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation for the nine months ended September 30, 2007 was \$1,616,000, of which \$763,000 and \$853,000 were recorded in the condensed statements of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the

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three months ended September 30, 2006 was \$362,000, of which \$131,000 and \$231,000 were recorded in the condensed statements of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the nine months ended September 30, 2006 was \$1.1 million of which \$408,000 and \$645,000 were recorded in the condensed statements of operations as research and development expenses and general and administrative expenses, respectively.

Recent Accounting Pronouncements

In July 2006, the Financial Accounting Standards Board (“FASB”) issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes-an interpretation of FASB Statement No. 109* (“FIN 48”), which clarifies the accounting for uncertainty in tax positions. FIN 48 requires the recognition of the impact of a tax position in the condensed financial statements if that position is more likely than not of being sustained on audit based on the technical merits of the position. The provisions of FIN 48 were effective as of January 1, 2007. The adoption of the standard had no effect on our financial condition or results of operations.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (“SFAS 157”), which defines fair value, establishes a framework for measuring fair value under GAAP and expands disclosures about fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. We do not expect the adoption of SFAS 157 to have a material impact on our financial position or results of operations.

In June 2007, the Emerging Issues Task Force issued EITF Issue 07-03, *Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development* (“EITF 07-03”). EITF 07-03 concludes that nonrefundable advance payments for future research and development activities should be deferred and capitalized and recognized as expense as the related goods are delivered or the related services are performed. EITF 07-03 is effective for fiscal years beginning after December 15, 2007. We do not expect the adoption of EITF 07-03 to have a material impact on our financial position or results of operations.

Results of Operations

Three Months Ended September 30, 2007 and 2006

Revenues

Revenues for the three months ended September 30, 2007 were \$1.7 million, as compared to \$1.1 million for the same period of 2006. Revenues in both periods included net sales of FARESTON® marketed for the treatment of metastatic breast cancer. Revenues also included collaboration income from Ipsen for ACAPODENE® in the third quarter of 2007 and 2006, and from Ortho Biotech for andarine in the third quarter of 2006. During the three months ended September 30, 2007 and 2006, FARESTON® net sales were \$268,000 and \$348,000, respectively, while cost of product sales were \$148,000 and \$118,000, respectively. Product sales revenue decreased by 23% for the three months ended September 30, 2007 compared to the same period in 2006 due to the reduction in the accrual for product returns in the prior period and a 12% decrease in sales volume. We expect that FARESTON® sales will continue to decline in future periods, particularly as a result of aromatase inhibitors continuing to capture breast cancer market share from SERMs, including from FARESTON®. Collaboration income was \$1.5 million for the three months ended September 30, 2007, and \$724,000 for the three months ended September 30, 2006.

[Table of Contents](#)**Research and Development Expenses**

Research and development expenses increased by \$267,000 to \$9.9 million for the three months ended September 30, 2007 from \$9.6 million for the same period of 2006. The following table identifies the research and development expenses for each of our product candidates, as well as expenses pertaining to our other research and development efforts for the three months ended September 30, 2007 and 2006. Research and development spending for past periods is not indicative of spending in future periods.

<u>Program</u>	<u>Product Candidate/ Indication</u>	<u>Three Months Ended September 30,</u>	
		<u>2007</u>	<u>2006</u>
		(in thousands)	
SERM	ACAPODENE® 80 mg Multiple serious side effects of ADT	\$2,470	\$2,016
	ACAPODENE® 20 mg Prevention of prostate cancer in high risk men with high grade PIN	2,122	2,455
SARM	Ostarine™ Cancer cachexia	1,808	3,014
	GTx-838 Sarcopenia	1,034	—
Other research and development		<u>2,447</u>	<u>2,129</u>
Total research and development expenses		<u>\$9,881</u>	<u>\$9,614</u>

General and Administrative Expenses

General and administrative expenses increased during the three months ended September 30, 2007 to \$3.2 million from \$2.9 million for the three months ended September 30, 2006. The increase was primarily the result of increased marketing and promotional expenses of approximately \$246,000, personnel related expenses of approximately \$263,000, and intellectual property related expenses of approximately \$126,000, and was partially offset by decreases in other administrative expenses.

Interest Income

Interest income increased to \$1.2 million for the three months ended September 30, 2007 from \$638,000 for the three months ended September 30, 2006. The increase was attributable to higher average interest rates in addition to higher average cash and cash equivalents balances during the three months ended September 30, 2007, as compared to the same period in 2006.

Results of Operations

Nine Months Ended September 30, 2007 and 2006

Revenues

Revenues for the nine months ended September 30, 2007 were \$5.2 million as compared to \$2.9 million for the same period of 2006. Revenues in both periods included net sales of FARESTON[®] marketed for the treatment of metastatic breast cancer. Revenues also included collaboration income from Ipsen for ACAPODENE[®] in the first nine months of 2007 and 2006, and from Ortho Biotech for andarine in the first nine months of 2006. During the nine months ended September 30, 2007 and 2006, FARESTON[®] net sales were \$820,000 and \$1.5 million, respectively, while cost of product sales were \$463,000 and \$755,000, respectively. During the nine months ended September 30, 2007, product sales revenue decreased by 46% and sales volume decreased by 50% as compared to the same period in 2006. Collaboration income was \$4.4 million for the nine months ended September 30, 2007 and \$1.4 million for the nine months ended September 30, 2006.

Research and Development Expenses

Research and development expenses were \$26.5 million for the nine months ended September 30, 2007 and 2006. The following table identifies the research and development expenses for each of our product candidates, as well as expenses pertaining to our other research and development efforts for each of the periods presented. Research and development spending for past periods is not indicative of spending in future periods.

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Program	Product Candidate/ Indication	Nine Months Ended September 30,	
		2007	2006
		(in thousands)	
SERM	ACAPODENE® 80 mg Multiple serious side effects of ADT	\$ 6,932	\$ 6,337
	ACAPODENE® 20 mg Prevention of prostate cancer in high risk men with high grade PIN	6,782	8,530
SARM	Ostarine™ Cancer cachexia	4,672	5,543
	GTx-838 Sarcopenia	1,164	—
Other research and development		<u>6,913</u>	<u>6,089</u>
Total research and development expenses		<u>\$26,463</u>	<u>\$26,499</u>

General and Administrative Expenses

General and administrative expenses increased during the nine months ended September 30, 2007 to \$9.9 million from \$8.5 million for the nine months ended September 30, 2006. The increase of \$1.4 million was primarily the result of increased marketing and promotional expenses of approximately \$610,000, personnel related expenses of approximately \$795,000, and intellectual property related expenses of approximately \$428,000, and was partially offset by decreases in other administrative expenses.

Interest Income

Interest income increased to \$4.1 million for the nine months ended September 30, 2007 from \$2.1 million for the nine months ended September 30, 2006. The increase of \$2.0 million was attributable to higher average interest rates in addition to higher average cash and cash equivalents balances during the nine months ended September 30, 2007, as compared to the same period in 2006.

Liquidity and Capital Resources

At September 30, 2007, we had cash and cash equivalents of \$90.9 million, compared to \$119.6 million at December 31, 2006. Net cash used in operating activities was \$28.5 million and \$29.0 million for the nine months ended September 30, 2007 and 2006, respectively. The use of cash in both periods

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resulted primarily from funding our net losses. Net cash used in investing activities was \$896,000 and \$516,000 for the nine months ended September 30, 2007 and 2006, respectively. Net cash used in investing activities for both periods was primarily for the purchase of research and development equipment, computer equipment, and software. We currently expect to make capital expenditures of approximately \$400,000 for the remainder of 2007.

Net cash provided by financing activities was \$767,000 for the nine month period ended September 30, 2007 and included proceeds from the exercise of employee stock options of \$771,000 offset by principal payments under a capital lease obligation of \$4,000. Net cash provided by financing activities for the nine months ended September 30, 2006 was \$62,000 and included proceeds from the exercise of employee stock options of \$66,000, offset by principal payments under a capital lease obligation of \$4,000.

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 quarter of 2009. This estimate does not include funding from milestone payments that we may receive under our existing collaboration with Ipsen, nor does it include any funding that we may receive under our proposed collaboration with Merck, potential future collaboration agreements with pharmaceutical companies, or the potential future issuances and sales of our securities, including the proposed sale of our common stock to Merck. This estimate also does not include any product launch costs that we may incur in connection with the potential marketing approval of ACAPODENE® by the FDA.

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

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- future clinical trial results;
- the achievement of certain milestone events under, and other matters related to, our collaboration and license agreement with Ipsen;
- whether our proposed collaboration with Merck becomes effective in a timely manner, or at all, including whether the proposed sale of our common stock to Merck is consummated, and, assuming our proposed collaboration with Merck becomes effective, the achievement of certain milestone events under, and other matters related to, our exclusive license and collaboration agreement with Merck;
- the terms and timing of any future collaborative, licensing and other arrangements that we may establish;

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- the cost and timing of regulatory approvals;
- potential future licensing fees, milestone payments and royalty payments, including any milestone payments or royalty payments that we may receive under our collaboration and license agreement with Ipsen;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we 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 Ipsen, as well as through interest income earned on the investment of our cash balances and revenues from the sale of FARESTON®. With the exception of payments that we may receive under our collaboration with Ipsen and our proposed collaboration with Merck, we do not currently have any commitments for future external funding. We cannot ensure that our collaboration with Merck will become effective, and 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, it may be necessary to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or to obtain funds through collaborations with others that are on unfavorable terms or that may require us to relinquish rights to some of our technologies or product candidates that we would otherwise seek to develop on our own.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the nine months ended September 30, 2007, there were no material changes to our market risk disclosures as set forth in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2006.

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 Exchange Act of 1934, as amended (the “Exchange Act”) that are designed to ensure that

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

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

There were no changes in our internal control over financial reporting during the third quarter of 2007 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

ITEM 1A. RISK FACTORS

We have identified the following additional risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. Investors should carefully consider the risks described below before making an investment decision. Our business faces significant risks and the risks described below may not be the only risks we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. If any of these risks occur, our business, results of operations or financial condition could suffer, the market price of our common stock could decline and you could lose all or part of your investment in our common stock.

We have marked with an asterisk (*) those risks described below that reflect substantive changes from the risks described under Part I, Item 1A "Risk Factors" included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 9, 2007.

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, 2007, we had an accumulated deficit of \$257.3 million. We have incurred losses in each year since our inception in 1997. Net losses were \$27.6 million for the nine months ended September 30, 2007, \$30.8 million in 2006, \$36.8 million in 2005 and \$22.3 million in 2004. We expect to continue to incur significant and increasing operating losses for the foreseeable future. These losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Because of the numerous risks and uncertainties associated with developing small molecule drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. We have primarily financed our operations and internal growth through sales of common stock and preferred stock. In addition, we have received up-front license fees and payments pursuant to our collaboration agreement

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with Ipsen Limited for European rights to ACAPODENE® and other toremifene-based products and a collaboration agreement with Ortho Biotech for andarine and certain other selective androgen receptor modulators, or SARMS, which was terminated in December 2006. Although we may receive up-front license fees, milestone and other payments from Merck in connection with our proposed collaboration with Merck, as well as approximately \$30.0 million in proceeds from the sale of our common stock to Merck, our proposed collaboration with Merck may not be consummated, and we may not receive any of the anticipated proceeds from our proposed collaboration with Merck or the proposed sale of our common stock to Merck. Please see “Risks Related to our Proposed Collaboration with Merck” for additional information regarding certain risks associated with our proposed collaboration with Merck. 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, 2007, we recognized \$820,000 in net revenues from the sale of FARESTON®.

We expect our research and development expenses to increase in connection with our ongoing clinical trials. 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.

Even if our proposed collaboration with Merck is consummated, we may 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 quarter of 2009. This estimate does not include funding from milestone payments that we may receive under our existing collaboration with Ipsen, nor does it include any funding that we may receive under our proposed collaboration with Merck, potential future collaboration arrangements with other pharmaceutical companies, or potential future issuances and sales of our securities, including the proposed sale of our common stock to Merck. This estimate also does not include any product launch costs that we may incur in connection with the potential marketing approval of ACAPODENE® by the FDA.

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 achievement of certain milestone events under, and other matters related to, our collaboration and license agreement with Ipsen;
- whether our proposed collaboration with Merck becomes effective in a timely manner, or at all,

including whether the proposed sale of our common stock to Merck is consummated and, assuming our proposed collaboration with Merck becomes effective, the achievement of certain milestone events under, and other matters related to our exclusive license and collaboration agreement with Merck;

- the terms and timing of any future 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, including any milestone payments or royalty payments that we may receive under our collaboration and license agreement with Ipsen;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop;
- the effect of competing technological and market developments;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

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

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

Risks Related to Development of Product Candidates

We will not be able to commercialize our product candidates if our preclinical studies do not produce successful results or 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.

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For example, several patients in our Phase III clinical trial of ACAPODENE® 80 mg for the multiple side effects of androgen deprivation therapy have withdrawn from the trial, in accordance with the trial protocol, to seek treatment for a significant loss in bone mineral density. Even if these patients are receiving a placebo, their withdrawal from the trial may result in delays or an inability to achieve the proscribed statistical endpoint. Also, in this trial, as well as in our other clinical studies, the efficacy and/or safety results from the trial may be insufficient to support the filing or approval of an NDA.

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 may 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.

For some of the indications for which we intend to conduct or are currently conducting clinical trials for our product candidates, we do not have evidence from prior preclinical studies in animals or clinical trials in humans of the potential effectiveness of such product candidates for such indications. In the absence of preclinical or clinical data, our beliefs regarding the potential effectiveness of our product candidates for these indications is generally based on pharmacokinetic data and analyses and pharmacological rationales. For example, our belief that ACAPODENE® has the potential to reduce hot flashes is based, in part, on our second Phase II clinical trial in which a higher percentage of the subjects in the placebo group experienced worsening in the frequency of hot flashes compared to the subjects treated with ACAPODENE®. Although this observation suggests that ACAPODENE® does not cause hot flashes or the worsening of hot flashes in men on androgen deprivation therapy, this trial was too small to establish the potential effects of ACAPODENE® on the reduction in incidence or severity of hot flashes. Similarly, an assessment of the potential to treat gynecomastia with ACAPODENE® in this second Phase II clinical trial was inconclusive. We are assessing the effect of ACAPODENE® on gynecomastia and hot flashes in our Phase III clinical trial. Our preclinical or clinical trials may produce negative or inconclusive results that would not support our belief regarding the potential effectiveness of our product candidates.

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

To date, in our two Phase III clinical trials for ACAPODENE[®], some patients have experienced venous thromboembolic events, such as deep vein thromboses and pulmonary embolisms, as well as myocardial infarctions, or heart attacks, one of which resulted in a patient's death, which were considered by investigators as possibly related to treatment with ACAPODENE[®]. Because these trials are blinded, we cannot establish whether these patients received placebo or ACAPODENE[®] in the trial. There have been no drug-related serious adverse events related to our other product candidates. In addition, in our Phase II clinical trial for Ostarine[™], we observed mild elevations of hepatic enzymes in a few patients, and in our preclinical studies for Ostarine[™], only at the highest doses, we observed expected selective effects on the reproductive and other target organs in the male population consistent with the stimulating and inhibiting effects on the androgen receptor which is located in these organs.

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

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

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® in the United States prior to December 31, 2009. If Orion terminates its obligation to cooperate in these activities, or does not cooperate with us or otherwise does not successfully file or maintain these regulatory filings, we would be required to make arrangements with a qualified alternative supplier, which could delay or prevent regulatory approval of ACAPODENE®.

We have relied on third party vendors for Ostarine™. We recently executed agreements with third party contractors for the manufacture of Ostarine™ drug substance and the supply of Ostarine™ drug product for our Phase IIb clinical trial for cancer cachexia. We continue to assess our manufacturing needs for additional clinical trial materials and commercial supply of Ostarine™ as we execute our clinical strategy for Ostarine™. However, if our proposed exclusive license and collaboration agreement with Merck becomes effective, Merck will assume primary manufacturing responsibilities for the collaboration. We will evaluate whether to continue to rely on the manufacturing capabilities of these third party contractors or whether some or all of the manufacturing process should be transferred to other contract manufacturers as we plan our additional clinical trials and the potential commercial launch of Ostarine™ and other SARM product candidates. If our current supply of Ostarine™ becomes unusable, if our Ostarine™ supply is not sufficient to complete our clinical trials, or if we are unsuccessful in identifying a contract manufacturer or negotiating a manufacturing agreement on a timely basis for our

clinical trials and potential commercial launch, we could experience a delay in receiving an adequate supply of Ostarine™.

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 third party vendors for Ostarine™, or to do so at an acceptable cost, or if these or other suppliers fail to meet our requirements for these product candidates or other SARM product candidates for any reason, we would be required to obtain alternate suppliers. However, we may not be permitted to obtain alternate suppliers for 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 from the FDA of an alternate supplier, would delay or prevent the clinical development and commercialization of these product candidates.

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

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

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

If we are not able to obtain adequate supplies of our product candidates, it will be more difficult for us to develop our product candidates and compete effectively. Our product candidates and any products that we 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®. Further, Orion has agreed to supply ACAPODENE® tablets to Ipsen for clinical trials and commercial supply in the European Territory. Orion also manufactures toremifene for third parties for sale outside the United States for the treatment of advanced breast cancer in postmenopausal women.

Our present or future manufacturing partners may not be able to comply with FDA-mandated current Good Manufacturing Practice regulations, other FDA regulatory requirements or similar regulatory requirements outside the United States. Failure of our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays,

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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 to commercialize our product candidates.

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

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

The loss of Ipsen as a collaborator in the development or commercialization of ACAPODENE®, any dispute over the terms of our collaboration with Ipsen, or any other adverse development in our relationship with Ipsen could materially harm our business and might accelerate our need for additional capital. For example, Ipsen is obligated to initiate and conduct appropriate clinical studies as required by the appropriate regulatory authorities in order to obtain marketing approvals of ACAPODENE® within the European Territory. Any failure on the part of Ipsen to initiate these studies could delay the commercialization of ACAPODENE® within the European Territory.

We may not be successful in entering into additional collaborative arrangements with other third parties. In particular, our proposed collaboration with Merck may not become effective as described in more detail under “Risks Related to our Proposed Collaboration with Merck.” If we fail to enter into additional collaborative arrangements on favorable terms, it could delay or impair our ability to develop and commercialize our other product candidates and could increase our costs of development and commercialization.

Dependence on collaborative arrangements, including our arrangement with Ipsen for the development and commercialization of ACAPODENE®, subjects us to a number of risks, including:

- we are not able to control the amount and timing of resources that Ipsen devotes to ACAPODENE®;
- we may not be able to control the amount and timing of resources that our potential future partners may devote to our product candidates;
- our partners may experience financial difficulties or changes in business focus;
- we may be required to relinquish important rights such as marketing and distribution rights.

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- under certain circumstances, Ipsen may not be required to commercialize ACAPODENE® in certain countries of the European Territory if Ipsen determines that it is not commercially reasonable for it to do so;
- pricing reimbursement constraints within the European Territory may diminish the prospects of our receiving royalty payments from Ipsen on aggregate net sales of ACAPODENE® in some or all of the countries within the European Territory;
- should a collaborator fail to develop or commercialize one of our compounds or product candidates, we may not receive any future milestone payments and will not receive any royalties for the compound or product candidate;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- a collaborator could move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our product candidates.

Additionally, we and Ipsen have agreed that neither party will seek to commercialize, promote, market or sell certain products within the European Territory for an agreed period of time subsequent to the time of the first commercial launch of ACAPODENE® within the European Territory. We and Ipsen have also agreed to grant to the other a right of first negotiation with respect to the development, marketing, sale and distribution of any new SERM-based products for the field of the prevention and treatment of prostate cancer or related side effects, or any other indication the parties agree on. Furthermore, our royalty rates under our collaboration agreement with Ipsen are subject to a possible reduction if a generic version of toremifene achieves specified sales levels in a major country within the European Territory or if Ipsen licenses patent rights from a third party that would otherwise be infringed by Ipsen's use, manufacture, sale or import of toremifene. Ipsen has the right to terminate the collaboration agreement with 12 months prior written notice for any reason and with 30 days prior written notice as a result of legitimate and documented safety concerns. If the royalty rates under our collaboration agreement are reduced or if Ipsen terminates the collaboration agreement, the anticipated benefits to us from this agreement would be significantly reduced or eliminated. In addition, if Ipsen terminates the collaboration agreement, the development of ACAPODENE® in the European Territory could be delayed and our costs of development would increase.

Risks Related to our Proposed Collaboration with Merck*

If our proposed collaboration with Merck does not become effective in a timely manner, or at all, we may face certain material risks to our business.*

On November 5, 2007, we entered into an exclusive license and collaboration agreement and a related stock purchase agreement with Merck. The effectiveness of our exclusive license and collaboration agreement with Merck, as well as Merck's obligation to purchase 1,285,347 shares of our common stock under the stock purchase agreement, are conditioned upon the satisfaction or waiver of a number of conditions, including:

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- the expiration or earlier termination of the waiting period under the Hart-Scott-Rodino Antitrust & Improvements Act of 1974, as amended;
- the accuracy of our representations and warranties in our agreements with Merck as of the date of the agreements and, with respect to certain of our representations and warranties, also as of the date of the closing of the transactions contemplated by the agreements;
- the lack of any injunction, rule, order or the like prohibiting the consummation of the transactions contemplated by our agreements with Merck; and
- the receipt of all necessary governmental and other third-party authorizations, consents, waivers or approvals.

Our agreements with Merck may also be terminated under specified circumstances. We cannot ensure that the conditions to the effectiveness of our exclusive license and collaboration agreement with Merck or the conditions to the consummation of the purchase and sale of our common stock under our stock purchase agreement with Merck will be met or waived, or that we will be able to successfully consummate the transactions contemplated by our agreements with Merck in a timely manner, or at all. If the transactions contemplated by our agreements with Merck are not consummated in timely manner, or at all, we will be subject to the adverse effects of a number of material risks, including:

- a potential decline in the price of our common stock;
- the diversion of the attention of our management and our employees from day-to-day operations and the diversion of financial resources during the negotiation and pendency of the transactions contemplated by our agreements with Merck;
- the possible loss of other strategic partnering or business development opportunities during the pendency of the transactions contemplated by our agreements with Merck; and
- the accrual of significant transaction costs, including legal and other costs relating to transactions contemplated by our agreements with Merck.

We may not realize the anticipated benefits from our proposed collaboration with Merck.*

Our exclusive license and collaboration agreement with Merck would govern our and Merck's joint research, development and commercialization of SARM products, including Ostarine™ and other SARMS currently being developed by us and Merck as well as those yet to be discovered, for all potential indications of interest. Merck agreed, assuming the effectiveness of our exclusive license and collaboration agreement with Merck, to pay us an upfront licensing fee of \$40.0 million and \$15.0 million in guaranteed three-year cost reimbursements for research funding (provided that with respect to Merck's obligations for such cost reimbursements, the agreement is not terminated for cause and there does not occur certain change of control events involving us during such three-year period). We are also eligible to receive under our exclusive license and collaboration agreement with Merck up to \$422.0 million in future milestone payments associated with the development and regulatory approval of a lead product candidate if multiple indications are developed and receive required regulatory approvals, as well as additional milestone payments for the development and regulatory approval of other product candidates developed under the agreement. Merck also has agreed to pay us tiered royalties on net sales of products that may be developed under our exclusive license and collaboration agreement with Merck. However, we may not receive any of the proceeds provided for under our exclusive license and collaboration agreement with Merck if the agreement does not become effective, and even if the agreement does become effective, we may not receive any future proceeds provided for under the agreement if certain clinical development and regulatory milestones under the agreement are not achieved, the agreement is

terminated, or we and Merck fail to develop and commercialize any of the SARMS included in or arising from the collaboration. In addition, even if required regulatory approvals are obtained to commercialize a SARM product, it is possible that Merck will not successfully market and sell any of the SARM products developed under the collaboration, in which case we would not receive royalties to the extent that we currently anticipate. We also may not be able to successfully develop new SARM products or identify new indications for existing and/or future SARM products. Further, under the terms of our exclusive license and collaboration agreement with Merck, Merck has the ability to terminate the agreement at its election after a certain period of time or at any time following our uncured material breach or bankruptcy. In any such or similar events, we may not realize the anticipated benefits from our proposed collaboration with Merck.

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

Under the terms of our license agreement with Orion, Orion may require us and Ipsen to modify our final 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 or Ipsen's development plans adversely affect these activities, any future modifications to our or Ipsen's plans imposed by Orion may limit our and Ipsen's ability to maximize the commercial potential of ACAPODENE®.

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

If some or all of our, or our licensors', patents expire or are invalidated or are found to be unenforceable, or if some or all of our patent applications do not yield issued patents or yield patents with narrow claims, or if we are 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. Additionally, Ipsen's ability

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to successfully market ACAPODENE® within a substantial portion of the European Territory may depend on having marketing and data exclusivity from the appropriate regulatory authorities.

Our rights to certain patent applications relating to SARM compounds that we have licensed from the University of Tennessee Research Foundation, or UTRF, are subject to the terms of UTRF's inter-institutional agreements with The Ohio State University, or OSU, and our rights to future related improvements in some instances are subject to UTRF's exercise of exclusive options under its agreements with OSU for such improvements, which UTRF can exercise at no additional cost to UTRF. In addition, under the terms of our agreements with the diagnostic companies to which we provide clinical samples from our Phase IIb and Phase III 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 for prescribed indications using these product candidates are covered by valid and enforceable patents and have claims with sufficient scope and support in the specification, the patents will provide protection only for a limited amount of time. For example, the patent that we have licensed from Orion covering the composition of matter of toremifene expires in the United States in September 2009. Foreign counterparts of this patent have either already expired or will expire in Australia, Italy, Sweden and Switzerland in 2008, that is, before we or Ipsen will receive regulatory approval to commercialize 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. Also, within the European Union, Ipsen may need to rely primarily on the protection afforded by marketing and data exclusivity for the ACAPODENE® products to be sold within the countries comprising the European Union. 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 extensions of patent terms under applicable United States laws pertaining to our method of use patents, we may not be able to secure any such regulatory exclusivity or extension of patent term. Loss of marketing and data exclusivity for the ACAPODENE® products to be commercialized within the European Union could adversely affect its ability to successfully commercialize these products, and our failure to obtain any extension of patent terms for our method of use patents could adversely affect our prospects for protecting our ACAPODENE® products from competitive pressures in the United States for the time periods we currently expect. We are not eligible for any such exclusivity or further extension of the composition of matter patent of toremifene licensed to us by Orion in the United States.

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

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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.

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

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

Off-label sale or use of toremifene products could decrease 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 and Ipsen 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 or Ipsen's 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 other toremifene products would not have been approved for those

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

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

There is a risk that we are infringing the proprietary rights of third parties because numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields that are the focus of our drug discovery 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.

In addition, under our collaboration and license agreement with Ipsen and our proposed exclusive license and collaboration agreement with Merck, Ipsen and Merck may be entitled to offset a portion of any royalties due to us in any calendar year on account of product sales to pay for costs incurred by Ipsen

or Merck to obtain a license to any dominant intellectual property rights that are infringed by such product sales.

Risks Related to Regulatory Approval of Our Product Candidates

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

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

Changes in the regulatory approval policy during the development period, changes in or the enactment of additional regulations or statutes, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. For example, the Food and Drug Administration Amendments Act of 2007 (“FDA Amendments Act”), which was enacted in September 2007, expands the FDA’s authority to regulate drugs throughout the product life cycle, including enhanced authority to require post-approval studies and clinical trials. Other proposals have been made to impose additional requirements on drug approvals, further expand post-approval requirements and restrict sales and promotional activities. This new legislation, and the additional proposals if enacted, may make it more difficult or burdensome for us or our collaborators to obtain approval of our product candidates. Even if the FDA approves a product candidate, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product, and may impose ongoing requirements for post-approval studies, including additional research and development and clinical trials. The approval may also require the adoption of risk management plans, referred to in the FDA Amendments Act as risk evaluation and mitigation strategies (“REMS”). The REMS may include requirements for special labeling or medication guides for patients, special communication plans to healthcare professionals, and restrictions on distribution and use. 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 are conducting our Phase III clinical trials of ACAPODENE® to treat the side effects of androgen deprivation therapy and for the prevention of prostate cancer in high risk men with high grade PIN under Special Protocol Assessments, or SPAs, from the FDA. An SPA is designed to facilitate the FDA's review and approval of drug products by allowing the FDA to evaluate the proposed design and size of clinical trials that are intended to form the primary basis for determining a drug product's efficacy. If agreement is reached with the FDA, an SPA documents the terms and conditions under which the design of the subject trial will be adequate for submission of the efficacy and human safety portion of an NDA. However, there are circumstances under which we may not receive the benefits of an SPA, notably if the FDA subsequently identifies a substantial scientific issue essential to determining the product's safety or efficacy. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Furthermore, even if we file an application with the FDA for marketing approval of a product candidate, it may not result in marketing approval from the FDA.

We may not receive regulatory approval for the commercial sale of any of our product candidates that are in development for at least another year, if ever. Similarly, it is not anticipated that Ipsen will receive the appropriate regulatory approvals to market ACAPODENE® within the European Territory any sooner than we will achieve regulatory approval in the United States, and it may be thereafter. The inability to obtain FDA approval or approval from comparable authorities in other countries for our product candidates would prevent us or our collaborators from commercializing these product candidates in the United States or other countries. See the section entitled "Business — Government Regulation" under Part I, Item 1 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2006 filed with the Securities and Exchange Commission for additional information regarding risks associated with marketing approval, as well as risks related to post-approval requirements.

Risks Related to Commercialization

The commercial success of any products that we may develop will depend upon the degree of market acceptance among physicians, patients, healthcare 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:

- efficacy and safety results in clinical trials;
- the prevalence and severity of any side effects;
- potential advantages over alternative treatments;
- the ability to offer our product candidates for sale at competitive prices;
- relative convenience and ease of administration;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

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

- the loss of the availability of Orion's website to market FARESTON®, which is an important source of advertising;
- the loss of one or more of our three largest wholesale drug distributors, which accounted for approximately 93% of our revenue generated from the sale of FARESTON® for the nine months ended September 30, 2007;
- the continued success of competing products, including aromatase inhibitors;
- the loss of coverage or reimbursement for FARESTON® from Medicare and Medicaid, private health insurers or other third-party payors;
- exposure to product liability claims related to the commercial sale of FARESTON®, which may exceed our product liability insurance;
- the failure of Orion to maintain regulatory filings or comply with applicable FDA requirements with respect to FARESTON®;
- the ability of third parties to market and sell generic toremifene products that will compete with FARESTON® for the treatment of breast cancer after the composition of matter patents that we license from Orion expire in the United States in September 2009;
- the loss of Orion, upon which we rely as a single source, as our supplier of FARESTON®; and
- our inability to manufacture FARESTON® until Orion's patents with respect to the composition of matter of toremifene expire if Orion terminates our license and supply agreement due to our uncured material breach or bankruptcy.

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

We have limited experience as a company in the sales, marketing and distribution of pharmaceutical products. There are risks involved with building our own sales and marketing capabilities, as well as entering into arrangements with third parties to perform these services. For example, building a sales force is expensive and time-consuming and could delay any launch of a product candidate. Similarly, we are relying on Ipsen to market and distribute our ACAPODENE® product candidates through Ipsen's

established sales and marketing network within the European Territory. If our collaboration and license agreement with Ipsen is terminated for any reason, our ability to sell our ACAPODENE® product candidates in the European Territory would be adversely affected, and we may be unable to develop or engage an effective sales force to successfully market and sell our ACAPODENE® product candidates in the European Territory. Currently, we do not have a partner outside of the European Territory and our success in regions other than the European Territory may be dependent on our ability to find suitable partners in other regions of the world. Likewise, if our exclusive license and collaboration agreement with Merck does not become effective, or, if the agreement does become effective and the agreement is subsequently terminated, our ability to successfully market and sell any of our SARM product candidates would be adversely affected. 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. For example, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 created a prescription drug benefit program for Medicare recipients. The prescription drug program established by this legislation may have the effect of reducing the prices that we are able to charge for products we develop and sell through the program. This legislation may also cause third-party payors other than the federal government, including the states under the Medicaid program, to discontinue coverage for products that we may develop or to lower the amount that they pay. In addition, members of the United States Congress have stated their desire to reduce the government's cost for reimbursements of prescription drugs by amending this legislation.

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

A primary trend in the United States health care industry is toward cost containment. In addition, in some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our 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

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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 may incur substantial liabilities and may be required to limit commercialization of any products that we may develop.

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

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

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

If our competitors are better able to develop and market products than any products that we 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 used off-label for some of the diseases and conditions that we are targeting, and a number of companies are or may be developing new treatments. These product uses, as well as promotional efforts by competitors and/or clinical trial results of competitive products, could significantly diminish our 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 androgen deprivation therapy, we are aware of a number of drugs marketed by Eli Lilly (Evista®),

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Merck (Fosamax®), Sanofi-Aventis and Procter & Gamble (Actonel®), Wyeth Pharmaceuticals (Effexor®), Boehringer Ingelheim (Catapres®), Novartis (Zometa®) and Bristol Myers Squibb (Megace®) that are prescribed to treat single side effects of this therapy; that external beam radiation and tamoxifen are used to treat breast pain and enlargement; and that Amgen is developing a product candidate for the treatment of osteoporosis in prostate cancer patients. While we have the only pharmaceutical product in clinical development to prevent prostate cancer in high risk men with high grade PIN, GlaxoSmithKline is conducting a Phase III study for Avodart® on prostate cancer prevention in men with elevated prostate specific antigen. In addition, there are nutritional supplement studies (for example, selenium) investigating prostate cancer prevention in men with high grade PIN. Similarly, while there are no drugs that have been approved by the FDA for the treatment of muscle wasting from cancer, there are drugs marketed by Steris Laboratories and Savient Pharmaceuticals that are being prescribed off-label for the treatment of some types of muscle wasting from cancer. Testosterone and other anabolic agents are used to treat involuntary weight loss in patients who have acute muscle wasting. Also, TAP Pharmaceuticals and Ligand Pharmaceuticals have entered into a collaboration agreement to develop a SARM and may be initiating Phase II studies in 2007. In addition, there are other SARM product candidates at an earlier stage of development that may compete with our product candidates. Wyeth and Amgen have myostatin inhibitors in development which may compete for similar patients as Ostarine™. This could result in reduced sales and pricing pressure on our product candidates, if approved, which in turn would reduce our ability to generate revenue and have a negative impact on our results of operations.

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

Risks Related to Employees and Growth

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

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

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

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Ostarine™ is initially commercialized, including 50 to 100 sales representatives. The competition for qualified personnel in the biotechnology field is intense.

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

Risks Related to Our Common Stock

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

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

- adverse results or delays in our clinical trials;
- the timing of achievement of our clinical, regulatory and other milestones, such as the commencement of clinical development, the completion of a clinical trial or the receipt of regulatory approval;
- announcement of FDA approval or non-approval of our product candidates or delays in the FDA review process;
- actions taken by regulatory agencies with respect to our product candidates or products, our clinical trials or our sales and marketing activities;
- the commercial success of any product approved by the FDA or its foreign counterparts;
- developments with respect to our collaboration with Ipsen;
- whether our proposed collaboration with Merck becomes effective, and assuming it becomes effective, future developments concerning the collaboration;
- 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;

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- sales of large blocks of our common stock;
- sales of our common stock by our executive officers, directors and significant stockholders;
- changes in accounting principles; and
- the loss of any of our key scientific or management personnel.

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

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

As of September 30, 2007, our officers, directors and holders of 5% or more of our outstanding common stock (based upon public filings) beneficially owned approximately 82.1% of our outstanding common stock and our officers and directors alone owned approximately 49.6% of our outstanding common stock. As a result, these stockholders, acting together, will be able to control all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders.

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

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

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

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

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 September 30, 2007, the average daily trading volume of our common stock on the NASDAQ Global Market was approximately 145,811 shares. As a result, future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the then-prevailing market price of our common stock. As of September 30, 2007, we had 34,922,124 shares of common stock outstanding.

Moreover, J.R. Hyde, III, and Oracle Partners, L.P., two of our largest stockholders, and their affiliates, have rights, subject to some conditions, to require us to file registration statements covering the approximately 10.9 million shares of common stock they hold in the aggregate which are subject to registration rights or to include these shares in registration statements that we may file for ourselves or other stockholders. In addition, we agreed to enter into a registration rights agreement with Merck if our proposed collaboration with Merck is consummated, pursuant to which we would file a registration statement covering the 1,285,347 shares we agreed to sell to Merck as soon as reasonably practicable following the closing of the purchase and sale of such shares to Merck. Finally, all shares of common stock that we may issue under our employee benefit plans can be freely sold in the public market upon issuance.

ITEM 5. OTHER INFORMATION

Amended and Restated License Agreement with the University of Tennessee Research Foundation

On September 24, 2007, we entered into an Amended and Restated License Agreement (the “New SERM License”) with the University of Tennessee Research Foundation (formerly known as the University of Tennessee Research Corporation) (“UTRF”). The New SERM License amends and replaces that certain Amended and Restated Exclusive License Agreement, made effective as of July 24, 1998, by and between us and UTRF (the “Prior SERM License”). Pursuant to the New SERM license, we were granted exclusive worldwide rights to UTRF’s method of use patents relating to SERMs, including ACAPODENE® for chemoprevention of prostate cancer as well as future related SERM technologies that may be developed by certain scientists at the University of Tennessee. Under the terms of the New SERM License, we agreed to pay to UTRF a one-time, upfront fee of \$290,000 as consideration for entering into the New SERM License. We also agreed to pay an annual license maintenance fee during the term of the New SERM License, which fee will be creditable against any royalties due to UTRF on sublicense revenues and net sales of products during the year in which the annual maintenance fees were paid. We also agreed to pay all expenses to file, prosecute and maintain the patents relating to the licensed SERM technologies. Under the New SERM License, we are obligated to use commercially reasonable efforts to develop and commercialize products based on the licensed SERM technologies. Unless terminated earlier, the term of the New SERM License will continue in a particular country for the longer of 20 years from the effective date of the Prior SERM License or until the expiration of the last valid claim of any licensed

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patent in such country. The New SERM License may be terminated by UTRF for our uncured breach or upon our bankruptcy. The foregoing is only a brief description of the material terms of the New SERM License and does not purport to be complete, and is qualified in its entirety by reference to the New SERM License which is filed as Exhibit 10.41 to this report and is incorporated by reference herein.

Termination of Prior License

In December 2006, we executed a letter of intent with UTRF pursuant to which we agreed to modify the Prior SERM License as well as (i) that certain Amended and Restated Exclusive License Agreement, made effective as of August 23, 2000, by and between us and UTRF, and (ii) that certain Amended and Restated Exclusive License Agreement, made effective as of August 23, 2000, by and between us and UTRF. In accordance with the transactions contemplated by the letter of intent, the New SERM License replaces and supersedes the Prior SERM License, which was effectively terminated upon our and UTRF's entry into the New SERM License. The entering into of the New SERM License and the related termination of the Prior SERM License was, among other things, intended to address certain provisions of the Prior SERM License pertaining to the time and amount of payments for annual license maintenance fees and royalty fees to be paid by us to UTRF. Under the Prior SERM License, UTRF granted to us a worldwide exclusive license under its method of use patents relating to ACAPODENE[®] to market, distribute and sell licensed products, licensed processes or generic products. Under the terms of the Prior SERM License, we were required to make annual license maintenance fee payments and future royalty payments to UTRF. The foregoing is only a brief description of the material terms of the Prior SERM License and does not purport to be complete, and is qualified in its entirety by reference to the Prior SERM License which was filed as Exhibit 10.22 to our Registration Statement on Form S-1 (File No. 333-109700), filed with the SEC on October 15, 2003, as amended.

Amendment and Restatement of Directors' Deferred Compensation Plan

Effective November 1, 2007, our Board of Directors amended and restated our Directors' Deferred Compensation Plan (the "Deferred Plan"). Under the Deferred Plan, as so amended and restated, each of our non-employee directors may elect to have part or all of his or her fees for service on our Board of Directors (including any Board committees) credited to his or her cash account or stock account under the Plan. A non-employee director may elect to receive a distribution of amounts credited to such accounts on a date selected by the non-employee director at the time of the election. However, if the non-employee director retires or separates from our Board of Directors prior to his or her selected distribution date, (i) the amount credited to the non-employee director's cash account under the Deferred Plan will be distributed within 30 days after commencement of the year following such retirement or separation, and (ii) the amount credited to the non-employee director's stock account will be distributed within the later of (a) 30 days after commencement of the year following such retirement or separation or (b) six months after such event. All distributions under the Deferred Plan will be made in the form of a single lump sum in cash (for amounts credited to cash accounts) or in shares of common stock (for amounts credited to stock accounts), provided that any fractional share amounts will be paid in cash. Cash accounts and stock accounts under the Deferred Plan will be credited with interest or the value of any cash and stock dividends, as applicable. Non-employee directors are fully vested in any amounts that they elect to defer under the Deferred Plan. Our deferred compensation obligations under the Deferred Plan, which are contractual obligations to pay or distribute to participants in the Deferred Plan compensation, the receipt of which the participants have elected to defer (the "Obligations"), are unsecured general obligations and rank *pari passu* with our other unsecured and unsubordinated indebtedness. There is no trading market for the Obligations. The Obligations are not subject in any manner, either voluntarily or involuntarily, to anticipation, alienation, sale, transfer, assignment, pledge, encumbrance, attachment or garnishment. A non-employee director may not transfer or assign benefits under the Deferred Plan to any person other than to a designated beneficiary who is to succeed to the non-employee director's right to receive

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payments under the Deferred Plan in the event of the non-employee director's death. The foregoing is only a brief description of the material terms of the Deferred Plan and does not purport to be complete, and is qualified in its entirety by reference to the Deferred Plan which is filed as Exhibit 10.7 to this report and is incorporated by reference herein.

ITEM 6. EXHIBITS

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

SIGNATURES

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

GTx, Inc.

Date: November 9, 2007

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

Date: November 9, 2007

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⁾
10.7*	Directors' Deferred Compensation Plan, as amended and restated effective November 1, 2007
10.40*†	Consolidated, Amended, and Restated License Agreement dated July 24, 2007, between Registrant and University of Tennessee Research Foundation
10.41*†	Amended and Restated License Agreement dated September 24, 2007, between Registrant and University of Tennessee Research Foundation
10.42	Stock Purchase Agreement, dated November 5, 2007, between the Registrant and Merck & Co., Inc. ⁽⁴⁾
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) ⁽⁵⁾
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) ⁽⁵⁾

* Filed herewith.

† Confidential treatment has been requested for certain portions of this exhibit.

- (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 3.2 to the Registrant's current report on Form 8-K (File No. 000-50549), filed with the SEC on July 26, 2007, and incorporated herein by reference.
- (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 10.42 to the Registrant's current report on Form 8-K (File No. 000-50549), filed with the SEC on November 6, 2007, and incorporated herein by reference.
- (5) 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.

GTx, INC.
DIRECTORS' DEFERRED COMPENSATION PLAN
(AMENDED AND RESTATED
EFFECTIVE NOVEMBER 1, 2007)

GTX, INC.
DIRECTORS' DEFERRED COMPENSATION PLAN

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**ARTICLE I
DEFINITIONS**

1.1 “Board” shall mean the Board of Directors of GTx, Inc.

1.2 “Cash Account” shall mean the account created by the Company pursuant to Article III of this Plan in accordance with an election by a Director to receive deferred cash compensation under Article II hereof.

1.3 “Common Stock” shall mean the Common Stock of the Company.

1.4 “Company” means GTx, Inc.

1.5 “Director” shall mean a member of the Board of Directors of the Company who is not an employee of the Company or any of its subsidiaries.

1.6 “Fees” shall mean amounts earned for serving as a member of the Board, including any committees of the Board.

1.7 “He”, “Him” or “His” shall apply equally to male and female members of the Board.

1.8 “Plan” shall mean the GTx, Inc. Directors’ Deferred Compensation Plan, as it may be amended from time to time.

1.9 “Stock Account” shall mean the account created by the Company pursuant to Article III of this Plan in accordance with an election by a Director to receive stock compensation under Article II hereof.

1.10 “Stock Value” shall mean, for any given day, the closing price of the Company’s Common Stock as reported on the Nasdaq Stock Market (“Nasdaq”) on the business day immediately preceding such day, except as otherwise provided in the Plan. If the closing price is not available from Nasdaq for the Common stock on a business day immediately preceding the date in question, then the immediately preceding practicable date for which such closing price is available shall be used.

1.11 “Year” shall mean calendar year.

**ARTICLE II
ELECTION TO DEFER**

2.1 A Director may elect, on or before December 31 of any Year, to defer payment of all or a specified part of all Fees earned during the Year following such election. Any person who shall become a Director during any Year, and who was not a Director of the

Company on the preceding December 31, may elect, within thirty (30) days after becoming a Director, to defer payment of all or a specified part of such Fees earned during the remainder of such Year.

2.2 The election to participate in the Plan and defer payments under the Plan shall be designated by submitting a letter in the form attached hereto as Appendix A to the Secretary of the Company by the applicable date under Paragraph 2.3.

2.3 The election is irrevocable with respect to the Year to which it relates upon the submission of such election to the Secretary of the Company. The election first submitted by a Director shall remain effective with respect to Fees earned during subsequent Years, unless the Director terminates it by written request delivered to the Secretary of the Company prior to the commencement of the Year for which the termination is first effective.

ARTICLE III DEFERRED COMPENSATION ACCOUNTS

3.1 The Company shall maintain separate memorandum accounts for the Fees deferred by each Director. Each Director shall be fully vested at all times in any amounts credited to his Cash Account and Stock Account.

3.2 The Company shall credit, on the date Fees become payable, to the Cash Account of each Director the deferred portion of any Fees due the Director as to which an election to receive cash has been made. Fees deferred in the form of cash (and interest thereon) shall be held in the general funds of the Company.

3.3 On the first day of each quarter, the Company shall credit the Cash Account of each Director with interest calculated on the basis of the balance in such account on the first day of each month of the preceding quarter at the prime rate of interest then in effect at First Horizon National Bank, Memphis, Tennessee, or if no such rate shall be available, then such rate of interest as is then published in the *Wall Street Journal* as the prevailing prime rate of interest.

3.4 The Company shall credit the Stock Account of each Director who has elected to receive deferred compensation in the form of Common Stock with the number of shares of Common Stock equal in value to (i) the deferred portion of any Fees due the Director as to which an election to receive Common Stock has been made, divided by the Stock Value on the date such Fees otherwise would have been paid, (ii) any cash dividends (or the fair market value of dividends paid in property other than dividends payable in Common Stock) payable on the number of shares of Common Stock represented in each Director's Stock Account, divided by the Stock Value on the date such cash dividends are paid, and (iii) any stock dividends payable on the number of shares of Common Stock represented in each Director's Stock Account, equal in value to the Stock Value of such stock dividends on the date such stock dividends are paid. Credits that are made to each Director's Stock Account pursuant to the preceding sentence shall be made, with respect to any Fees, on the date that such Fees become payable and, with respect to any dividends, on the date that such dividends are paid on Common Stock. If adjustments are made to the outstanding shares of Common Stock as a result of stock-splits, recapitalizations,

mergers, consolidations and the like, an appropriate adjustment also will be made in the number of shares of Common Stock credited to the Director's Stock Account.

3.5 Common Stock shall be computed to three decimal places.

3.6 The right to receive Common Stock at a later date shall not entitle any person to rights of a stockholder with respect to such Common Stock unless and until shares of Common Stock have been issued to such person pursuant to Article IV hereof.

3.7 The Company shall not be required to acquire, reserve, segregate, or otherwise set aside shares of Common Stock for the payment of its obligations under the Plan, but shall make available as and when required a sufficient number of shares of Common Stock to meet the needs of the Plan, provided that the Company shall not be required to issue any fractional shares of Common Stock, and any fractional share amounts shall be paid in cash to the Director, at the time the shares of Common Stock are issued to such Director, based on the Stock Value of such Common Stock on the payment date.

3.8 Nothing contained herein shall be deemed to create a trust of any kind or any fiduciary relationship. To the extent that any person acquires a right to receive payments from the Company under the Plan, such right shall be no greater than the right of any unsecured general creditor of the Company.

ARTICLE IV PAYMENT OF DEFFERED COMPENSATION

4.1 Amounts credited to a Director's Cash Account and Stock Account shall be distributed in a single lump sum to the Director on the date, if any, selected by the Director pursuant to the Director's election (made pursuant to Paragraph 2.2 of Article II) (or as soon as administratively practicable thereafter); *provided, however*, that if the Director has not selected a distribution date or the Director's selected distribution date is after his retirement or separation from the Board, distribution shall be made in accordance with the following: (i) the amount credited to the Director's Cash Account shall be distributed in the form of a single lump sum within thirty (30) days after commencement of the Year following the Director's retirement or separation from the Board, and (ii) the shares of Common Stock credited to the Director's Stock Account shall be distributed in the form of a single lump sum within the later of (a) thirty (30) days after commencement of the Year following the Director's retirement or separation from the Board or (b) six (6) months after such event. Amounts credited to a Director's Cash Account shall be paid in cash. Amounts credited to a Director's Stock Account shall be paid in shares of Common Stock, subject to Paragraph 3.7 hereof.

Any payments made pursuant to this Paragraph 4.1 shall be subject to the distribution requirements of Section 409A(a)(2)(A) of the Code, if applicable, including, without limitation, the requirement of Section 409A(a)(2)(B)(i) of the Code that payment be delayed until six (6) months after separation from service if the Director is a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code at the time of such separation from service.

4.2 Each Director shall have the right to designate a beneficiary who is to succeed to his right to receive payments hereunder in the event of death. Any designated beneficiary shall receive payments in the same manner as the Director if he had lived. In case of a failure of designation or the death of a designated beneficiary without a designated successor, the balance of the amounts contained in the Director's Cash Account and/or Stock Account shall be payable in accordance with Paragraph 4.1 to the Director's or former Directors' estate in full within thirty (30) days after commencement of the Year following the Year in which he dies. No designation of beneficiary or change in beneficiary shall be valid unless in writing signed by the Director and filed with the Secretary of the Company.

**ARTICLE V
ADMINISTRATION**

5.1 The Company shall administer the Plan at its expense. The Company has the exclusive discretion and authority to construe and interpret the Plan, and to decide any and all questions of fact, interpretation, definition, computation or administration arising in connection with the operation of the Plan, including, without limitation, eligibility to participate in the Plan and amount of benefits to be paid under the Plan. The rules, interpretations, computations and other actions of the Company shall be final and binding on all parties.

5.2 Except to the extent required by law, the right of any Director or any beneficiary to any benefit or to any payment hereunder shall not be subject in any manner to attachment or other legal process for the debts of such Director or beneficiary; and any such benefit or payment shall not be subject to alienation, sale, transfer, assignment or encumbrance.

**ARTICLE VI
AMENDMENT OF PLAN**

6.1 The Plan may be amended, suspended or terminated in whole or in part from time to time by the Board, except that no amendment, suspension, or termination shall apply to the payment to any Director or beneficiary of a deceased Director of any amounts previously credited to a Director's Cash Account or Stock Account without such Director's (or beneficiary's, if applicable) express written consent.

APPENDIX A

Date: _____

Corporate Secretary
GTx, Inc.

Dear Mr. _____:

Pursuant to the GTx, Inc. Directors' Deferred Compensation Plan, as amended to date (the "**Plan**"), I hereby elect to defer receipt of all or a portion of my Director's fees for the calendar year commencing on January 1, 20_____ in accordance with the percentages indicated below.

[Insert the following paragraph for election forms completed in 2007 only:] I hereby also elect to make this election effective for all of my Director's fees previously deferred under the Plan and any other amounts previously credited to my Cash Account and Stock Account under the Plan. I understand that this election will supersede all my previous elections under the Plan.

I acknowledge and agree that this election is irrevocable and shall remain effective with respect to my Director's fees earned during subsequent calendar years, unless I terminate it by written request to the Secretary of the Company prior to the commencement of the year for which the termination is to be effective.

I elect to have my Director's fees (and committee fees, if any) credited as follows (fill in appropriate percentages for options a, b and c, below).

- (a) _____% of the aggregate Director's fees shall be credited to my Cash Account (as defined in the Plan);
- (b) _____% of the aggregate Director's fees shall be credited to my Stock Account (as defined in the Plan);
- (c) _____% of the aggregate Director's fees shall not be deferred, but shall be paid to me directly as they accrue.

Optional: I elect to receive a distribution of the amount credited to my Cash Account and Stock Account on the following date (or as soon as administratively practicable thereafter): _____.

I understand that if I do not select a distribution date for the amount credited to my Cash Account and Stock Account OR the distribution date I select is after my retirement or separation from the Board, then notwithstanding my selected distribution date, the amount credited to my

Cash Account and Stock Account will be distributed to me as follows: my Cash Account will be distributed in the form of a single lump sum (in cash) within thirty (30) days after commencement of the year following my retirement or separation from the Board; and my Stock Account will be distributed in the form of a single lump sum (in shares of Common Stock) within the later of (a) thirty (30) days after commencement of the year following my retirement or separation from the Board or (b) six months after such event.

I understand that if I am considered a "specified employee" under Section 409A of the Internal Revenue Code of 1986, as amended, at the time of my separation from service with the Company, payments from my Cash Account and Stock Account may be delayed until six (6) months after such separation from service.

In the event of my death prior to receipt of the amounts credited to my Cash Account and/or Stock Account, I designate _____ as my beneficiary to receive the amounts so credited.

Very truly yours,

Appendix A

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

UNIVERSITY OF TENNESSEE RESEARCH FOUNDATION

and

GTx, INC.

CONSOLIDATED, AMENDED, AND RESTATED LICENSE AGREEMENT

THIS CONSOLIDATED, AMENDED, AND RESTATED LICENSE AGREEMENT made and entered into this 24th day of July, 2007, having an effective date of August 23, 2000 (the "Effective Date") by and between University of Tennessee Research Foundation (formerly known as The University of Tennessee Research Corporation), a Tennessee corporation having an office at 1534 White Avenue, Knoxville, Tennessee 37996. (hereinafter "UTRF"), and GTx, Inc. (formerly known as Genotherapeutics, Inc.), a Delaware corporation, located at 3 N. Dunlap St., Memphis, Tennessee 38163 (hereinafter "GTx"), hereinafter sometimes referred to individually as a "Party" and collectively as the "Parties".

RECITALS

WHEREAS, UTRF owns, in whole or in part, certain Licensed Patents (as defined herein) and Licensed Technology (as defined herein), the subject matter of which was initially developed by one or more of the UT Contributors (as defined herein) in the course of their employment with The University of Tennessee ("UT");

WHEREAS, the UT Contributors submitted to UT multiple invention disclosure forms pertaining to SARMS (as defined herein), including (i) [*], designated by UTRF as file number PD [*]; (ii) [*], designated by UTRF as file number PD [*]; (iii) [*], designated by UTRF as file number PD [*]; (iv) [*], designated by UTRF as file number PD [*]; and (v) [*] designated by UTRF as file number PD [*] (individually, an "Initial SARMS Disclosure" and, collectively, the "Initial SARMS Disclosures");

WHEREAS, UTRF and GTx have previously entered into two separate agreements, each being titled "Amended and Restated Exclusive License Agreement" and made effective as of August 23, 2000, whereby GTx was granted exclusive licenses to Licensed Patents (as defined therein) and Licensed Technology (as defined therein) which arose out of the technology described in the Initial SARMS Disclosures (collectively, the "Prior License Agreements");

WHEREAS, after submission of the Initial SARMS Disclosures to UT, Dr. James T. Dalton, a UT Contributor, left the employ of UT, accepted employment as a faculty member at The Ohio State University ("OSU") and in the capacity of an OSU researcher, continued to perform research at OSU relating to the subject matter of the Initial SARMS Disclosures with the assistance of other staff and students of OSU working under his supervision, said research being funded by various sponsors, including the United States government and GTx;

WHEREAS, a number of the UT Contributors (excluding Dr. Dalton as an OSU employee), subsequently submitted to UT an invention disclosure form titled [*] designated by UTRF as file number PD [*] (the "Third Generation SARMS Disclosure"), a copy of which is attached hereto as Exhibit A;

WHEREAS, with the consent of GTx, UTRF entered into that certain agreement titled “Bridged SARMS Inter-Institutional Agreement” with OSU effective December 22, 2004 (hereinafter “OSU IIA#1”), attached hereto and incorporated by reference herein as Exhibit B;

WHEREAS, pursuant to the provisions of OSU IIA#1, UTRF holds a license, with the right to sublicense, to the interest of OSU in EXISTING INVENTIONS (defined below) pertaining to BRIDGED SARMS the subject matter of which was conceived, created, developed, designed, invented, or reduced to practice in whole or in part by OSU researcher Dr. Dalton and/or other OSU research staff and students under Dr. Dalton’s direction before December 22, 2004;

WHEREAS, pursuant to the provisions of OSU IIA#1, UTRF holds an option to a license, with the right to sublicense, to OSU’s interest in IMPROVEMENT INVENTIONS (defined below) pertaining to BRIDGED SARMS conceived, created, developed, designed, invented, or reduced to practice, in whole or in part by OSU faculty researchers, research staff, or students after December 22, 2004.

WHEREAS, UTRF also entered into that certain agreement entitled “New SARM Inventions Inter-Institutional Agreement” with OSU effective as of December 22, 2004 (“OSU IIA#2”), attached hereto and incorporated by reference herein as Exhibit C;

WHEREAS, pursuant to the provisions of OSU IIA#2, UTRF holds an option to a license, with the right to sublicense, to OSU’s interest in NEW INVENTIONS` (defined below) pertaining to certain SARMS conceived, created, developed, designed, invented, or reduced to practice, in whole or in part, by Dr. Dalton, or other OSU research staff, or students and not otherwise subject to OSU IIA#1;

WHEREAS, the Parties now desire to enter into this “Consolidated, Amended, and Restated License Agreement” for the purpose of (i) consolidating the Prior License Agreements into one agreement; (ii) granting GTx an exclusive license in UTRF’s interest in EXISTING INVENTIONS and IMPROVEMENT INVENTIONS that were not previously licensed to GTx under the Prior License Agreements, if any; (iii) granting GTx an exclusive license, subject to the provisions of OSU IIA#1, in OSU’s interest in all LICENSED INVENTIONS (as defined in OSU IIA#1), to the extent licensed to UTRF; (iv) granting GTx an exclusive license, subject to the provisions of OSU IIA#2, in OSU’s interest in all LICENSED INVENTIONS (as defined in OSU IIA#2), to the extent licensed to UTRF, and in UTRF’s interest in NEW INVENTIONS; and (v) making certain other changes regarding the rights and obligations of the Parties, including but not limited to those changes that are necessary for UTRF to comply with the provisions of OSU IIA#1 and OSU IIA#2; and

WHEREAS, the Parties intend that this Agreement shall supersede the Prior License Agreements and render them null and void.

NOW, THEREFORE, for and in consideration of the premises and other good and valuable consideration, including a payment in the amount of Two Hundred Ninety Thousand Dollars (\$290,000; the “Consideration Fee”), which is paid by GTx in consideration of UTRF’s execution of this Agreement, the Parties hereto expressly agree as follows:

SECTION 1

Definitions

1.1 “Actions” shall have the meaning set forth in Section 17.1 hereof.

1.2 “Active Ingredient” means the material(s) in a pharmaceutical product which provide its

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

pharmacological activity (excluding formulation components such as coatings, stabilizers or controlled release technologies).

1.3 “Affiliate” shall mean any corporation, partnership, or other entity that at any time during the Term of this Agreement, directly or through one or more intermediaries, Controls or is Controlled by or is under common Control with a Party to this Agreement or a Sublicensee, but only for so long as the relationship exists. A corporation or other entity shall no longer be an Affiliate when through loss, divestment, dilution or other reduction of ownership, the requisite Control no longer exists.

1.4 “Agreement” shall mean this Consolidated, Amended and Restated License Agreement.

1.5 “BRIDGED SARMS” shall have the meaning set forth in OSU IIA#1.

1.6 “Claims” shall have the meaning set forth in Section 8.1 hereof.

1.7 “Combination Product” means either (i) any pharmaceutical product that consists of a SARM and at least one other Active Ingredient that is not a SARM, or (ii) any combination of a SARM and another pharmaceutical product that contains at least one other Active Ingredient that is not a SARM where such products are not formulated together but are sold together as a single product and invoiced as one product.

1.8 “Confidential Information” shall have the meaning set forth in Section 18.2 hereof.

1.9 “Control” or “Controls” or “Controlled” shall mean: (i) in the case of a corporation, ownership or control, directly or indirectly, of at least fifty one percent (51%) of the shares of stock entitled to vote for the election of directors; or (ii) in the case of an entity other than a corporation, ownership or control, directly or indirectly, of at least fifty one percent (51%) of the assets of such entity.

1.10 “Effective Date” shall have the meaning set forth in the introductory paragraph hereof.

1.11 “Exception Countries” shall have the meaning set forth in Section 6.6 hereof.

1.12 “EXISTING INVENTION” shall have the meaning set forth in OSU IIA#1.

1.13 “Federal Policy” shall have the meaning set forth in Section 2.3 hereof.

1.14 “Generic Product” shall mean a product that is derived from, made with, uses, or incorporates, in whole or in part, Licensed Technology, but is not covered or claimed in whole or in part by a Valid Claim of the Licensed Patents in the country of manufacture, use, or sale or import.

1.15 “GTx” shall mean GTx, Inc. and its Affiliate(s) (unless such Affiliates are clearly excluded from the referencing provision(s) at issue), provided that in no instance shall GTx, Inc. be relieved of any duty or obligation hereunder by the inclusion of its Affiliates in the definition of “GTx”.

1.16 “IMPROVEMENT INVENTION” shall have the meaning set forth in OSU IIA#1.

1.17 “Independent SARM Invention” shall have the meaning set forth in Section 2.8 hereof.

1.18 “Initial SARMS Disclosure” and “Initial SARMS Disclosures” shall have the meaning set forth in the Recitals.

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1.19 “IP RIGHTS” shall have the meaning set forth in OSU IIA#1 when referring to an EXISTING INVENTION or an IMPROVEMENT INVENTION and the meaning set forth in OSU IIA#2 when referring to a NEW INVENTION.

1.20 “License Maintenance Fee” shall have the meaning set forth in Section 4.1A. hereof.

1.21 “License Year” shall mean a 12-month period beginning on August 20 of one year and ending on August 19 of the following year.

1.22 “Licensed Patent” or “Licensed Patents” shall mean any or all of the (a) the patents set forth on Appendix A, attached hereto and incorporated herein by reference, (b) the patent applications set forth on Appendix A and any patents issuing therefrom, and (c) any other patent applications that may in the future be filed pursuant to Section 6.1 of this Agreement by GTx, whether in the United States of America or any other country, and any patents issuing therefrom, including, as they pertain to patents and patent applications described in (a)-(c) hereof, any and all substitutions for and divisional applications, continuation applications, continuation-in-part applications, provisional applications, and non-provisional applications, renewal applications, reissue applications, any foreign patent applications and divisional, continuation and continuation-in-part applications therefrom or national phase applications which claim priority from any of the pending patent applications set forth on Appendix A.

1.23 “Licensed Product” or “Licensed Products” shall mean any Patented Product or Generic Product, provided that in the case of a Combination Product (as defined under Section 1.7), Licensed Product shall mean only that portion of the Combination Product containing a SARM or SARMS, and Net Sales for such Licensed Product contained within a Combination Product shall be determined as set forth under Section 1.29.

1.24 “Licensed Subject Matter” shall mean Licensed Patents and Licensed Technology.

1.25 “Licensed Technology” shall mean, except to the extent published or otherwise generally known to the public:

- A. any know-how that is (i) related to an EXISTING INVENTION and/or an IMPROVEMENT INVENTION licensed by UTRF from OSU under OSU IIA#1; or (ii) related to a NEW INVENTION licensed by UTRF from OSU under OSU IIA#2; and
- B. any technology, trade secrets, methods, processes, know-how, show-how, data, information, or results (except technology, trade secrets, methods, processes, know-how, show-how, data, information, or results solely related to NON-TGS NEW INVENTIONS to the extent not published or otherwise generally known to the public) that are (i) developed by any one or more of the UT Contributors in the course of employment by UT or developed by any other UT employee directly from his or her research or clinical investigation of SARMS utilizing any Proprietary SARM Know-How; and (ii) owned solely or in part by UTRF (but, if owned in part by UTRF, only to the extent of the part owned by UTRF); and (iii) necessary or reasonably useful for the practice of any of the Licensed Patent(s), including (for purposes of explaining, and without expanding, the meaning of Sections 1.25B. (i) through (iii)) any: (1) SARMS, and compositions and compounds containing SARMS, and analogs or isomers of SARMS, including without limitation radiolabeled SARMS, fluorescent labeled SARMS, and SARMS with radioisotopes incorporated therein, and SARMS comprising small molecules of R-bicalutamide; (2) methods of making, developing, or characterizing such SARMS, agents, compositions, and compounds of (1); and (3) any therapeutic, diagnostic, and prognostic methods of use of (1), including but not limited to methods of treating prostate cancer,

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methods of imaging, or methods related to fertility, contraceptive, andropause, muscle wasting, bone loss and muscle or bone mass uses.

1.26 "Major Countries" shall have the meaning set forth in Section 6.6 hereof.

1.27 "Major Markets" shall mean and include the United States, Great Britain, France, Germany, and Japan.

1.28 "Negotiation Period" shall have the meaning set forth in Section 2.8D. hereof.

1.29 "Net Sales" shall mean the gross amount actually received by GTx or any Sublicensee for the use, sale or distribution (hereinafter "Sale") of a Licensed Product (hereinafter "Gross Receipts"), less the following:

- A. refunds, credits, and/or discounts actually given in connection with a particular Sale in amounts customary in the trade for quantity purchases, cash payments, and prompt payments, but only if such refunds, credits, and/or discounts constitute a return of amounts already included in Gross Receipts;
- B. refunds, credits and/or discounts actually given for Licensed Products that are rejected, recalled, returned, or destroyed by customers, but only if such refunds, credits and/or discounts constitute a return of amounts already included in Gross Receipts;
- C. sales, tariff duties and/or use taxes directly imposed and with reference to a particular Sale, to the extent included in Gross Receipts;
- D. outbound transportation expenses (including insurance relating thereto) directly related to a particular Sale, to the extent included in Gross Receipts;
- E. the cost of export licenses, import duties, value added tax, and prepaid freight directly related to a particular Sale, to the extent included in Gross Receipts;
- F. sales commissions paid by GTx to individuals who are not employees of GTx, a Sublicensee, or their respective Affiliates, to the extent such commissions are directly related to a particular Sale;
- G. out-of-pocket service fees consistent with normal industry practice paid to distributors or wholesalers of drug product in payment for distribution of Licensed Product, provided that (a) such distributors and wholesalers are not Affiliates of GTx; (b) if any such distributor or wholesaler is an Affiliate of a Sublicensee, such fees are no more than that which such distributor/wholesaler actually and contemporaneously charges unaffiliated third party pharmaceutical companies for the same or similar service; (c) such fees may not be deducted more than once; (d) if a Sublicense shall be in effect, the fees paid by a Sublicensee may be deducted from Net Sales under this Agreement only if such fees are deducted from the equivalent of Net Sales under the relevant Sublicense agreement for purposes of calculating the royalty owed to GTx;
- H. retroactive price reductions, chargeback payments and rebates actually granted in connection with a particular Sale to managed health care organizations or to federal, state and local governments, their agencies, purchasers, and reimbursers, but only if such reductions, chargeback payments, and rebates constitute a return of amounts already included in or calculated as part of Gross Receipts; and

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- I. [*] of any royalty (including a lump-sum payment) that is paid to a Third Party by GTx pursuant to a patent license agreement between GTx and such Third Party, provided that at the time of such payment (1) such Third Party owns or controls an issued patent containing a Valid Claim that, in the absence of such patent license agreement, would be infringed by the use, sale, or distribution of the composition of matter of a SARM licensed to GTx hereunder; and (2) the purpose of such royalty is for licensing of or acquiring such issued patent; and (3) the dollar amount of the [*] deduction for any calendar quarter shall not exceed the dollar amount of Net Sales in the same calendar quarter (computed without the application of this Section 1.29I.) from the use, sale, or distribution of Licensed Products containing such SARM in the country(ies) where such Third Party owns or controls such issued patent, it being agreed, however, that GTx may carry forward to future quarter(s) the amount by which the dollar amount of the [*] deduction exceeds the cumulative dollar amount of the actual deductions taken; and (4) GTx has not entered into such patent license agreement as of the date of execution of this Agreement.

For avoidance of doubt, no deductions shall be made for sales commissions paid to individuals who are employees of GTx, a Sublicensee, or their respective Affiliates, or for cost of collections. Notwithstanding the foregoing, Net Sales shall not include the amount received by GTx for the transfer of Licensed Product to a GTx Affiliate or a Sublicensee or the amount received by a Sublicensee for transfer or distribution of Licensed Product to GTx or a GTx Affiliate. Sales of Licensed Product for use in conducting clinical trials of a Licensed Product candidate in a country shall be excluded from Net Sales calculations for all purposes. Net Sales shall be determined in a consistent manner for all products sold by or on behalf of GTx and its Sublicensees and in accordance with applicable U.S. generally accepted accounting principles for GTx and any U.S. based Sublicensee.

Combination Product. In the event one or more Licensed Products are sold as part of a Combination Product in a particular country, the Net Sales of such Licensed Product(s), for the purposes of determining payments based on Net Sales, shall be determined by multiplying the Net Sales of the Combination Product in such country, during the applicable Net Sales reporting period, by the fraction, $A/(A+B)$, where:

A is the average sale price of the Licensed Product(s) by GTx or Sublicensees when sold separately in finished form in such country and B is the average sale price by GTx or Sublicensees, or, if they have no such right of sale, by a Third Party of the other product(s) included in the Combination Product when sold separately in finished form in such country, in each case during the applicable Net Sales reporting period.

In the event one or more Licensed Products are sold as part of a Combination Product and are sold separately in finished form in such country, but the other product(s) included in the Combination Product are not sold separately in finished form in such country, the Net Sales of the Licensed Product, for the purposes of determining payments based on Net Sales, shall be determined by multiplying the Net Sales of the Combination Product in such country by the fraction C/D where:

C is the average sale price, in such country, of the Licensed Product(s) contained in such Combination Product when sold separately and D is the average sale price, in such country, for the Combination Product, in each case during the applicable Net Sales reporting period. Under no circumstances can C/D exceed one hundred percent (100%).

In the event that one or more of the Licensed Product(s) are not sold separately in finished form in the country, but all of the other product(s) included in the Combination Product in such country are sold separately, the Net Sales of the Licensed Product, for the purposes of determining payments based on Net Sales, shall be determined by multiplying the Net Sales of the Combination Product in such country by the fraction $(D-E)/D$, where:

D is the average sale price, in such country, of the Combination Product, and E is the average sale price of the other product(s) included in the Combination Product in finished form in such country, in each case during the applicable Net Sales reporting period.

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In the event that the Net Sales of the Licensed Product(s) when included in a Combination Product cannot be determined using the methods above, Net Sales for the purposes of determining payments based on Net Sales shall be calculated by multiplying the Net Sales of the Combination Product by the fraction of $F/(F+G)$ where:

F is the fair market value of the Licensed Product(s) and G is the fair market value of all other pharmaceutical product(s) included in the Combination Product, as reasonably determined in good faith by the Parties.

1.30 "NEW INVENTION" shall have the meaning set forth in OSU IIA#2, but limited for purposes of this Agreement to invention(s) described in the Third Generation SARMS Disclosure.

1.31 "NON-TGS NEW INVENTION" shall have the meaning set forth for NEW INVENTION in OSU IIA#2, but excluding for purposes of this Agreement invention(s) described in the Third Generation SARMS Disclosure.

1.32 "Option" shall have the meaning set forth in Section 2.8 hereof.

1.33 "Option Period" shall have the meaning set forth in Section 2.8A. hereof.

1.34 "OSU" shall mean The Ohio State University, except that where it is used in reference to OSU IIA#1 or OSU IIA#2 in which case it shall mean The Ohio State University and OSURF, as set forth therein.

1.35 "OSU Contributors" shall mean Dr. James T. Dalton and/or other research staff and students at OSU.

1.36 "OSU IIA#1" shall have the meaning set forth in the Recitals.

1.37 "OSU IIA#2" shall have the meaning set forth in the Recitals.

1.38 "OSURF" shall mean The Ohio State University Research Foundation.

1.39 "Patented Product" shall mean any product whose manufacture, use, sale or import is covered in whole or in part by a Valid Claim of the Licensed Patents in the country of manufacture, use, sale or import.

1.40 "Party" and "Parties" shall have the meaning set forth in the introductory paragraph hereof.

1.41 "Prior License Agreements" shall have the meaning set forth in the Recitals.

1.42 "Proprietary SARM Know-How" shall mean know-how pertaining to an EXISTING INVENTION, IMPROVEMENT INVENTION or NEW INVENTION that is obtained from GTx or a UT Contributor and is not published or otherwise generally known to the public.

1.43 "Regulatory Approval" shall mean any approvals granted by a governmental authority in a particular regulatory jurisdiction (with the exception of conditional approvals) that are necessary for the commercial manufacture, use, storage, importation, export, transport or sale of Licensed Products in that regulatory jurisdiction.

1.44 "Running Royalty" shall have the meaning set forth in Section 4.1B. hereof.

1.45 "SARM" or "SARMS" shall mean selective androgen receptor modulator(s) whose primary pharmacologic effect at any dose observed in vivo is mediated by the androgen receptor.

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1.46 “Sublicense” shall mean a direct grant of right, license, or option to any Licensed Subject Matter from GTx to a GTx Affiliate or a Third Party and any further such grant at any tier.

1.47 “Sublicense Revenue” shall mean all payments actually received by GTx pursuant to each Sublicense, including, without limitation, up-front license fees, milestone payments, license maintenance fees, election fees, and all other fees and payments paid to GTx under each Sublicense agreement, excluding running royalties received by GTx that are calculated as a percentage of Sublicensee’s Net Sales and up-front fees paid by Ortho Biotech Products L.P. pursuant to the Joint Collaboration and License Agreement entered into with GTx effective as of March 16, 2004. GTx may deduct from Sublicense Revenue attributable to a particular Sublicense agreement payments received by GTx as reimbursement for actual, otherwise unreimbursed, out-of-pocket expenses as set out in such Sublicense agreement, provided that only reimbursements for expenses incurred in the development of one or more Licensed Products covered by such Sublicense may be deducted from Sublicense Revenue and then only to the extent of expenses incurred from and after the date of the Sublicense for pre-clinical or clinical research and development, including development of the formulation and manufacturing process, manufacturing of preclinical and clinical supplies and analytical and stability testing as required by the Food and Drug Administration to support a New Drug Application (NDA) filing for the Licensed Product. For the avoidance of doubt, Sublicense Revenue will not include any payments made to Third Parties by or on behalf of a Sublicensee for conducting clinical trials, filing new drug applications, commercially launching a product and/or marketing and selling a product, since these are not payments received by GTx from a Sublicensee on account of the Sublicense.

1.48 “Sublicense Royalty” shall have the meaning set forth in Section 4.1C. hereof.

1.49 “Sublicensee” shall mean and include any recipient of a Sublicense.

1.50 “Sublicensee Patent Rights” shall have the meaning set forth in Section 6.2 hereof.

1.51 “Term” shall have the meaning set forth in Section 12.1 hereof.

1.52 “Third Generation SARMS Disclosure” shall have the meaning set forth in the Recitals.

1.53 “Third Party” or “Third Parties” shall mean any person, party or entity other than GTx, its Affiliates, UTRF, or UT.

1.54 “UT” shall mean The University of Tennessee.

1.55 “UT Contributor” and “UT Contributors” shall mean one or more of James T. Dalton, Yali He, Dong-Jin Hwang, Leonid Kirkovsky, Craig Marhefka, Duane Miller, Michael Mohler, Arnab Mukherjee, Igor Rakov, Huiping Xu, Donghua Yin and any other UT employee who, while under the supervision of Duane Miller or James T. Dalton, contributed, either before or after the Effective Date, to the development of the Licensed Subject Matter.

1.56 “Valid Claim” shall mean (a) a claim of an issued patent which has not expired and which has not been held revoked, invalid or unenforceable by decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed with the time allowed for appeal having expired, and which has not been admitted to be invalid through reissue or disclaimer or otherwise; or (b) any claim of a pending patent application, which (i) was filed in good faith; and (ii) has not been pending for more than eight (8) years.

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SECTION 2

Grant

2.1 During the Term hereof, and subject to the terms and conditions of this Agreement, UTRF hereby grants to GTx for the purpose of developing, making, having made, using, marketing, selling, having sold, importing, distributing, and offering for sale the Licensed Product:

- A. an exclusive, worldwide right and license, with the right to grant Sublicenses, to practice under the Licensed Patents that are owned solely or in part by UTRF, excluding Licensed Patents to which a license is granted in Section 2.1B.; and
- B. subject to the provisions of OSU IIA#1 and OSU IIA#2, as applicable, an exclusive, worldwide right and license, with the right to grant Sublicenses, to practice under the Licensed Patents and the IP RIGHTS that are owned jointly by UTRF and OSU or owned solely by OSU and that cover an EXISTING INVENTION, an IMPROVEMENT INVENTION or a NEW INVENTION, provided that OSU's interest is licensed to UTRF with the right to grant sublicenses pursuant to the provisions of OSU IIA#1 or OSU IIA#2, as the case may be; and
- C. subject to the provisions of OSU IIA#1 and OSU IIA#2, as applicable, an exclusive, worldwide right and license, with the right to grant Sublicenses, of the non-exclusive rights received by UTRF from OSU under OSU IIA#1 and OSU IIA#2 to utilize the Licensed Technology described in Section 1.25A.; and
- D. subject to the provisions of OSU IIA#1 and OSU IIA#2, as applicable, an exclusive, worldwide, right and license, with the right to grant sublicenses, to utilize the Licensed Technology described in Section 1.25B.

Subject to the other provisions of this Agreement, the Parties hereby agree that the term "exclusive" means that to the extent of UTRF's rights in the Licensed Subject Matter and subject to Federal Policy and the provisions of OSU IIA#1 and OSU IIA#2, UTRF shall not grant any other license under Licensed Subject Matter to any Third Party or take any action inconsistent with the rights granted to GTx under this Agreement. The Parties further acknowledge and agree that to the extent UTRF owns any Licensed Subject Matter "in part", the license herein granted to GTx will not give GTx or its Sublicensees the right to exclude UTRF's co-owner(s) from exercising any rights attendant to such co-ownership, whether such rights arise by law or contract, provided that UTRF agrees that it will not negotiate or enter into a license agreement or sublicense agreement, or otherwise grant any option or licenses or other rights with respect to such Licensed Subject Matter (whether in whole or in part), except as required by Federal Policy. For avoidance of doubt, the exercise by GTx of its right to grant Sublicenses will not serve to restrict GTx's exercising of its right, as granted above, to practice under the Licensed Patents and/or to utilize the Licensed Technology.

2.2 GTx agrees that UT and those persons who, as of the date of signature hereto on behalf of UTRF, are named UT Contributors shall have the royalty-free non-exclusive right to practice under the Licensed Patents and to utilize the Licensed Technology for non-commercial educational, research, and academic purposes only. GTx acknowledges and agrees that OSU retains the non-exclusive right to use EXISTING INVENTIONS and IMPROVEMENT INVENTIONS and associated IP RIGHTS under OSU IIA#1, as well as NEW INVENTIONS and associated IP RIGHTS under OSU IIA#2, to the extent of any of its respective rights therein, solely for non-commercial educational, research (including non-commercial clinical research), and academic purposes, but that OSU has contractually acknowledged that it has no rights for clinical research using a UTRF or GTx proprietary BRIDGED SARMS compound or to refer to any GTx regulatory filing without prior written approval from UTRF or GTx. UTRF agrees that during the Term hereof, it will not, without obtaining GTx's prior written consent, enter

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into a modification of OSU IIA#1 or OSU IIA#2 that (i) grants any additional ownership rights to OSU in an EXISTING INVENTION, IMPROVEMENT INVENTION, or NEW INVENTION; or (ii) places any additional obligations on GTx.

2.3 To the extent that any research pertaining to inventions included in Licensed Technology and/or claimed in Licensed Patents has been or is in the future funded in whole or in part by the United States government, the United States government retains certain rights and requires certain obligations concerning such inventions as set forth in 35 U.S.C. §§200-212 and all regulations promulgated thereunder, as amended, and any successor statutes and regulations and applicable policies of such United States government sponsors, including, without limitation, to the extent applicable, the utilization and capability requirements found in the National Institutes of Health (NIH) Grants Policy Statement; "Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts", Federal Register, Vol. 59, No. 215, Tuesday, November 8, 1994, pp. 55675-55679 (collectively, "Federal Policy"). GTx acknowledges that all rights herein granted to GTx may be subject to any such rights held by the United States government and further subject to any restrictions or obligations that may be imposed by the United States government pursuant to such rights. GTx shall materially comply with all aspects of Federal Policy applicable to a licensee pertaining to Licensed Technology and/or Licensed Patents and shall include and require its Sublicensees to include a provision in each Sublicense agreement, at any tier, that requires the Sublicensee to materially comply with all applicable aspects of Federal Policy. In the event UTRF or GTx shall receive notice of any action or notification by the United States government with respect to any rights and/or obligations under Federal Policy pertaining to any rights licensed hereunder to GTx, the Party receiving such notice shall provide prompt written notice thereof to the other Party.

2.4 Intentionally omitted.

2.5 GTx shall have the right to enter into Sublicenses and to permit further sublicensing by Sublicensees through multiple tiers with respect to the Licensed Subject Matter, subject to notifying UTRF of the identity and address of each Sublicensee within thirty (30) days after execution of such agreement by the parties thereto. No GTx Affiliate or Third Party shall have the right to practice under the Licensed Patents or utilize the Licensed Technology to make, have made, use, market, sell, have sold, import, distribute, or offer for sale any Licensed Product in the absence of a written Sublicense agreement. Any grant of rights by GTx or a Sublicensee to practice under the Licensed Patents or to utilize the Licensed Technology to make, have made, use, market, sell, have sold, import, distribute, or offer for sale any Licensed Product shall constitute a Sublicense. All Sublicenses shall be subject to this Agreement in all respects and shall include provisions that such Sublicensee is being granted a license under the Licensed Subject Matter as defined herein and subject to the terms hereof.

2.6 GTx shall be responsible for its Affiliates and Sublicensees and shall not grant any rights that are inconsistent with the rights granted to and obligations of GTx hereunder. Each Sublicense agreement shall include a requirement that the Sublicensee use its commercially reasonable efforts to bring the subject matter of the Sublicense into commercial use. In addition, each Sublicense agreement shall include an acknowledgement that the ownership of the Licensed Patents are and shall remain in the name of UTRF and/or OSU, as set forth in OSU IIA#1 or OSU IIA#2, as the case may be, with the exception of Licensed Patents that are properly assigned to GTx, and, except as set forth in Section 6.2 hereof, an obligation on the part of the Sublicensee to assign, transfer and convey ownership of Licensed Patents to UTRF and/or, as UTRF may direct, to OSU, OSURF, or GTx. Upon termination of this Agreement, each Sublicensee's rights under any Sublicense agreement shall also terminate, provided that if UTRF terminates this Agreement for default by GTx, a Sublicensee's rights under a Sublicense agreement shall terminate only if UTRF has given such Sublicensee notice of default at least thirty (30) days prior to the effective date of termination and the Sublicensee shall have failed to cure such default, as provided in Section 12.3. UTRF shall have discharged its obligation to give notice of such default to a Sublicensee by sending (through any means contemplated under Section 15) a copy of GTx's notice of default to the Sublicensee's most recent street address of which UTRF has received written notice from GTx or the Sublicensee. No Sublicense shall relieve GTx of any of its

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obligations under this Agreement, except that a Sublicensee shall have the right to cure a default of GTx as set out in Section 12.3. GTx shall forward to UTRF a complete copy of each Sublicense agreement (including, without limitation, all amendments and addenda) granted hereunder within thirty (30) days after execution of such agreement by the parties thereto, provided that each such Sublicense agreement (and any amendments and addenda related thereto) shall be deemed GTx's Confidential Information and UTRF shall receive such information and documents in confidence and shall not publicly disclose, discuss or release such information or document to Third Parties (other than such information as may be reasonably necessary to be disclosed to UT Contributors and those persons within UT who have a need to know such information, provided that only such information concerning the Sublicense that is necessary to explain any payments to be made to a UT Contributor will be shared with the UT Contributors) without the prior written approval of GTx except for the purposes of enforcement of UTRF's rights, defense of any claim against UTRF, UT, UT Contributors, OSU, OSURF, or OSU Contributors, compliance with Federal Policy, compliance with OSU IIA#1 or OSU IIA#2, or compliance with applicable law, regulation, or court order. GTx shall be responsible for payment of royalties from Sublicensees' Net Sales provided, however, that GTx may arrange for such payments to be made to UTRF by a Sublicensee, with the understanding that the amount paid to UTRF shall not be decreased thereby and that UTRF's acceptance of such payments from a Sublicensee does not relieve GTx of the ultimate responsibility for any other or future payment required hereunder. Each such Sublicense agreement shall include an audit right by UTRF of the same scope as provided in Section 5.1 herein with respect to UTRF's audit of GTx's books of account.

2.7 Any act or omission of an Affiliate or Sublicensee, which would constitute a breach of this Agreement if performed by GTx, shall be deemed to be a breach by GTx of this Agreement, subject however to the same cure provisions in favor of GTx, an Affiliate, or Sublicensee as are otherwise provided herein for breach by GTx.

2.8 During the Term hereof, UTRF shall promptly notify GTx in writing (i) upon becoming aware of any SARM invention owned solely or in part by UTRF which is not (a) based on or developed from Proprietary SARM Know-How or (b) developed at UT from grants or research payments made to UT by GTx; or (ii) upon acquiring from OSU a license pursuant to OSU IIA#2, with the right to sublicense, to a NON-TGS NEW INVENTION (each invention described in subsection (i) and subsection (ii) herein being an "Independent SARM Invention"). Subject to the rights of Third Parties (in the event UTRF co-owns such Independent SARM Invention with a Third Party), GTx will have an exclusive option to acquire, to the extent possible, a worldwide, exclusive (as defined in Section 2.1), royalty-bearing license to such Independent SARM Invention ("Option"), provided that the grant of such Option does not violate Federal Policy and further subject to the following:

- A. The Option shall commence upon UTRF's written notice to GTx of the existence of such Independent SARM Invention and shall terminate upon the earlier of (i) the expiration of six (6) calendar months from the date of such notice; or (ii) the giving of written notice to UTRF by GTx that it does not intend to exercise the Option; or (iii) the termination of this Agreement ("Option Period")
- B. GTx may exercise the Option during the Option Period by giving written notice of same to UTRF, provided that GTx is not then in default or breach of any of its obligations under this Agreement.
- C. Upon proper exercise of the Option by GTx, UTRF and GTx shall negotiate in good faith in an effort to reach agreement on the economic terms of a license to GTx of the Independent SARM Invention that is the subject of such Option, it being the intent that upon agreement of the Parties as to such economic terms, they will be expeditiously incorporated into a new license agreement with non-economic terms that are substantially similar to those contained herein, to the extent applicable.

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- D. In the event GTx does not exercise the Option for a particular Independent SARM Invention within the Option Period or the Parties do not execute a license agreement within six (6) months after exercise of the Option for a particular Independent SARM Invention by GTx, which time period may be extended by written agreement of the Parties (the "Negotiation Period"), UTRF shall have no further obligation to GTx under this Agreement with regard to such Independent SARM Invention. In the absence of a license agreement granting GTx rights to such Independent SARM Invention, GTx agrees that it will not use such Independent SARM Invention for any commercial or non-commercial purpose.
- E. During the Option Period and the Negotiation Period, if any, UTRF will confer with GTx concerning proper protection of such Independent SARM Invention, but UTRF will have sole authority regarding decisions concerning such protection, including patent activities, provided that if GTx exercises the Option, UTRF shall coordinate all decisions regarding patent protection with GTx and shall take no actions with regard to intellectual property protection for such Independent SARM Invention that are contrary to GTx's advice unless UTRF reasonably believes rights may be lost unless it acts to protect those rights. From and after the commencement of the Option Period, whether or not GTx exercises the Option and whether or not the Parties subsequently execute a license agreement for GTx to secure rights to the Independent SARM Invention prior to the end of the Negotiation Period, GTx shall, within thirty (30) days after receipt of each invoice, reimburse UTRF for all reasonable and documented out-of-pocket expenses incurred by UTRF during the Option Period and the Negotiation Period, if any, for filing, prosecution, and maintenance of United States and foreign patent applications, issued patents, and other forms of intellectual property protection for such Independent SARM Invention, which intellectual property rights shall be assigned solely to UTRF or jointly to UTRF and its co-owner(s), if any, provided that UTRF shall have consulted with GTx regarding such proposed patent protection and UTRF shall have undertaken to make those filings that are reasonably necessary to protect and preserve its rights in the Independent SARM Invention to reasonably minimize the expenses GTx may be required to reimburse in accordance with this Section 2.8E until the Option Period and Negotiation Period shall have expired. If GTx shall fail to enter into a license agreement with UTRF for such Independent SARM Invention, it shall be entitled to receive a dollar for dollar reduction against Running Royalties and/or Sublicense Revenue (in the same manner as the reduction is to be applied in Section 4.1D) for the total amount of costs it shall have reimbursed to UTRF for the expenses incurred by UTRF under this Section 2.8E.

SECTION 3

Diligence

3.1 GTx shall use its commercially reasonable efforts to develop and commercialize Licensed Products through a commercially reasonable program for exploitation of the Licensed Patents and the Licensed Technology.

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SECTION 4
Payments and Royalties

4.1 For the rights, privileges and license granted hereunder, GTx shall pay to UTRF, in addition to the Consideration Fee, the following fees and royalties in the manner hereinafter provided until this Agreement expires or is terminated.

- A. **License Maintenance Fee.** GTx shall pay UTRF a license maintenance fee in the amount of [*] on [*] and on [*] thereafter during the Term of this Agreement (“License Maintenance Fee”). The License Maintenance Fee actually paid for a particular License Year shall reduce, dollar for dollar, the Running Royalty (defined below) payable in the same License Year. License Maintenance Fees paid in excess of the Running Royalty payable in the same License Year shall not be creditable to the Running Royalty for future years. The Parties acknowledge and agree that there are no License Maintenance Fees due and owing to UTRF by GTx under the Prior License Agreements.
- B. **Running Royalty.** For the purposes of this Section 4.1(B), royalties on Net Sales of all Patented Products and Generic Products incorporated in Combination Products shall be subject to the calculation of Net Sales with respect to Combination Products, as applicable, as set forth in Section 1.29.
- (1) GTx shall pay UTRF [*] of Net Sales of all Patented Products; and
 - (2) GTx shall pay UTRF a percentage of Net Sales attributable to the use, sale or distribution of Generic Products, which percentage shall be determined on a Generic Product-by-Generic Product, country-by-country, and calendar quarter-by-calendar quarter basis. In each country the percentage shall be calculated as the [*] during the applicable calendar quarter divided by the [*] during the same calendar quarter [*] (provided that in no event shall the resulting percentage [*]). Furthermore, until such time as this Agreement shall expire in accordance with Section 12.1, should there be no sales in the Major Markets by GTx or Sublicensees of the same Licensed Product covered by a Valid Claim of Licensed Patents during the same calendar quarter, the percentage shall be [*];

(the royalty under 4.1B.(1) and 4.1B.(2) being the “Running Royalty”). Notwithstanding the foregoing, in the event that, for a particular Licensed Product in a given License Year under a specific Sublicense agreement, the running royalty (as a percentage of Net Sales) owed to GTx (including the Running Royalty owed to UTRF, if to be paid by the Sublicensee) is less than [*] of Sublicensee’s Net Sales after deduction of running royalties (calculated as a percentage of Net Sales) owed and actually paid by or on behalf of GTx to one or more Third Parties as consideration for the grant by such Third Party(ies) of a license to technology incorporated in such Licensed Product, the Running Royalty owed to UTRF shall be [*] of the amount owed to GTx (including the Running Royalty owed to UTRF, if to be paid by the Sublicensee) for that License Year. By way of example only, in the event that during a particular License Year GTx is entitled to receive a running royalty equal to [*] of its Sublicensee’s Net Sales of a particular Licensed Product in the EU and is in turn required to pay, and does actually pay, [*] of Sublicensee’s Net Sales of that Licensed Product in the EU to a Third Party, then UTRF’s Running Royalty would be [*] of Sublicensee’s Net Sales of that Licensed Product in the EU.

- C. **Sublicense Royalty.** GTx shall pay UTRF [*] of Sublicense Revenue (“Sublicense Royalty”)

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D. Reduction. GTX shall be entitled to reduce dollar-for-dollar the Running Royalties and/or the Sublicense Royalties (such reduction to be applied at GTX's sole discretion) which are otherwise payable to UTRF by a total of [*] to reimburse GTX for certain shared legal expenses previously borne by GTX in connection with the negotiation of OSU IIA#1.

4.2 In the event that any taxes are required by law or regulation to be levied in any foreign country by a foreign taxing authority on any Running Royalty or Sublicense Royalty payable in UTRF's name under this Agreement and GTX determines in good faith that it or its Sublicensee must withhold such taxes:

- A. GTX or its Sublicensee shall have the right to withhold and pay such taxes withheld on the Running Royalty and/or Sublicense Royalty to the local tax authorities in UTRF's name;
- B. GTX or its Sublicensee shall pay the net amount of Running Royalty and/or Sublicense Royalty due after reduction by the amount of such taxes that are actually withheld and paid;
- C. GTX or its Sublicensee shall provide UTRF with appropriate documentation and receipts supporting such withholding; and
- D. GTX or its Sublicensee shall inform UTRF in writing within thirty (30) days of being notified that taxes will be or have been required by a taxing authority to be withheld on the Running Royalty and/or Sublicense Royalty.

4.3 In the event that a Running Royalty is payable to UTRF on the same Net Sales revenue or a Sublicense Royalty is payable to UTRF on the same Sublicense Revenue under this Section 4 and under one or more other UTRF/GTx license agreements, GTX shall only be required to pay UTRF such royalty under one such license agreement, subject to the provisions of Section 5.2 and provided that if the amount due varies from one such license agreement to another, GTX shall pay the highest amount.

4.4 Within [*] following the close of each calendar quarter in which Net Sales revenue is received by GTX or a Sublicensee, or Sublicense Revenue is received by GTX, payment of all amounts due to UTRF, including but not limited to Running Royalty and Sublicense Royalty, shall be made to UTRF or its designee in United States dollars in Knoxville, Tennessee, or at such other place as UTRF may reasonably designate consistent with the laws and regulations controlling in any foreign country, provided that the [*] period may be extended for up to [*] after the close of each calendar quarter if a Sublicensee under a Sublicense requires more time than [*] to make its sales and royalty calculation and its royalty payment available to GTX. In the event GTX arranges for any payment under this Section 4.4 to be made to UTRF by a Sublicensee pursuant to Section 2.6, if such payment is not received by UTRF within the [*] period set forth herein (or within up to [*] extension period as stated above), GTX shall be deemed to be in breach of this Agreement, subject to the same cure provisions in favor of GTX as set forth in Section 12. If any currency conversion shall be required in connection with the payment of royalties hereunder, such conversion shall be made by using the exchange rate procedure listed in a Sublicense, if applicable, or in the absence of an applicable Sublicense provision addressing this issue, using the exchange rate listed in the Wall Street Journal for major New York banks on the last business day of the calendar quarter during which the royalty-bearing revenue was received by GTX or its Sublicensees, as the case may be.

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SECTION 5
Reports and Records

5.1 No more often than once each License Year, UTRF or its accounting agents shall have the right to inspect the books of account of GTx. GTx shall keep full, true and accurate books of account containing all particulars that may be necessary for the purpose of showing the amounts payable to UTRF hereunder. Said books of account shall be kept at GTx's principal place of business or the principal place of business of the appropriate division of GTx to which this Agreement relates. Said books and the supporting data shall be open at all reasonable times for [*] following the end of the License Year to which they pertain, to the inspection of UTRF or its accounting agents for the purpose of verifying GTx's royalty statements. If any examination reveals a shortage in amounts paid to UTRF, GTx shall promptly reimburse UTRF for the shortage, together with interest thereon as provided in Section 5.4, and if the shortage is equal to or greater than [*] of the total amount due in the period under audit, GTx shall reimburse UTRF for the cost of the examination as well. If the examination reveals an overpayment to UTRF, GTx may deduct the amount of such overpayment from future amounts owed to UTRF hereunder.

5.2 GTx shall deliver to UTRF true and accurate reports to confirm a royalty accounting hereunder within [*] after the close of each calendar quarter (provided that the [*] period may be extended for up to [*] after the close of each calendar quarter if a Sublicensee under a Sublicense requires more time than [*] to make such information and its royalty payment available to GTx) and a summary of GTx's activities during such quarter to develop and commercialize Licensed Products. These reports shall be deemed GTx's Confidential Information and shall include at least the following, on a Licensed Product-by-Licensed Product, country-by-country, and Sublicensee-by-Sublicensee basis:

- A. The number/amount of Licensed Product used, sold, or imported by and/or for GTx and Sublicensees and other information that is reasonably necessary to allow UTRF to properly calculate royalties due to OSU under OSU IIA#1 and, if applicable, OSU IIA#2 (e.g., the number/amount of BRIDGED SARMS or other SARMS sold);
- B. The total amounts invoiced and received by GTx and Sublicensees for Licensed Products used or sold by GTx and/or Sublicensees including (i) an accounting of Net Sales for Running Royalty payments due to UTRF under Section 4.1B. above, with separate calculations for Patented Products, Generic Products, and Combination Products reflecting the type and amount of all deductions from Gross Receipts; and (ii) an accounting of Sublicense Revenue for Sublicense Royalty payments due to UTRF under Section 4.1C above reflecting the type and amount of all amounts deducted or excluded from Sublicense Revenue;
- C. The Running Royalty and Sublicense Royalty due, showing the application of any reduction pursuant to Section 4.1D and Section 2.8E., if applicable;
- D. For all royalties due to UTRF pursuant to Section 4.1, the report shall include (i) the manner in which such royalties were calculated and the amount allocable to each Licensed Product; and (ii) if any such royalties are payable to UTRF under this Agreement and under one or more other UTRF/GTx license agreements, GTx shall set out in its report the amount of such royalties covered by multiple license agreements and identify all such license agreements to which such royalties apply, notwithstanding that GTx is required to pay such royalties under only one such license agreement;
- E. The names and addresses of all Sublicensees for or on whose account royalty payments are being made in accordance with the terms hereof; and

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F. Upon request by UTRF, any other information that may be necessary for the purpose of showing the amounts payable to UTRF hereunder, amounts payable to OSU pursuant to IIA#1 and/or IIA#2 and/or compliance by GTx with the diligence provisions of Section 3.

5.3 With each such report submitted, GTx shall pay to UTRF the royalties due and payable under this Agreement. If no royalties shall be due, GTx shall so report. UTRF is hereby authorized to provide to OSU or OSURF a copy of any written reports provided to UTRF by GTx, subject to the confidentiality provisions of OSU IIA#1, and if applicable, OSU IIA#2.

5.4 Any amount owed by GTx under this Agreement that is not received by UTRF on or before the date due shall bear interest at a per annum rate [*] above the prime rate quoted in the Wall Street Journal for major New York banks on the date due, or if not quoted on the date due, the rate quoted on the first business day after the date due. GTx shall also pay all reasonable collection costs at any time incurred by UTRF in obtaining payment of amounts past due, including reasonable attorneys fees. If the transfer or the conversion into United States Dollar equivalents in any such instance is not lawful or possible, the payment of such part of the royalties as is necessary shall be made by the deposit thereof, in the currency of the country where the sales were made on which the royalty was based, to the credit and account of UTRF or its nominee in any commercial bank or trust company of its choice located in that country, prompt notice of which shall be given by GTx to UTRF.

SECTION 6

Patent Prosecution

6.1 During the Term and subject to the terms hereof and the applicable provisions of OSU IIA#1 and OSU IIA#2, GTx shall have (a) complete control of the prosecution of the Licensed Patents listed on Appendix A and will be responsible for maintaining any patents issuing therefrom and (b) the exclusive right and responsibility to prepare, file, prosecute and maintain all patent applications and patents claiming (i) EXISTING INVENTIONS and IMPROVEMENT INVENTIONS that are solely or partly owned by UTRF or licensed to UTRF under OSU IIA#1 with the right to sublicense; (ii) NEW INVENTIONS that are licensed to UTRF under OSU IIA#2 with the right to sublicense; (iii) inventions solely owned by UTRF that are described in the Initial SARMS Disclosures; (iv) invention(s) disclosed in the Third Generation SARMS Disclosure that are owned in whole or in part by UTRF and are not covered by Section 6.1(ii); and (v) Licensed Technology defined in Section 1.25B., and such patent applications and patents shall be added to Appendix A. GTx shall use patent counsel of its own choice, at its own expense. GTx agrees to pay all costs incident to the United States and foreign applications, patents and like protection relating to the Licensed Subject Matter, including all costs incurred for filing, prosecution, issuance and maintenance fees as well as any costs incurred in filing continuations, continuations-in-part, divisionals or related applications and any re-examination, reissue, opposition, or interference proceedings. Subject to the provisions of Section 6.4, GTx shall file and maintain patent applications claiming Licensed Technology defined in Section 1.25B. in such countries as GTx in its sole discretion shall select. Except for Licensed Patents listed on Appendix A that are assigned to GTx or Sublicensee Patent Rights as described in Section 6.2, UTRF shall have the sole and exclusive right, title and ownership in and to all Licensed Patents, including Licensed Patents claiming Licensed Technology defined in Section 1.25B., which now exist or may exist in the future, including all United States and foreign patent applications filed and patents issued pursuant to this Section 6, except Licensed Patents claiming invention(s) made in whole or in part by one or more OSU Contributors or other Third Parties as determined in accordance with applicable patent laws, ownership of which shall be subject to the provisions of Section 6.2.

6.2 GTx and its Sublicensees shall assign, transfer and convey to UTRF all right, title and interest in and to all Licensed Patents, except (i) those claiming invention(s) made in whole or in part by one or more OSU Contributors or Third Parties, which Licensed Patents are to be assigned, in whole or in part, as the case may be, to OSU, OSURF, or in accordance with the instructions of such Third Party(ies); and (ii) those listed on Appendix A that, as of the Effective Date, have been assigned to GTx. GTx shall be responsible for recording an assignment, as

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appropriate, to UTRF and/or OSU and/or OSURF and/or to such individual(s) or entity(ies) as such Third Party(ies) may direct, of patent applications filed pursuant to this Section 6 with the United States Patent and Trademark Office and with each foreign Patent Office in which such applications are filed. Notwithstanding the foregoing, GTx may permit its Sublicensees to retain ownership of patent applications or patents claiming invention(s) made by employee(s) or agent(s) of such Sublicensee which result from the Licensed Subject Matter ("Sublicensee Patent Rights"), provided that the pertinent Sublicense agreement shall include provision(s) granting to UTRF, UT, OSU, and OSURF a perpetual worldwide non-exclusive royalty-free right to practice, for non-commercial educational, research and academic purposes only (such right to exclude the practice of Licensed Patents for any fee-for-services arrangement or for sponsored research on behalf of any commercial entity), under Sublicensee Patent Rights claiming inventions necessary or reasonably useful in the practice of the Licensed Patents.

6.3 GTx agrees to provide UTRF with reasonable (which the Parties agree generally means not less than two weeks) advance notice prior to filing of new patent applications containing new subject matter, including, without limitation, continuation-in-part applications, within Licensed Patents. Copies of applications that are divisional or continuation applications of Licensed Patents shall be furnished to UTRF and OSU or OSURF within thirty (30) days of their being initially filed with an appropriate patent office. GTx shall keep UTRF and OSU or OSURF informed, at GTx's expense, of filing, prosecution, maintenance, and abandonment of applications and issued patents within Licensed Patents pursuant to this Section 6, including submitting to UTRF and OSU or OSURF copies of all patent applications in accordance with the previous sentence, and submitting to UTRF and OSU or OSURF copies of material, official actions and responses thereto, and other material written communications it or its patent counsel receives from or files with the U.S. Patent and Trademark Office and the equivalent foreign offices within forty-five (45) days of filing or receipt, as the case may be. Notwithstanding the foregoing, GTx shall submit information and copies of documents to OSU or OSURF only with regard to EXISTING INVENTIONS, IMPROVEMENT INVENTIONS, and NEW INVENTIONS. GTx shall consult with UTRF prior to the abandonment of applications or issued patents with the Licensed Patents.

6.4 UTRF agrees to reasonably cooperate with GTx, at GTx's request and expense, to whatever extent is reasonably necessary but not inconsistent with OSU IIA#1 or OSU IIA#2, when applicable, to procure patent protection for Licensed Technology, including execution of all appropriate documents to provide GTx the full benefit of the licenses granted herein.

6.5 In the event that GTx decides not to continue prosecution of any United States or foreign patent application within Licensed Patents to issuance or not to maintain any United States or foreign patent within Licensed Patents in a particular jurisdiction, GTx shall timely notify UTRF in writing in order that UTRF may continue said prosecution or maintenance of such patent applications or patents at its option and at its own expense in such jurisdiction. GTx's right under this Agreement to practice the invention(s) under such patents and patent applications shall immediately terminate in such jurisdiction upon UTRF's assuming said costs provided that the application for which GTx decides not to continue prosecution, or the patent which GTx decides not to maintain, is before the patent office of a country that is a Major Market. Subject to the provisions of Section 6.6 below, GTx shall not be considered in default and this Agreement shall not terminate as to any particular jurisdiction merely due to the fact that GTx decides not to continue prosecution of a patent application to issuance, or not to maintain any patent in any country that is not a Major Market. If GTx fails to notify UTRF in sufficient time for UTRF to reasonably continue prosecution, or the maintenance of, a patent or patent application in a Major Market, GTx shall be considered in default of this Agreement.

6.6 If (a) GTx and UTRF decide not to file a patent application claiming an EXISTING INVENTION or an IMPROVEMENT INVENTION or a NEW INVENTION, which is licensed to GTx hereunder, or (b) if GTx allows a pending patent application in Licensed Patents claiming an EXISTING INVENTION or an IMPROVEMENT INVENTION or a NEW INVENTION licensed to GTx hereunder to go abandoned without filing a continuation, division, re-issue or other application having the same priority and without issuance of a patent

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having the same priority and UTRF does not assume said costs pursuant to Section 6.5, or (c) GTx decides not to maintain a previously-filed patent application or issued patent claiming an EXISTING INVENTION or IMPROVEMENT INVENTION or a NEW INVENTION licensed to GTx hereunder and UTRF does not assume said costs pursuant to Section 6.5, in each such case in the United States, England, France, Germany, Italy, Spain, Canada, Australia, China, India, Russia, Switzerland, and Japan (collectively, the “Major Countries”), OSU or OSURF may elect to file, prosecute, and/or maintain, as the case may be, such application or patent in any Major Country in which GTx did not file, prosecute, or maintain (collectively, the “Exception Countries”), at its sole expense. In that event, GTx agrees that OSU or OSURF will be free to exploit and to assign or license its interest in such patent application and/or patent to Third Parties in the Exception Countries, provided that any such assignment or license will be limited to domestic manufacture and sale in the Exception Countries, with no right to export or sell products or otherwise to compete with GTx or Sublicensees in the rest of the world. In the event GTx believes that any exploitation, assignment or license of OSU’s or OSURF’s interests in the Exception Countries competes with or interferes with GTx’s exclusive commercialization and exploitation of Licensed Technology licensed hereunder in any Major Country other than the Exception Countries, GTx agrees to so notify OSU or OSURF. GTx acknowledges that OSU or OSURF has contractually committed to take all reasonable measures to preclude such competition or interference, including without limitation terminating any license in the Exception Countries and taking enforcement action.

6.7 GTx agrees to forward in a timely manner all correspondence in need of signature by OSU Contributors to the Memphis office of UTRF (unless UTRF shall otherwise direct) in a timely manner. UTRF agrees, in turn, to promptly forward such correspondence to OSU or OSURF for signature, but UTRF shall have no responsibility for costs or other damages that may be incurred because of delay at OSU or OSURF in returning signed documents.

6.8 UTRF agrees to use reasonable business efforts to promptly notify GTx of any option to license an IMPROVEMENT INVENTION or NEW INVENTION upon such option arising in favor of UTRF under either OSU IIA#1 or OSU IIA#2 and to take such actions as are necessary and appropriate to exercise any such option upon receiving notice from GTx that it wishes to file a Licensed Patent claiming such IMPROVEMENT INVENTION or NEW INVENTION.

6.9 GTx and all its Sublicensees shall mark all products covered by Licensed Patents with patent numbers in accordance with the statutory requirements in the country(ies) of manufacture, use, and sale.

6.10 UTRF and GTx agree that one or more senior administrator representing each of the Parties will meet at least on a semi-annual basis at a mutually agreeable time and place so that GTx may provide UTRF with an oral update on the current development, licensing, regulatory, and commercialization status of Licensed Products and to discuss any issues raised by either UTRF or GTx arising out of, under, or in connection with this Agreement. UTRF agrees to notify OSURF no less than 14 days in advance of any such meeting, and that a representative from OSURF shall have the right to attend if they agree to confidentiality terms no less stringent than described in Section 18.

SECTION 7

Infringement

7.1 GTx shall inform UTRF and UTRF shall inform GTx promptly in writing of any alleged assertion and/or claim of infringement of the Licensed Patents by a Third Party and of any available evidence thereof.

7.2 GTx shall have the first, sole and exclusive right, but shall not be obligated, to prosecute or defend at its own expense all infringements or opposition, interference and ex parte proceedings of the Licensed Patents, including prosecuting for any misappropriation of Licensed Technology or Licensed Products. The Parties

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acknowledge that as to Licensed Patents that UTRF owns “in part”, such right on the part of GTx shall not preclude UTRF’s co-owner(s) from taking any action they may have available to them in law or by contract. In furtherance of such right granted to GTx, UTRF hereby agrees that GTx may include UTRF as a party plaintiff in any such suit, without expense to UTRF. The total cost of any such infringement action commenced or defended by GTx shall be borne by GTx. No settlement, consent judgment, or other voluntary final disposition of such suits may be entered into without the consent of UTRF, provided that such consent shall not be unreasonably withheld and that UTRF shall not condition such consent on an increase in payments to UTRF hereunder.

7.3 If within six (6) months after having been notified of an alleged infringement by a Third Party, GTx has not brought or is not diligently prosecuting an infringement action, or if GTx has notified UTRF at any time prior thereto of its intention not to bring suit against any alleged infringement of the Patents, then, and in those events only, UTRF shall have the right, but shall not be obligated, to prosecute at its own expense any infringement of the Licensed Patents, and UTRF may, for such purposes, use the name of GTx as party plaintiff. No settlement, consent judgment, or other voluntary final disposition of the suit may be entered into without the consent of GTx, which consent shall not unreasonably be withheld. After deduction of outstanding expenses of UTRF, including attorney fees, and any expenses of GTx, including attorney fees incurred prior to UTRF’s pursuit of such infringement, the balance remaining from any such recovery shall be divided equally between GTx and UTRF.

7.4 If both UTRF and GTx elect not to enforce or continue to enforce the right of the parties in Licensed Patents claiming an EXISTING INVENTION or IMPROVEMENT INVENTION under OSU IIA#1, or a NEW INVENTION under OSU IIA#2, GTx agrees that OSU or OSURF shall have the right to elect to prosecute the alleged infringers provided that (i) OSU or OSURF shall pay all costs and expenses arising out of such prosecution, and (ii) OSU or OSURF shall not have any right to surrender OSU’s, OSURF’s, UTRF’s or GTx’s rights or to grant any infringer any rights in the Licensed Patents without the prior written approval of UTRF and GTx, such approval not to be unreasonably withheld.

7.5 In the event that GTx undertakes the enforcement and/or defense of the Licensed Patents by litigation, opposition, interference or ex parte proceedings or an *inter partes* proceeding (including the defense of a declaratory judgment action pursuant to Section 7.6) in the United States or a foreign country against a Third Party, GTx may withhold up to [*] of the payments otherwise thereafter due UTRF under Section 4 that are attributable to sales of Licensed Products in the country where such litigation or *inter partes* proceeding takes place and apply the same toward reimbursement of up to [*] of GTx’s expenses, including reasonable attorneys’ fees, in connection therewith. GTx may not withhold any portion of the payments due UTRF under Section 4 in the event that GTx undertakes the enforcement and/or defense of the Licensed Patents by litigation or an *inter partes* proceeding in the United States or a foreign country against an Affiliate or Sublicensee. Any recovery of damages by GTx resulting from each such suit or *inter partes* proceeding shall be applied first in satisfaction of any unreimbursed expenses and legal fees of GTx relating to such suit, and next toward reimbursement of any unreimbursed expenses and legal fees of UTRF relating to such suit, and next toward reimbursement of UTRF for any payments under Section 4 withheld and applied pursuant to this Section 7.5, and the remaining balance, if any, shall be divided equally between GTx and UTRF unless the damage award is identified by judgment of the court or in a settlement in such suit as compensating GTx for loss of sales revenue for Licensed Product on account of such Third Party’s unlicensed or illegal actions, in which event (instead of dividing the remaining balance equally between the Parties), GTx shall pay to UTRF an amount equal to the lesser of: (i) [*] the remaining balance; or (ii) [*] of the equivalent of the lost Net Sales upon which such judgment or settlement award is based, and GTx shall retain the rest. For sake of clarity, any recovery attributable to loss or diminution of the value of Licensed Patents shall be divided equally between UTRF and GTX. As to a settlement of such claim or suit, the rebuttable presumption shall be that any payment to be made to GTX under the settlement agreement is not attributable to lost sales revenue and GTx shall have the burden of proof to reasonably establish that the recovery of damages resulting from such settlement represents compensation for loss of sales revenue (i.e., the equivalent of lost Net Sales hereunder).

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7.6 In the event that a declaratory judgment action alleging invalidity or noninfringement of any of the Licensed Patents shall be brought against UTRF, GTx at its option shall have the right, within thirty (30) days after commencement of such action, to intervene and take over the sole defense of the action against UTRF at its own expense, provided that GTx may not enter into a settlement, consent judgment, or other voluntary final disposition of the matter without the prior written approval of UTRF, which approval shall not be unreasonably withheld. This section shall not apply to OSU's and OSURF's interest in the Licensed Patents.

SECTION 8

Liability and Indemnification

8.1 GTx shall at all times during the Term of this Agreement, indemnify, defend and hold UTRF, UT, OSU, OSURF, and their respective trustees, directors, officers, employees and Affiliates, harmless against all claims, proceedings, demands and liabilities of any kind whatsoever, including legal expenses and reasonable attorneys fees (collectively, "Claims"), arising out of the death of or injury to any person or persons or out of any damage to property, to the extent resulting from the production, manufacture, sale, use, lease, or consumption of the Licensed Products, Licensed Technology, or associated intellectual property rights, including Licensed Patents, or arising from any obligation or act of GTx hereunder, except, as to UTRF and UT, for Claims arising (i) out of the use or practice of Licensed Subject Matter by UT as described in Section 2.2 or (ii) from the willful misconduct or misrepresentation by UTRF, UT, or their respective trustees, directors, officers, employees or Affiliates; or (iii) breach of this Agreement by UTRF; and except, as to OSU and OSURF, for Claims arising (i) out of the use or practice of Licensed Subject Matter by OSU as described in Section 2.2 or (ii) from the willful misconduct or misrepresentation by OSURF, OSU, or their respective trustees, directors, officers, employees or Affiliates. Infringement of a Third Party patent by GTx, a GTx Affiliate, or a Sublicensee shall not be deemed for purposes of this Agreement an improper action, omission, or negligent act on the part of UTRF, UT, OSU, OSURF, or their respective trustees, directors, officers, employees or Affiliates.

8.2 GTx shall obtain and carry in full force and effect from the first manufacture, use or sale of the Licensed Products or Licensed Technology to [*] such manufacturing, use or sales cease, commercial, general liability insurance which shall protect GTx, UTRF, UT, OSU, OSURF, and their respective trustees, directors, officers, employees and Affiliates with respect to events covered by Section 8.1 above. Such insurance shall be written by a reputable insurance company, reasonably acceptable to UTRF, shall list UTRF as an additional named insured, shall be endorsed to include product liability coverage and shall require thirty (30) days written notice to be given to UTRF prior to any cancellation or material change thereof. The limits of such insurance shall not be less than [*] per occurrence with an aggregate of [*] for personal injury or death. Upon the request of UTRF, GTx shall provide UTRF with Certificates of Insurance evidencing the same.

8.3 GTx, UTRF, UT, OSURF, OSU, AND THEIR RESPECTIVE TRUSTEES, DIRECTORS, OFFICERS, EMPLOYEES, AND AFFILIATES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR THE ABSENCE OF LATENT OR OTHER DEFECTS, WHETHER OR NOT DISCOVERABLE, IN ANY LICENSED PRODUCT, LICENSED TECHNOLOGY OR LICENSED PATENT. SUBJECT TO THE PROVISIONS OF SECTION 8.1 AND EXCEPT FOR A BREACH OF SECTION 18, IN NO EVENT SHALL GTx, UTRF, UT, OSURF, OSU, OR THEIR RESPECTIVE TRUSTEES, DIRECTORS, OFFICERS, EMPLOYEES OR AFFILIATES BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING, WITHOUT LIMITATION, ECONOMIC DAMAGE, INJURY TO PROPERTY OR LOST PROFITS, REGARDLESS OF WHETHER GTx, UTRF, UT, OSURF, OR OSU, SHALL BE ADVISED, SHALL HAVE OTHER REASON TO KNOW, OR IN FACT SHALL KNOW OF THE POSSIBILITY OF ANY OF THE FOREGOING. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS:

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- A. A REPRESENTATION MADE OR WARRANTY GIVEN BY UTRF, OSURF OR OSU THAT THE PRACTICE BY GTX OF ANY LICENSE OR SUBLICENSE GRANTED HEREUNDER SHALL NOT INFRINGE THE PATENTS OF ANY THIRD PARTY;
- B. A REPRESENTATION MADE OR WARRANTY GIVEN BY UTRF, OSURF OR OSU THAT ANY PATENT APPLICATION INCLUDED IN THE PATENTS WILL ULTIMATELY ISSUE AS A PATENT;
- C. A REPRESENTATION MADE OR WARRANTY GIVEN THAT GTX SHALL HAVE THE RIGHT TO USE ANY PORTION OF THE LICENSED PATENTS THAT IS CLAIMED IN A PATENT OF ANY THIRD PARTY;
- D. A REQUIREMENT THAT UTRF, OSURF OR OSU SHALL BE RESPONSIBLE FOR THE EXPENSES OF FILING OR PROSECUTING ANY PATENT APPLICATION OR MAINTAINING ANY LICENSED PATENTS IN FORCE
- E. AN OBLIGATION ON THE PART OF UTRF, OSURF OR OSU TO BRING OR PROSECUTE ACTIONS OR SUITS AGAINST THIRD PARTIES FOR INFRINGEMENT OF THE LICENSED PATENTS OR FOR UNAUTHORIZED USE OF THE PATENTS OR MISAPPROPRIATION OF THE LICENSED TECHNOLOGY;
- F. AN OBLIGATION ON THE PART OF UTRF, OSURF OR OSU TO DEFEND ANY ACTION OR SUIT BROUGHT BY ANY THIRD PARTY;
- G. A REPRESENTATION MADE OR WARRANTY GIVEN BY UTRF, OSURF OR OSU AS TO THE SAFETY, RELIABILITY OR EFFICACY OF: 1) THE LICENSED TECHNOLOGY OR THE INVENTIONS COVERED BY THE LICENSED PATENTS; OR 2) ANY LICENSED PRODUCT; OR
- H. A REPRESENTATION MADE OR WARRANTY GIVEN BY UTRF, OSURF OR OSU THAT ANY OF THE UT CONTRIBUTORS OR THE OSU CONTRIBUTORS WILL AGREE TO PROVIDE TECHNICAL ASSISTANCE OR CONSULTATION TO GTX, OR THAT SUCH TECHNICAL ASSISTANCE OR CONSULTATION, IF PROVIDED, WOULD BE SUFFICIENT TO ENABLE GTX TO SUCCESSFULLY EXPLOIT THE LICENSED TECHNOLOGY OR THE LICENSED PATENTS.

8.4 UTRF represents and warrants that to the best of its actual knowledge as of the Effective Date: (i) it has the full corporate power and authority to enter into this Agreement, to carry out the provisions of this Agreement, and to grant the rights granted to GTX herein; (ii) it has not previously granted and shall not grant to any Third Party any rights which are inconsistent with the rights granted to GTX herein; (iii) it is the owner of the entire right, title, and interest in and to the Licensed Patents and Licensed Technology except for such rights held by GTX, OSU, OSURE, UT, the United States government, Sublicensees, and/or their respective designees and/or assignees, if any; and (iv) it has fully complied with all requirements of 35 U.S.C. § 200 *et seq.* and all implementing regulations necessary to perfect title to the rights and license granted to GTX herein.

8.5 UTRF acknowledges and understands that Dr. Mitchell S. Steiner is an employee of UT and that as of the Effective Date, he is the Chief Executive Officer of GTX.

8.6 GTX represents that: (i) it has full corporate power and authority to enter into this Agreement and

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carry out all the provisions of this Agreement; (ii) it is authorized to execute this Agreement on its behalf; (iii) the person executing this Agreement is duly authorized to do so; and (iv) no consent, approval or authorization of any Third Party is required. GTx further represents and warrants that it shall not deny, contest (through declaratory judgment action or otherwise), or take any action inconsistent with UTRF's and/or OSU's and/or OSURF's ownership in or the validity or enforceability of any of the Licensed Patents or IP RIGHTS associated with or arising from the Licensed Subject Matter except those Licensed Patents listed on Appendix A that are assigned to GTx.

SECTION 9

Export Controls

9.1 GTx acknowledges that the export of goods and/or technical data from the United States may require some form of export control license from the United States Government. GTx agrees that neither it nor its Sublicensees will disclose, export or re-export any materials or technical data received under this Agreement to any countries for which the U.S. Government requires an export license, unless GTx or its Sublicensees have obtained prior written authorization from the U.S. Department of State, Directorate of Defense Trade Controls, Department of Commerce, U.S. Bureau of Industry and Security or other authority responsible for such matters. GTx agrees that it or its Sublicensees are responsible for any fees or expenses associated with obtaining an export license, if required, and acknowledges that failure to obtain such export control license may result in criminal liability. UTRF neither represents that a license shall not be required nor that, if required, it shall be issued.

SECTION 10

Non-Use of Names

10.1 GTx shall not use the names or trademarks of UTRF, UT, OSURF, or OSU, or any adaptation thereof, in any advertising, promotional or sales literature without prior written consent obtained from UTRF, UT, OSURF, or OSU, as the case may be, except that GTx may state that it has licensed the Licensed Patents and Licensed Technology from UTRF.

10.2 Neither UTRF nor UT shall use the names or trademarks of GTx, or any adaptation thereof, in any advertising, promotional or sales literature without prior written consent obtained from GTx, except that UTRF may state that it has licensed the Licensed Patents and Licensed Technology to GTx.

SECTION 11

Dispute Resolution

11.1 Except for the right of either party to apply to a court of competent jurisdiction for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or to prevent irreparable harm, any and all claims, disputes or controversies arising under, out of, or in connection with this Agreement, shall be resolved upon thirty (30) days written notice of either party to the other by final and binding arbitration in Knoxville, Tennessee under the Commercial Arbitration Rules of the American Arbitration Association, or the Patent Arbitration Rules if applicable, then in effect. The arbitrator(s) shall have no power to add to, subtract from or modify any of the terms or conditions of this Agreement, nor to award punitive damages. The prevailing party in any such arbitration shall, in addition to recovering reasonable out-of-pocket costs of the arbitration, be entitled to an award of reasonable attorneys fees incurred in connection with the arbitration, with any action necessary to perfect the arbitration award as a judgment, and for any collection action required to secure payment of any arbitration award. Any award rendered in such arbitration may be entered and enforced by either party in either the courts of the State of Tennessee or in the United States District Court for the Eastern District of

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Tennessee, to whose jurisdiction for such purposes UTRF and GTx each hereby irrevocably consents and submits, or in any other United States court having jurisdiction.

11.2 Notwithstanding the foregoing, nothing in this Section shall be construed to waive any rights or timely performance of any obligations existing under this Agreement.

SECTION 12

Term of Agreement and Termination

12.1 This Consolidated, Amended, and Restated License Agreement shall take effect for all purposes upon the date of execution by the Parties, and unless earlier terminated in accordance with the provisions of this Section 12, shall continue in full force and effect on a country-by-country basis for the longer of (i) a period of twenty (20) years from the Effective Date, or (ii) in each country in which a Valid Claim for any Licensed Patent shall continue to exist, until the last Valid Claim for any Licensed Patent shall expire in the country, at which time this Agreement shall expire as to such country (“Term”).

12.2 After expiration of the Term in a country, GTx shall have a perpetual, fully paid, royalty-free license to the Licensed Patents and Licensed Technology in such country, such license being of no greater scope than that granted hereunder. GTx shall continue to be obligated to pay (i) Running Royalties on account of Licensed Product used, marketed, sold, manufactured or distributed in or imported from any country for which the Term shall not have expired; and (ii) Sublicense Royalties on Sublicense Revenue generated under any Sublicense that includes a grant of rights in any Major Country for which the Term shall not have expired; and (iii) the License Maintenance Fee as long as there is at least one Major Country for which the Term shall not have expired. GTx shall continue to enjoy the rights and license to the Licensed Subject Matter granted hereunder in each country for which the Term shall not have expired.

12.3 In the event of default or failure by GTx to perform any of the terms, covenants or provisions of this Agreement (hereinafter, “default”), GTx shall have thirty (30) days to cure such default after the giving of written notice of such default by UTRF. In accordance with Section 2.6, no Sublicensee’s rights under a Sublicense shall terminate on account of a default by GTx unless UTRF shall have given written notice of such default to the Sublicensee and the Sublicensee shall have failed to cure or have cured such default within thirty (30) days of such notice. If such default is not cured by GTx, its Affiliates, and/or its Sublicensees within the said thirty (30) day period, UTRF shall have the right, at its option, to terminate this Agreement. The failure of UTRF to exercise such right of termination for non-payment of royalties or otherwise shall not be deemed to be a waiver of any right UTRF might have, nor shall such failure preclude UTRF from exercising or enforcing said right upon any subsequent failure by GTx.

12.4 UTRF shall have the right, at its option, to terminate this Agreement in the event that GTx is finally declared bankrupt, or is placed in receivership pursuant to proceedings affecting the operation of its business. In the event of termination of this Agreement pursuant to Sections 12.3 or 12.4 hereof, all rights to the Licensed Patents and Licensed Technology granted to GTx herein shall revert to UTRF, except as otherwise provided in Section 2.6.

12.5 Upon termination of this Agreement for any reason, nothing herein shall be construed to release either party from any obligation that matured prior to the effective date of such termination; and Sections 1, 4.4, 5, 8, 9-12, 14, 18, 20, and 21 shall survive any such termination.

12.6 No termination of this Agreement shall constitute a termination or a waiver of any rights of either Party against the other Party accruing at or prior to the time of such termination.

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12.7 GTx shall have the right to terminate this Agreement at any time on three (3) months notice to UTRF and upon payment of all amounts due UTRF through the effective date of the termination.

SECTION 13

Assignability

13.1 This Agreement shall be binding upon and shall inure to the benefit of UTRF and its assigns and successors, and shall be binding upon and shall inure to the benefit of GTx and its assigns provided that prior written approval by UTRF is first obtained, which approval shall not be unreasonably withheld. Notwithstanding the foregoing, no prior written approval from UTRF shall be required for any assignment by GTx to (i) an Affiliate of GTx (or any entity into which GTx shall have been merged or consolidated, provided that at least 51% of such merged or consolidated entity is owed by shareholders holding at least 51% of GTx immediately prior to such merger or consolidation) or (ii) a Third Party which acquires all or substantially all of GTx's assets or a Controlling interest in the business to which this Agreement relates if, but only if, the Third Party can reasonably demonstrate a financial net worth or market cap equal to or better than the financial net worth of GTx existing prior to the acquisition, but not less than a net worth of One Hundred Million Dollars (\$100,000,000) or a market cap of Five Hundred Million Dollars (\$500,000,000). No assignment shall be deemed effective unless such assignee has agreed in writing to be bound by the terms and provisions of this Agreement. Any attempt to assign or assignment made in violation of this Section 13.1 shall be void *ab initio*. GTx shall give notice to UTRF of any assignment of this Agreement within thirty (30) days thereafter, such notice to include a copy of assignee's written agreement to be bound by the terms and provisions of this Agreement.

SECTION 14

Governmental Compliance

14.1 GTx shall at all times during the Term of this Agreement and for so long as it shall develop, make, have made, use, market, sell, have sold, import, distribute, or offer to sell Licensed Products or Licensed Technology comply and cause its Sublicensees to comply with all laws that may control the import, export, manufacture, use, sale, marketing, distribution and other commercial exploitation of Licensed Products, Licensed Technology, or Licensed Patents or any other activity undertaken pursuant to this Agreement.

SECTION 15

Notices

15.1 Any notice or other communication required or permitted hereunder (hereinafter "notice") shall be in writing and shall be hand-delivered, sent by overnight courier, mailed by certified United States mail, return receipt requested, or sent by email, to the addresses given below or to such other addresses as the parties may hereafter specify in writing. Notice shall be deemed given and received five (5) days after being deposited with the U.S. Postal Service with sufficient postage, or if notice is hand-delivered or sent by overnight courier, upon the date of actual delivery, or if sent by email, upon the date the receiving party acknowledges receipt. An email notice shall be given concurrently to all the email address(es) provided by the recipient party and the first acknowledgment of receipt from the recipient party shall establish the date on which such notice is given.

UTRF:

If notice is given by means other than email, to:

University of Tennessee Research Foundation

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1534 White Avenue, Suite 403
Knoxville, Tennessee, U.S.A. 37996-1527
Attn: President

With a copy to:

University of Tennessee Research Foundation
920 Madison, Suite 515
Memphis, TN 38163

If notice is given by email, to:

rmagid1@utmem.edu
jlsnider@utk.edu
vhunley@tennessee.edu

GTx:

If notice is given by means other than email, to:

GTx, Inc.
3 N. Dunlap Street, 3rd Floor
Memphis, Tennessee 38163
Attn: Dr. Mitchell Steiner, CEO

With a copy to:

GTx, Inc.
3 N. Dunlap Street, 3rd Floor
Memphis, TN 38163
Attn: Henry P. Doggrell, Vice President, General Counsel

If notice is given by email, to:

msteiner@gtxinc.com
hdoggrell@gtxinc.com

OSU or OSURF:

If notice is given by means other than email, to:

1960 Kenny Road, 2nd Floor
Columbus, OH 43210
Attn: Jane New

If notice is given by email, to:

new.16@osu.edu

Notice or other material provided to the above address will satisfy any obligation under this Agreement for notice or copying either OSU and OSURF.

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SECTION 16
Severability of Provisions

16.1 If any provision of this Agreement shall be declared by a court of competent jurisdiction to be invalid, illegal or incapable of being enforced in whole or in part, the remaining conditions and provisions or portions thereof shall nevertheless remain in full force and effect and enforceable to the extent they are valid, legal and enforceable, and no provision shall be deemed dependent upon any other covenant or provision unless so expressed herein.

SECTION 17
Governing Law

17.1 This Agreement shall be deemed to be subject to, and have been made under, and shall be construed and interpreted in accordance with the laws of the State of Tennessee. This Agreement is expressly acknowledged to be subject to all applicable federal laws. No conflict-of-laws rule or law that might refer such construction and interpretation to the laws of another state, republic, or country shall be considered. The Parties irrevocably and unconditionally agree that the exclusive place of jurisdiction for any action, suit or proceeding for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or to prevent irreparable harm, arising under, out of, or in connection with this Agreement (“Actions”), shall be in the courts of the United States of America sitting in the city, state and country of State of Tennessee, or, if such courts shall not have jurisdiction over the subject matter thereof, in the courts of the State of Tennessee sitting therein, and each such party hereby irrevocably and unconditionally agrees to submit to the jurisdiction of such courts for the purposes of any such Actions. If any such State court also does not have jurisdiction over the subject matter thereof, then such an Action may be brought in the federal or state courts located in the states of the principal place of business of any Party hereto.

SECTION 18
Confidentiality

18.1 Nothing herein shall preclude a Party from disclosing the existence of this Agreement and the general scope of the license granted hereunder. However, neither Party shall disclose the economic terms of this Agreement except that UTRF may disclose such economic terms to the UT Contributors, UT, OSURF, and OSU or as required by Federal Policy.

18.2 Subject to the exceptions set forth herein, all information or material disclosed pursuant to this Agreement and/or related to the Licensed Patents, Licensed Products, Licensed Technology, and Independent SARM Inventions shall be confidential (“Confidential Information”). Recipient (the “Receiving Party”) of another Party’s Confidential Information (the “Providing Party”) agrees to hold in confidence, and not to distribute or disseminate to any person or entity, for any reason for a period of seven (7) years after receipt, any Confidential Information received, under or relating to this Agreement, except for Confidential Information of the Providing Party which:

- A. was known or used by the Receiving Party prior to the date of disclosure to the Receiving Party as evidenced by written records; or
- B. either before or after the date of disclosure is lawfully disclosed to the Receiving Party by sources other than the Providing Party which are rightfully in possession of the Confidential Information and not subject to any obligation of confidentiality, as evidenced by written records; or

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- C. either before or after the date of disclosure to the Receiving Party becomes published, through no fault or omission on the part of the Receiving Party; or
- D. is independently developed by or for the Receiving Party without reference to, knowledge of, or reliance upon the Confidential Information as evidenced by written records; or
- E. is required to be disclosed by the Receiving Party to comply with applicable laws or court order, to defend or prosecute litigation or arbitration or to comply with governmental regulations or Federal Policy, provided that the Receiving Party provides prior written notice of such disclosure to the Providing Party and takes reasonable and lawful actions to avoid and/or minimize the degree of such disclosure, and further provided that specific information shall not be deemed to be within any of these exclusions merely because it is embraced by more general information falling with these exclusions; or
- F. is disclosed by either Party to OSU or OSURF pursuant to the requirements of OSU IIA#1 or OSU IIA#2; or
- G. is disclosed by UTRF to UT, the UT Contributors, or the State of Tennessee, such disclosure being subject to the provisions of Section 2.6, if and as applicable.

All information concerning (i) Licensed Patents and/or Licensed Technology owned solely or partly by UTRF and (ii) Independent SARM Inventions shall be deemed Confidential Information of UTRF. Disclosures of Confidential Information to GTx concerning (i) and (ii), including, without limitation, disclosures that are made to GTx by UT Contributors or OSU Contributors, shall be deemed, for purposes of this Section, to be disclosures made by UTRF. Nothing herein shall be construed in such a manner as to permit UTRF, UT, any UT Contributor, OSU, OSURF, or any OSU Contributor to take any action with regard to Licensed Patents, Licensed Technology, or Independent SARM Inventions that is contrary to the rights herein granted to GTx or to permit UTRF, UT, any UT Contributor, OSU, OSURF, or any OSU Contributor to include any Confidential Information of GTx in any patent application or regulatory filing or application without obtaining GTx's prior written approval except to the extent such activity falls within the exceptions to confidentiality set forth in Sections 18.2A through G.

18.3 GTx recognizes that under UTRF and UT policy, research results must be publishable and agrees that researchers engaged in such research shall have the right, with regard to the Licensed Subject Matter, to present at symposia, professional meetings and to publish in journals, theses or dissertations, or otherwise of their own choosing ("Publications") provided that UTRF shall provide to GTx a copy of a draft of such Publication, if received by UTRF in draft form, or a copy of the final Publication, if first received by UTRF in that form, in either case promptly upon receipt and in the manner and form in which received in order that GTx may review the Publication to identify and protect any Confidential Information of GTx that may be contained therein and to allow for the preparation and filing of a patent application by GTx or Sublicensees. UTRF shall not be deemed in breach or default of this Agreement merely due to a Publication that UTRF does not receive prior to publication.

18.4 The Parties recognize that GTx has previously entered into certain research agreement(s) with OSURF, UT has entered into certain agreement(s) with OSU and/or OSURF either as a contractor and/or a subcontractor, GTx has entered into certain consulting agreement(s) with one or more of the UT Contributors and/or the OSU Contributors, and that UTRF has entered into OSU IIA#1 and OSU IIA#2 with OSU, which agreements may contain confidentiality obligations and/or restrictions on publication regarding information or material related to this Agreement, the Licensed Patents and/or the Licensed Technology. While UTRF acknowledges the need for such confidentiality obligations and restrictions on publication in order for GTx to preserve United States and foreign patent rights, UTRF MAKES NO REPRESENTATIONS OR WARRANTIES, AND HAS NO OBLIGATION HEREUNDER, REGARDING THE CONFIDENTIALITY OR PUBLICATION OBLIGATIONS OF UT, THE UT CONTRIBUTORS, OSU, OSURF, OR THE OSU CONTRIBUTORS.

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18.5 The Parties agree that counsel of the Parties, who have a duty of confidentiality to the respective Parties, may receive Confidential Information.

SECTION 19

Reformation

19.1 All Parties hereby agree that neither Party intends to violate any public policy, statutory or common law, rule, regulation, treaty or decision of any government agency or executive body thereof of any country or community or association of countries; that if any word, sentence, paragraph or clause or combination thereof of this Agreement is found, by a court or executive body with judicial powers having jurisdiction over this Agreement or any of its Parties hereto, in a final unappealed order to be in violation of any such provision in any country or community or association of countries, such words, sentences, paragraphs or clauses or combination shall be inoperative in such country or community or association of countries, and the remainder of this Agreement shall remain binding upon the Parties hereto.

SECTION 20

Non-Waiver

20.1 The Parties covenant and agree that if a Party fails or neglects for any reason to take advantage of any of the terms provided for the termination of this Agreement or if a Party, having the right to declare this Agreement terminated, shall fail to do so, any such failure or neglect by such Party shall not be a waiver or be deemed or be construed to be a waiver of any cause for the termination of this Agreement subsequently arising, or as a waiver of any of the terms, covenants or conditions of this Agreement or of the performance thereof. None of the terms, covenants and conditions of this Agreement may be waived by a Party except by its written consent.

SECTION 21

Entire Agreement

21.1 This Agreement, as amended and restated herein, contains the entire agreement and understanding of the parties as of the Effective Date with respect to the subject matter hereof, supersedes any prior agreements and understandings with respect thereto, including, without limitation, the Prior License Agreements, and cannot be modified, amended or waived, in whole or in part, except in writing signed by the Party to be charged. Any such purported non-written modification, amendment, or waiver shall be null and void. A discharge of the terms of this Agreement shall not be deemed valid unless by full performance of the Parties hereto or by writing signed by the Parties hereto. A waiver by UTRF of any breach by GTx of any provision or condition of this Agreement to be performed by GTx shall not be deemed a waiver of similar or dissimilar provisions or conditions at the same or any prior or subsequent time.

SECTION 22

Effect of Agreement

22.1 This Consolidated, Amended, and Restated License Agreement shall supersede and render null and void the Prior License Agreements.

IN WITNESS WHEREOF, the Parties hereto have executed and delivered this Agreement in multiple originals by their duly authorized officers and representatives on the respective dates shown below. The undersigned representative of UTRF is authorized to execute this Agreement on its behalf and bind UTRF to the terms and

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conditions set forth herein, and the undersigned representative of GTx is authorized to execute this Agreement on its behalf and bind GTx to the terms and conditions set forth herein.

UNIVERSITY OF TENNESSEE
RESEARCH FOUNDATION
(UTRF)

GTx, INC. (GTx)

By: /s/ Fred D. Tompkins
Name: Fred D. Tompkins
Title: President

By: /s/ Henry P. Doggrell
Name: Henry P. Doggrell
Title: Vice President, General Counsel &
Secretary

Date: 7/25/07

Date: July 24, 2007

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EXHIBIT A

Third Generation SARMS Disclosure

[*]
[*]
[*]
[*]
[*]

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EXHIBIT B

OSU IIA #1

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**BRIDGED SARMS
INTER-INSTITUTIONAL AGREEMENT
BETWEEN
THE OHIO STATE UNIVERSITY
AND
THE UNIVERSITY OF TENNESSEE RESEARCH FOUNDATION**

THIS BRIDGED SARMS INTER-INSTITUTIONAL AGREEMENT (the "AGREEMENT") is effective the 22nd day of December, 2004 (hereafter, the "EFFECTIVE DATE") by and between The Ohio State University on behalf of itself and The Ohio State University Research Foundation and its Office for Technology Licensing (collectively, hereinafter "OSU") having an address at 1960 Kenny Road, Columbus, Ohio 43210, and the University of Tennessee Research Foundation (hereinafter "UTRF") having an address at 1534 White Avenue, Knoxville, Tennessee 37996.

BACKGROUND

OSU and UTRF wish to establish an understanding between the parties with respect to the patenting, enforcement, and commercialization of EXISTING INVENTIONS and IMPROVEMENT INVENTIONS (as defined below) and how any commercialization revenues derived therefrom will be divided between the parties.

In furtherance thereof, OSU wishes to exclusively license its interest in the EXISTING INVENTIONS to UTRF and UTRF wishes to obtain an exclusive License to OSU's interest in the EXISTING INVENTIONS pursuant to the provisions of this AGREEMENT.

OSU also wishes to grant UTRF an exclusive option to obtain an exclusive license to OSU's interest in IMPROVEMENT INVENTIONS and UTRF wishes to obtain an exclusive option to obtain an exclusive license to OSU's interest in IMPROVEMENT INVENTIONS pursuant to the provisions of this AGREEMENT.

Therefore, in consideration of the mutual obligations set forth below, OSU and UTRF agree as follows:

1. **DEFINITIONS.** The following capitalized terms used in this AGREEMENT have the following meanings:
 - 1.1 "BRIDGED SARMS" means SARM compounds [*], including those described in the patents and patent applications listed in Attachment A.
 - 1.2 "EXISTING INVENTIONS" means any TECHNOLOGY that pertains to BRIDGED SARMS (as defined above) conceived, created, developed, designed, invented, or reduced to practice, in whole or in part by OSU researcher Dr. James Dalton and/or other OSU research staff and students under his direction before the EFFECTIVE DATE, including inventions that are the subject of one or more VALID CLAIMS of the issued patents or patent applications set forth in Attachment A and foreign counterparts thereof.
 - 1.3 "IMPROVEMENT INVENTION" means any TECHNOLOGY that pertains to BRIDGED SARMS conceived, created, developed, designed, invented, or reduced to practice, in whole or in part by OSU faculty researchers, research staff, or students following the EFFECTIVE DATE, and which is the subject of a VALID CLAIM of a continuation in part application or a new application claiming priority from an issued

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patent or patent application listed in Attachment A or whose manufacture, use, or sale would infringe or fall within the scope of a VALID CLAIM covering an Existing Invention or an Improvement Invention.

- 1.4 "IP COSTS" means the documented, unreimbursed, out-of-pocket, reasonable expenses incurred by UTRF in the preparation, filing, prosecution, defense, enforcement and maintenance of IP RIGHTS associated with the EXISTING INVENTIONS and IMPROVEMENT INVENTIONS.
- 1.5 "IP RIGHTS" means any and all right, title and interest (whether now existing or arising in the future) in, to and under EXISTING or IMPROVEMENT INVENTIONS, including, without limitation, patents, patent applications, provisional patent applications and any divisions, reissues, renewals, reexaminations, substitutions, continuations, continuations-in-part, and any corresponding foreign counterparts thereof; and other proprietary rights arising or enforceable under any United States federal or state law, rule or regulation, non-United States law, rule or regulation or international treaty.
- 1.6 "LICENSE AGREEMENT" means any agreement that is entered into by UTRF that grants to a third party any right or license to the LICENSED INVENTIONS, including, without limitation, the two existing Amended and Restated Exclusive License Agreements dated August 23, 2000 by and between UTRF and GTx, Inc., as the same may be amended from time to time (the two referenced pre-existing agreements between UTRF and GTx, Inc., being hereinafter referred to as the "Exclusive License Agreements"), and any agreement entered into by UTRF granting an option for such a right or license.
- 1.7 "LICENSEE" means any 3rd party licensee to a LICENSE AGREEMENT.
- 1.8 "LICENSED INVENTIONS" means EXISTING INVENTIONS, IMPROVEMENT INVENTIONS, and associated IP RIGHTS licensed to UTRF in Sections 2.1 and/or 2.7 herein.
- 1.9 "NET REVENUES" means all gross proceeds received by UTRF from the licensing of the LICENSED INVENTIONS and/or associated IP RIGHTS less IP COSTS.
- 1.10 "[*]BRIDGE SARMS" means SARM compounds [*].
- 1.11 "SARM" means selective androgen receptor modulator.
- 1.12 "[*]BRIDGE SARMS" means SARM compounds [*].
- 1.13 "SUBLICENSE AGREEMENT" means any agreement that is entered into by LICENSEE that grants to SUBLICENSEE thereunder any right or license to the LICENSED INVENTIONS, or any agreement granting an option for such a right or license.

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1.14 "SUBLICENSEE" means any sublicensee to a SUBLICENSE AGREEMENT.

1.15 "TECHNOLOGY" means any and all compounds; compositions; conclusions; designs; inventions; methods; procedures; processes; products; services; substances; techniques; and/or business, engineering, manufacturing, scientific, medical, clinical, pharmacology, toxicology, or other data or material, in any form, method or manner of expression or communication now known or that hereinafter becomes known (whether or not tangible or intangible, or able to be protected by patent or trademark), and any documentation or work product comprising the same.

1.16 "TERM" shall have the meaning set forth in Section 10.1 hereof.

1.16 "VALID CLAIM(s)" means any claim(s) in an unexpired patent or pending in a patent application or provisional application which has not been held unenforceable, unpatentable, or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been abandoned or admitted to be invalid or unenforceable through reissue or disclaimer. The parties acknowledge the requirement under United States law that patent claims must satisfy the written description requirement of 35 U.S.C. §112.

2. GRANT OF LICENSE

2.1 Subject to Section 2.8 herein, OSU hereby grants to UTRF an exclusive, worldwide, sublicensable (through multiple tiers) license to OSU's interest in the EXISTING INVENTIONS and associated IP RIGHTS for the duration of each such IP RIGHT.

2.2 Subject to Section 2.8, OSU hereby grants to UTRF a non-exclusive, sublicensable (through multiple tiers) license to OSU's interest in know-how related to the EXISTING INVENTIONS.

2.3 Subject to the terms of this AGREEMENT, UTRF shall be the sole party which (i) negotiates the terms of any LICENSE AGREEMENT, including any amendments thereto, (ii) collects all proceeds paid pursuant to any such LICENSE AGREEMENT, and (iii) accounts to OSU for OSU's portion of all NET REVENUE and pays such portion thereof to OSU as required by this AGREEMENT.

2.4 OSU hereby grants to UTRF an exclusive option to an exclusive, worldwide, sublicensable (through multiple tiers) license to OSU's interest in each IMPROVEMENT INVENTION and associated IP RIGHTS for the duration of each IP RIGHT and an option to a non-exclusive, sublicensable (through multiple tiers) license to OSU's interest in know-how related to an IMPROVEMENT INVENTION under the terms of this AGREEMENT (collectively, the "OPTION").

2.5 The OPTION shall commence for each IMPROVEMENT INVENTION when it becomes known to the OSU Office for Technology Licensing or UTRF and shall expire [*].

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- 2.6 UTRF may exercise the OPTION as to each IMPROVEMENT INVENTION by notifying OSU in writing during the OPTION PERIOD for that IMPROVEMENT INVENTION.
- 2.7 Subject to Section 2.8 herein, upon UTRF's exercise of its OPTION as to a particular IMPROVEMENT INVENTION, OSU grants and agrees to grant to UTRF an exclusive, worldwide, sublicensable (through multiple tiers) license to OSU's right, title, and interest in such IMPROVEMENT INVENTION and associated IP RIGHTS for the duration of each such IP RIGHT and a non-exclusive sublicensable (through multiple tiers) license to OSU's interest in know-how related to the same IMPROVEMENT INVENTION under the terms of this AGREEMENT. OSU and UTRF agree to amend the AGREEMENT to include each licensed IMPROVEMENT INVENTION on Attachment A, which shall be incorporated by reference herein.
- 2.8 To the extent that any research pertaining to a LICENSED INVENTION has been or is in the future funded in whole or in part by the United States government, the United States government retains certain rights and requires certain obligations concerning such inventions as set forth in 35 U.S.C. §§200-212 and all regulations promulgated thereunder, as amended, and any successor statutes and regulations and applicable policies of such United States government sponsors, including, without limitation, to the extent applicable, the utilization and capability requirements found in the National Institutes of Health (NIH) Grants Policy Statement: "Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts", Federal Register, Vol. 59, No. 215, Tuesday, November 8, 1994, pp. 55674-55679 (collectively, "Federal Policy"). UTRF and OSU acknowledge and shall materially comply with all aspects of Federal Policy applicable to EXISTING INVENTIONS and IMPROVEMENT INVENTIONS and shall require that each LICENSE AGREEMENT include a provision requiring the LICENSEE to materially comply with all applicable aspects of Federal Policy. In the event that either party receives notice of any action or notification by the United States government with respect to such rights and/or obligations, the party agrees to provide the other prompt written notice of such action or notification.
- 2.9 If UTRF fails to exercise its OPTION to an IMPROVEMENT INVENTION and associated IP RIGHTS within the OPTION PERIOD, then UTRF's OPTION to that IMPROVEMENT INVENTION shall automatically terminate upon the expiration of the OPTION PERIOD.
- 2.10 OSU shall retain the right to use the LICENSED INVENTIONS and associated IP RIGHTS (to the extent of any of its respective rights therein) solely for non-commercial educational, research (including non-commercial clinical research), and academic purposes. OSU, however, shall have no rights for clinical research using a UTRF or LICENSEE proprietary BRIDGED SARMS compound or to refer to any LICENSEE regulatory filing without prior written approval from UTRF or its LICENSEE, in their discretion.

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2.11 OSU agrees that during the TERM, it will not negotiate or enter into any LICENSE AGREEMENT or SUBLICENSE AGREEMENT, or otherwise grant any options or licenses or other rights with respect to the LICENSED INVENTIONS and associated IP RIGHTS, except as required by Federal Policy as set forth in Section 2.8 of this AGREEMENT. Further, during the TERM and notwithstanding the duty of candor and good faith under 37 CFR §1.56, neither OSU nor any party on its behalf, will -oppose, request reexamination, or take any action that would otherwise diminish the IP RIGHTS in the EXISTING OR IMPROVEMENT INVENTIONS. OSU agrees to forward as soon as possible to UTRF any and all information which it has knowledge of or believes is material under § 1.56 in order for submission of such material to the Patent Office by patent counsel. OSU and UTRF reserve the right to correct inventorship and contest ownership of the IP RIGHTS associated with the LICENSED INVENTIONS, provided that all such LICENSED INVENTIONS and associated IP RIGHTS are still and shall continue to be licensed to UTRF under this AGREEMENT.

3. PATENT PROSECUTION AND PROTECTION

3.1 As determined by UTRF and/or its LICENSEE, UTRF and/or its LICENSEE shall control prosecution and be responsible to prepare, file and/or maintain appropriate United States patent applications covering the LICENSED INVENTIONS, provided, however, that OSU may advise and consult with UTRF in such filing, prosecution, and/or maintenance. UTRF shall provide or require its LICENSEE to provide OSU with reasonable notice prior to filing a patent application containing any new matter claiming priority to an application for an EXISTING INVENTION or an IMPROVEMENT INVENTION. UTRF shall also provide or require its LICENSEE to provide OSU with copies of all office actions and other written communications it or its patent counsel receives from or files with the U.S. Patent and Trademark Office and the equivalent foreign offices after the EFFECTIVE DATE with respect to the LICENSED INVENTIONS.

3.2 UTRF and/or its LICENSEE shall make an election whether, when, and in what countries, it wishes to file foreign patent applications covering the LICENSED INVENTIONS, provided, however, that OSU may advise and consult with UTRF in such election. UTRF shall notify or require its LICENSEE to notify OSU in writing of any decision after the EFFECTIVE DATE regarding foreign filing for LICENSED INVENTIONS.

3.3 OSU shall have no responsibility for any costs incurred by UTRF and/or its LICENSEE for patent filing, prosecution, maintenance and enforcement of the LICENSED INVENTIONS.

3.4 As required, UTRF and/or its LICENSEE will record and/or maintain assignments of IP RIGHTS in the LICENSED INVENTIONS in the United States Patent and Trademark Office and UTRF will provide or require its LICENSEE to provide OSU with a photocopy of each recorded assignment.

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- 3.5 If, after the EFFECTIVE DATE, UTRF and/or its LICENSEE determine (a) not to file a patent application under IP RIGHTS in the LICENSED INVENTIONS or (b) to allow a pending patent application under IP RIGHTS in the LICENSED INVENTIONS to go abandoned without filing a continuation, division, re-issue or other application having the same priority and without issuance of a patent having the same priority, or (c) not to maintain a previously-filed patent application or issued patent under IP RIGHTS in the LICENSED INVENTIONS in the United States, England, France, Germany, Italy, Spain, Canada, Australia, China, India, Russia, Switzerland, and Japan (collectively, the "Major Countries"), it shall provide reasonable prior written notice to OSU of such determination as required under Section 3.1 of this AGREEMENT. Following such determination by UTRF and/or its LICENSEE, OSU may, by written notice to UTRF, elect to file, prosecute, and/or maintain such application or patent in any Major Country in which UTRF and/or its LICENSEE did not file (the "Exception Countries"), at OSU's sole expense. In that event, OSU will be free to exploit and to assign or license OSU's interest in such patent application and/or patent to third parties in the Exception Countries, provided that any such assignment or license will be limited to domestic manufacture and sale in the Exception Countries, with no right to export or sell products or otherwise to compete with UTRF and/or its LICENSEE (including SUBLICENSEES) in the rest of the world. In the event UTRF and/or its LICENSEE believes that any exploitation, assignment, or license of OSU's interests in the Exception Countries competes with or interferes with UTRF's or its LICENSEE's exclusive commercialization and exploitation of the LICENSED INVENTIONS in the Major Countries other than the Exception Countries, OSU shall, upon notice, take all reasonable measures to preclude such competition or interference, including terminating any license in the Exception Countries and taking enforcement action. [*]
- 3.6 OSU agrees to cooperate with UTRF and/or its LICENSEE in the preparation, filing, prosecution, and maintenance of patent applications and patents under IP RIGHTS in the LICENSED INVENTIONS by disclosing such information as may be necessary or appropriate and promptly executing such documents as UTRF and/or its LICENSEE may reasonably request. Each party will bear its own costs in connection with its cooperation with the other party under this Section. UTRF and/or its LICENSEE agree to forward all correspondence in need of signature by OSU inventors to OSU's Office for Technology Licensing in a timely manner. OSU's Office for Technology shall obtain signatures from OSU inventors in a timely manner and promptly return such documents upon reasonable notice and request by UTRF or its LICENSEE. If costs for extensions of time become due because of unreasonable delay at OSU in returning signed documents, OSU shall provide reimbursement for such reasonable costs.
4. LICENSING
- 4.1 UTRF shall use reasonable efforts to maintain and/or seek a LICENSEE for the commercial development of the LICENSED INVENTIONS. The parties acknowledge that, as of the EFFECTIVE DATE, UTRF has complied with this section by virtue of the current EXCLUSIVE LICENSE AGREEMENTS. UTRF shall promptly provide OSU

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with copies of all LICENSE AGREEMENTS and amendments thereto that relate to the LICENSED INVENTIONS. UTRF shall use reasonable efforts to require LICENSEE'S compliance with the terms of any LICENSE AGREEMENT provided that this provision shall not be interpreted to require UTRF to bring suit against LICENSEE.

- 4.2 Any LICENSE AGREEMENT must include, but is not limited to, the following terms: an earned royalty, payment of patent costs associated with the IP RIGHTS licensed thereunder by the LICENSEE, commercially reasonable diligence terms, a disclaimer of warranties on the part of OSU and UTRF, and a prohibition of the use of the name of OSU. OSU shall be provided with reasonable time to review and comment on LICENSE AGREEMENTS and amendments to LICENSE AGREEMENTS. If any LICENSE AGREEMENT would cause OSU to violate any law, rule, regulation or Federal Policy to which it is subject, the parties agree to negotiate in good faith a revision to such LICENSE AGREEMENT to be proposed to the LICENSEE to enable OSU to be in compliance with any such law, rule or regulation.
- 4.3 UTRF shall include a provision in each LICENSE AGREEMENT that the LICENSEE shall indemnify, defend, and hold OSU harmless against all claims resulting from the production, manufacture, sale, use, lease, or consumption of the LICENSED INVENTIONS and associated IP RIGHTS, excluding any claim resulting from the willful misconduct or misrepresentation by OSU, its trustees, directors, officers, employees, and affiliates, as the case may be.

5. WARRANTIES, INDEMNIFICATION, AND DISCLAIMERS

5.1 OSU represents and warrants that:

- 5.1.1 OSU has the right to enter into this AGREEMENT, to grant the licenses herein and to bind The Ohio State University Research Foundation to the terms of this Agreement in the same manner that The Ohio State University is bound, and hereby binds OSURF thereto;
- 5.1.2 To the best of its knowledge, by entering into and performing under this AGREEMENT, it shall not be in violation of any applicable law, rule, regulation, or contractual obligation owed to any third party, and that it shall have obtained all permits, licenses, or permissions required to comply with such laws, rules, regulations, or obligations;
- 5.1.3 Prior to and at any time during the TERM, it knowingly has not nor will it make any agreements and/or transfer of rights or powers in the LICENSED INVENTIONS or otherwise encumber the LICENSED INVENTIONS or the associated IP RIGHTS (including IMPROVEMENT INVENTIONS during the OPTION PERIOD) in a manner that is inconsistent with or in derogation of the exclusive license or the OPTION granted to UTRF herein, except as permitted under Sections 2 and 3 herein;

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5.1.4 As of the EFFECTIVE DATE, OSU, to the best of its knowledge, is not aware of any pending or threatened litigation involving the EXISTING INVENTIONS, IMPROVEMENT INVENTIONS, or associated IP RIGHTS and agrees to notify UTRF in the event it becomes aware of pending or threatened litigation involving any of the EXISTING INVENTIONS, IMPROVEMENT INVENTIONS or associated IP RIGHTS thereafter.

5.2 UTRF represents and warrants that:

5.2.1 UTRF has the right to enter into this AGREEMENT, to accept and grant the licenses herein.

5.2.2 To the best of its knowledge, by entering into and performing under this AGREEMENT, it shall not be in violation of any applicable law, rule, regulation or contractual obligation owed to any third party, and that it shall have obtained all permits, licenses, or permissions required to comply with such laws, rules, regulations, or obligations.

5.3 EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, EACH PARTY, ITS AFFILIATES, AND THEIR TRUSTEES, DIRECTORS, OFFICERS, EMPLOYEES, AND AGENTS MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OF IP RIGHTS, CLAIMS ISSUED OR PENDING, AND THE ABSENCE OF LATENT OR OTHER DEFECTS, WHETHER OR NOT DISCOVERABLE. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A REPRESENTATION MADE OR WARRANTY GIVEN BY EITHER PARTY THAT THE PRACTICE BY ANY LICENSEE OR SUBLICENSEE OF THE LICENSE GRANTED SHALL NOT INFRINGE THE IP RIGHTS OF ANY THIRD PARTY. NEITHER PARTY SHALL BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING ECONOMIC DAMAGE OR INJURY TO PROPERTY AND LOST PROFITS, REGARDLESS OF WHETHER THE OTHER PARTY IS ADVISED, HAS OTHER REASON TO KNOW, OR IN FACT DOES KNOW OF THE POSSIBILITY.

6. FINANCIAL TERMS

6.1 [*]

6.2 Each party is solely responsible for calculating and distributing to its respective inventors any share of NET REVENUES due in accordance with its respective patent, inventorship, or intellectual property policy.

7. RECORDS AND REPORTS

7.1 [*]

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- 7.2 Within thirty (30) days following its receipt, UTRF shall provide to OSU a copy of any written reports provided to UTRF by a LICENSEE pertaining to LICENSED INVENTIONS, if any.
- 7.3 Each of UTRF and OSU agrees to be responsible for its own reporting to federal agencies as required. OSU and UTRF agree to cooperate as necessary for effecting such reporting.
8. PATENT INFRINGEMENT
- 8.1 In the event that UTRF or OSU becomes aware of the infringement or claim of infringement of any IP RIGHTS in the LICENSED INVENTIONS in whatever territory those IP RIGHTS exist, each will inform the other in writing of all details available.
- 8.2 UTRF and its LICENSEE shall have the first right to enforce the rights of the parties. If both UTRF and its LICENSEE elect not to enforce or to continue to enforce the right of the parties, UTRF shall notify OSU in writing. Under such circumstances, OSU may elect to prosecute the infringers [*] provided that (i) [*], and (ii) OSU shall not have any right to surrender OSU's, UTRF's or any LICENSEE'S rights or to grant any infringer any rights in the IP RIGHTS without the prior written approval of UTRF and any LICENSEE, such approval not to be unreasonably withheld.
- 8.3 In any infringement suit instituted to enforce the IP RIGHTS pursuant to this AGREEMENT, both parties will, at the request of the party initiating such suit, and to the extent permitted by law, make a reasonable effort to cooperate in all respects and, to the extent possible, have its employees testify when requested and make available relevant records, papers, information, samples, and the like. [*]
- 8.4 Any sums recovered by UTRF or OSU, excluding such amounts as are otherwise payable to (or to be retained by) any LICENSEE under a LICENSE AGREEMENT, with respect to any such action will be [*].

9. NOTICES

Any notice and/or correspondence required or permitted to be given to the parties hereto is properly given if delivered in writing, in person, sent by first-class certified mail, or by overnight carrier, or if transmitted by confirmed facsimile or email (with a copy provided by another means specified in this Section) to the following addresses, or to such other addresses as may be designated in writing by the parties from time to time during the

TERM of this AGREEMENT:

- to OSU: [*]
- to UTRF : [*]
- with a copy to: [*]

10. TERMINATION

10.1 This AGREEMENT is in full force and effect from the EFFECTIVE DATE and remains

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in effect for the life of the last-to-expire patent in IP RIGHTS, unless otherwise terminated under Section 10.2 or by mutual written agreement of the parties (the "TERM").

- 10.2 Upon any breach of this AGREEMENT by either party, the other party has the right to terminate this AGREEMENT [*].
- 10.3 The parties acknowledge and agree that any provision that by its nature survives shall survive cancellation or termination of this AGREEMENT.
- 10.4 Should UTRF breach Section [*], all of UTRF's right, title, and interest in and to OSU's interests in any LICENSED INVENTIONS and the associated IP RIGHTS shall revert to OSU. Any LICENSE AGREEMENT or SUBLICENSE AGREEMENT executed prior to any expiration or termination of this AGREEMENT between UTRF or a LICENSEE and a third party (a "PRIOR LICENSEE") shall remain in effect for the duration of such agreement as if this AGREEMENT was in full force and effect with OSU standing in the shoes of UTRF as licensor to the extent only of OSU's interest in the LICENSED INVENTIONS, provided that any such LICENSE AGREEMENT or SUBLICENSE AGREEMENT was not subject to a notice of termination by UTRF at the time of cancellation or termination of this AGREEMENT. The parties further acknowledge and agree that UTRF's right to exercise the OPTION provided under Section 2.4 herein for any IMPROVEMENT INVENTION shall expire upon termination of this AGREEMENT. Following such expiration, a PRIOR LICENSEE shall have the right, subject to Section 2.8 herein, to exercise the OPTION to negotiate a license to an IMPROVEMENT INVENTION under terms acceptable to OSU and the PRIOR LICENSEE.
- 10.5 Should OSU (i) breach its obligation under this Agreement [*], then its rights under the LICENSED INVENTIONS shall revert to UTRF as follows. The grant to UTRF in Section 2.1 shall become fully paid up, permanent, and irrevocable, and there shall be no further payment or reporting obligations to OSU.

11. CONFIDENTIALITY

- 11.1 To the extent permitted by law, UTRF and OSU, respectively, shall hold in confidence the TECHNOLOGY, proprietary business information, patent prosecution information or other information related to the LICENSED INVENTIONS or associated IP RIGHTS of the other party, or any information of or pertaining to a LICENSEE or SUBLICENSEE that has been disclosed to UTRF or OSU agents, personnel or employees (collectively, "PROPRIETARY INFORMATION") using at least the same degree of care as that party uses to protect its own proprietary information of a like nature, but no less than reasonable care, and shall not use or disclose the PROPRIETARY INFORMATION of the disclosing party without the prior written consent of the disclosing party, except as otherwise contemplated by this AGREEMENT. Notwithstanding the foregoing, UTRF and OSU agree that this section does not apply to proprietary business information or other information related to the LICENSED INVENTIONS disclosed by a LICENSEE or

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SUBLICENSEE to an OSU employee while that employee is acting solely in the capacity as a private consultant or employee of the LICENSEE or SUBLICENSEE. The disclosing party shall label or mark confidential, or as otherwise appropriate, all such PROPRIETARY INFORMATION, provided that the parties agree that all patent applications and related patent filings and correspondence shall be and remain PROPRIETARY INFORMATION and covered by the confidentiality provision hereof without any further written notification. If PROPRIETARY INFORMATION is orally disclosed, the disclosing party shall reduce the PROPRIETARY INFORMATION to writing or to some other physically tangible form and deliver it to the receiving party within thirty (30) days of the oral disclosure, marked and labeled as set forth above. Nothing herein shall be construed in such a manner as to preclude UTRF from disclosing PROPRIETARY INFORMATION of OSU to a third party without the prior written consent of OSU for the purpose of marketing, licensing, protecting, or defending LICENSED INVENTIONS or otherwise performing its obligations or exercising its rights as contemplated by this AGREEMENT, provided that such disclosure is made under the same degree of care as UTRF uses to protect its own confidential and proprietary information of a like nature, but with no less than reasonable care and conditions of confidentiality.

11.2 Except as otherwise set forth in Section 2, nothing in this AGREEMENT in any way restricts or impairs the right of OSU and UTRF to use, disclose, or otherwise deal with any PROPRIETARY INFORMATION that recipient can demonstrate by written records:

- (i) was previously known to it, excluding, however, any PROPRIETARY INFORMATION known to recipient on account of a confidentiality agreement to which it is subject;
- (ii) is now, or becomes in the future, public knowledge other than through acts or omissions of recipient;
- (iii) is lawfully obtained without restrictions by recipient from sources independent of the disclosing party;
- (iv) was made independently without the use of PROPRIETARY INFORMATION received hereunder or under an existing confidentiality agreement; or
- (v) is required by applicable federal, state, or local law or court order to be disclosed.

11.3 In the event one of the parties to this AGREEMENT shall desire to publish or present a manuscript, poster, abstract, presentation, thesis, dissertation, or any other type of public disclosure (together, "Publications") relating to the EXISTING INVENTIONS or any IMPROVEMENT INVENTION, the publishing party shall provide the other party and any LICENSEE or SUBLICENSEE about which the party has received prior notification with a copy of such Publication 60 days prior to submission of such Publication for publication for purposes of protecting PROPRIETARY INFORMATION or associated IP RIGHTS that might be contained in such Publication. Should the receiving party or

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any LICENSEE or SUBLICENSEE identify potentially patentable information in the proposed Publication, the receiving party or any LICENSEE or SUBLICENSEE shall notify the publishing party, and the publishing party agrees to delay the submission of the Publication for an additional sixty (60) days to allow for the preparation and filing of a patent application if requested by a party having the right to file a patent application hereunder. The parties agree to cooperate with each other to avoid publication of trade secrets or other sensitive or potentially damaging information of any LICENSEE or SUBLICENSEE.

11.4 The confidentiality obligations of the recipient under these terms will remain in effect as to each item of PROPRIETARY INFORMATION for [*], and such obligations will survive termination of this AGREEMENT should this AGREEMENT terminate prior to completion of the period that the obligations are to remain in effect. Nothing herein shall be construed to abrogate or reduce any existing confidentiality obligations relating to the subject matter hereof.

12. GENERAL

12.1 UTRF and OSU each represent and warrant that they have the full corporate power and authority to enter into this AGREEMENT, and that this AGREEMENT constitutes the binding legal obligation of the parties.

12.2 Other than for the licensing activities contemplated by this AGREEMENT, this AGREEMENT does not confer any right to use any name, trade name, trademark, or other designation of either party to this AGREEMENT (including contraction, abbreviation or simulation of any of the foregoing) in advertising, publicity or other promotional activities.

12.3 This AGREEMENT may not be assigned by UTRF or OSU without the written consent of an authorized representative of the other party, which consent may be granted or withheld in such party's sole and absolute discretion, except that either party may assign this AGREEMENT without consent only (a) along with its ownership of the LICENSED INVENTIONS and associated IP RIGHTS and (b) to a successor that is a university or an organization which has as one of its primary functions the management of LICENSED INVENTIONS (a Bayh-Dole organization). This Agreement shall apply to, inure to the benefit of, and be binding upon, the parties' permitted successors and assigns.

12.4 The scope and validity of any patent or patent application in IP RIGHTS in LICENSED INVENTIONS are governed by applicable laws of the country of that patent or patent application.

12.5 No waiver by either party hereto of any breach or default of any of the covenants or agreements herein set forth may be deemed a waiver as to any subsequent and/or similar breach or default.

12.6 This AGREEMENT does not confer by implication, estoppel, or otherwise any license or

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rights under any patents of either party other than the specific LICENSED INVENTIONS and associated IP RIGHTS licensed hereunder, regardless of whether such patents are dominant or subordinate to such IP RIGHTS.

12.7 This AGREEMENT, including the Attachments and the NEW SARMS INVENTIONS INTER-INSTITUTIONAL AGREEMENT being executed contemporaneously, constitutes the entire agreement, both written and oral, between the parties, and it supersedes all prior and contemporaneous agreements between the parties respecting the subject matter of this AGREEMENT, written or oral, expressed or implied. This AGREEMENT shall not be amended or modified except by written instrument that has been duly executed by the signature of an authorized representative of each of the parties. This AGREEMENT may not be amended or modified by conduct manifesting assent and each party is hereby put on notice that any individual purporting to amend or modify this AGREEMENT by conduct manifesting assent is not authorized to do so. In the event this AGREEMENT is modified except as provided in this Section, any party may deem such modification to be voidable at will.

12.8 [*]

12.9 THE PARTIES INTEND THAT THIS AGREEMENT IS VALID AND SHALL BE ENFORCED AS WRITTEN. In the event any provision of this AGREEMENT shall for any reason be held by a court of law or an agency of the United States government with jurisdiction thereover to be invalid, illegal or unenforceable in any respect (whether on the ground that it is excessively broad or unreasonable as to scope or subject, or otherwise) ("AFFECTED PROVISION"), such AFFECTED PROVISION shall be enforced, modified, or replaced by another equivalent provision, to the extent necessary to render it valid, legal and enforceable under the circumstances and to the extent consistent with applicable law, while reflecting as closely as possible the original intent of the Parties with respect to the AFFECTED PROVISION, as expressed or implied therein. If, however, such enforcement, modification or replacement is not permissible under applicable law, then the AFFECTED PROVISION shall be severed from this AGREEMENT. The invalidity, illegality or unenforceability of the AFFECTED PROVISION, or the enforcement, modification, replacement or severance thereof (as the case may be), shall not affect the validity, legality or enforceability of the other provisions of this AGREEMENT, which shall remain in full force and effect

12.10 To facilitate execution, this AGREEMENT may be executed in as many counterparts as may be required. It shall not be necessary that the signature of or on behalf of each party appears on each counterpart, but it shall be sufficient that the signature of or on behalf of each party appears on one or more of the counterparts. All counterparts shall collectively constitute a single agreement. It shall not be necessary in any proof of this AGREEMENT to produce or account for more than a number of counterparts containing the respective signatures of or on behalf of all of the parties. Further, this AGREEMENT may be executed through the use of facsimile transmission, and a counterpart of this AGREEMENT that contains the facsimile signature of a party shall constitute an

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executed counterpart of this AGREEMENT.

{AUTHORIZED SIGNATURES APPEAR ON THE FOLLOWING PAGE}

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IN WITNESS WHEREOF, the parties have caused this AGREEMENT to be executed by their respective duly authorized officers or representatives.

UNIVERSITY OF TENNESSEE RESEARCH FOUNDATION

By /s/ Fred D. Tompkins
Name Fred D. Tompkins, Ph.D.
Title President
Date 12-22-04

THE OHIO STATE UNIVERSITY

By /s/ Ellen J. Purpus
Name Ellen J. Purpus, Ph.D.
Title Director, Office for Technology Licensing
Date Dec. 22, 2004

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**ATTACHMENT A
PATENTS AND PATENT APPLICATIONS
COVERING BRIDGED SARMS
[*]**

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EXHIBIT C

OSU IIA #2

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**NEW SARM INVENTIONS
INTER-INSTITUTIONAL AGREEMENT
BETWEEN
THE OHIO STATE UNIVERSITY
AND
THE UNIVERSITY OF TENNESSEE RESEARCH FOUNDATION**

This NEW SARM INVENTIONS INTER-INSTITUTIONAL AGREEMENT (the "AGREEMENT") is effective the 22nd day of December, 2004 (hereafter, the "EFFECTIVE DATE") by and between The Ohio State University on behalf of itself and The Ohio State University Research Foundation and the Ohio State University Office for Technology Licensing (collectively, hereinafter "OSU") having an address at 1960 Kenny Road, Columbus, Ohio 43210, and the University of Tennessee Research Foundation (hereinafter "UTRF") having an address at 1534 White Avenue, Knoxville, Tennessee 37996.

BACKGROUND

OSU and UTRF executed a formal inter-institutional agreement effective the same date hereof (hereinafter referred to as the "BRIDGED SARM IIA") with respect to the patenting, enforcement, sharing of proceeds, and commercialization of certain BRIDGED SARM inventions developed in whole or in part by OSU researcher Dr. James Dalton and/or other OSU research staff and students.

OSU and UTRF now wish to establish an understanding between the parties with respect to the patenting, enforcement, and commercialization of NEW INVENTIONS (as defined below) and how any commercialization revenues derived therefrom will be divided between the parties.

In furtherance thereof, OSU wishes to grant UTRF an option to obtain an exclusive license to OSU's interest in the NEW INVENTIONS and UTRF wishes to obtain such an option pursuant to the provisions of this AGREEMENT.

Therefore, in consideration of the mutual obligations set forth below, OSU and UTRF agree as follows:

1. DEFINITIONS. The following capitalized terms used in this AGREEMENT have the following meanings:
 - 1.1 "BRIDGED SARMS" means SARM compounds [*], including those described in the patents and patent applications listed in Attachment A to BRIDGED SARM IIA.

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- 1.2 “IP COSTS” means the documented, un-reimbursed, out-of-pocket, reasonable expenses incurred by UTRF or OSU in the preparation, filing, prosecution, defense, enforcement and maintenance of IP RIGHTS associated with the NEW INVENTIONS.
- 1.3 “IP RIGHTS” means any and all right, title and interest (whether now existing or arising in the future) in, to and under NEW INVENTIONS, including, without limitation, patents, patent applications, provisional patent applications and any divisions, reissues, renewals, reexaminations, substitutions, continuations, continuations-in-part, and any corresponding foreign counterparts thereof; and other proprietary rights arising or enforceable under any United States federal or state law, rule or regulation, non United States law, rule or regulation or international treaty.
- 1.4 “LICENSE AGREEMENT” means any agreement that is entered into by UTRF that grants to a third party any right or license to the LICENSED INVENTIONS, including, without limitation, the two existing Amended and Restated Exclusive License Agreements dated August 23, 2000 by and between UTRF and GTx, Inc., as the same may be amended from time to time (the two referenced pre-existing agreements between UTRF and GTx, Inc., being hereinafter referred to as the “Exclusive License Agreements”), and any agreement entered into by UTRF granting an option for such a right or license.
- 1.5 “LICENSEE” means any 3rd party licensee to a LICENSE AGREEMENT.
- 1.6 “LICENSED INVENTIONS” means NEW INVENTIONS and associated IP RIGHTS licensed to UTRF under Section 2 herein.
- 1.7 “NET REVENUES” means all gross proceeds received by UTRF from the licensing of the LICENSED INVENTIONS and/or associated IP RIGHTS less IP COSTS.
- 1.8 “NEW INVENTIONS” means any TECHNOLOGY pertaining to SARMS conceived, created, developed, designed, invented, or reduced to practice, in whole or in part by OSU researcher Dr. James Dalton and/or other OSU research staff and students that is not a LICENSED INVENTION under the BRIDGED SARM IIA, and is patentably distinct therefrom and directly results from: (i) research or clinical investigation utilizing any EXISTING INVENTION or IMPROVEMENT INVENTION as defined in the BRIDGED SARM IIA; (ii) research or investigation conducted pursuant to specific National Institutes of Health or other federally-funded projects, which involve collaboration between UT and/or UTRF and OSU; or (iii) non-federally-funded research at OSU that is sponsored by UT or UTRF or any of their respective licensees or sublicensees relating to SARMS. Any other invention will be considered to be a NEW INVENTION subject to this Agreement if OSU and UTRF agree thereto in writing. The parties acknowledge and agree that a NEW INVENTION shall not include

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TECHNOLOGY, EXISTING INVENTIONS, or IMPROVEMENT INVENTIONS as defined in the BRIDGED SARM IIA.

- 1.9 "SARM" means selective androgen receptor modulator.
- 1.10 "SUBLICENSE AGREEMENT" means any agreement that is entered into by LICENSEE that grants to SUBLICENSEE thereunder any right or license to the LICENSED INVENTIONS, or any agreement granting an option for such a right or license.
- 1.11 "SUBLICENSEE" means any sublicensee to a SUBLICENSE AGREEMENT.
- 1.12 "TECHNOLOGY" means any and all compounds; compositions; conclusions; designs; inventions; methods procedures; processes; products; services; substances; techniques; and/or business, engineering, manufacturing, scientific, medical, clinical, pharmacology, toxicology, or other data or material, in any form, method or manner of expression or communication now known or that hereinafter becomes known (whether or not tangible or intangible, or able to be protected by patent or trademark), and any documentation or work product comprising the same.
- 1.13 "TERM" shall have the meaning set forth in Section 10.1 hereof.
- 1.14 "VALID CLAIM(s)" means any claim(s) in an unexpired patent or pending in a patent application or provisional application which has not been held unenforceable, unpatentable, or invalid by a decision of a court or other governmental agency of compete jurisdiction, unappealable or unappealed within the time allowed for appeal, and o which has not been abandoned or admitted to be invalid or unenforceable through issue or disclaimer. The parties acknowledge the requirement under United States law that patent claims must satisfy the written description requirement of 35 U.S. C. §112.

2. GRANT OF OPTION FOR LICENSE

- 2.1 OSU hereby grants to UTRF an exclusive option to an exclusive, worldwide, sublicensable (through multiple tiers) license to OSU's interest in each NEW INVENTION and associated IP RIGHTS and an option to a nonexclusive, sublicensable (through multiple tiers) license to OSU's interest in know-how related to an IMPROVEMENT INVENTION under the terms of this AGREEMENT (collectively, the "OPTION").
- 2.2 Within [*]. The OPTION shall commence for each NEW INVENTION upon the date of such notice and shall expire [*].

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- 2.3 UTRF may exercise the OPTION as to each NEW INVENTION by notifying OSU in writing during the OPTION PERIOD for that NEW INVENTION.
- 2.4 Upon UTRF's exercise of its OPTION as to a particular NEW INVENTION, OSU grants and agrees to grant to UTRF an exclusive, worldwide, sublicensable (through multiple tiers) license to OSU's right, title, and interest in such NEW INVENTION and associated IP RIGHTS for the duration of each such IP RIGHT and a non-exclusive sublicensable (through multiple tiers) license to OSU's interest in know-how related to the same NEW INVENTION, on the same terms and conditions as the license to LICENSED INVENTIONS granted by OSU in the BRIDGED SARM IIA, [*].
- 2.5 Neither party shall be obligated to reimburse the other party for any IP COSTS incurred by the other party with regard to a NEW INVENTION unless agreed to in writing by the parties in advance on a case-by-case basis. Nothing in this AGREEMENT shall be construed in such a manner as to preclude UTRF from entering into a LICENSE AGREEMENT that provides for reimbursement by the LICENSEE of IP COSTS, in whole or in part. If OSU has incurred IP COSTS for a particular NEW INVENTION prior to the date of execution of this Agreement, OSU shall provide UTRF with a detailed accounting of these IP COSTS and UTRF shall seek reimbursement of these IP COSTS by a LICENSEE and shall provide such reimbursement to OSU upon UTRF's receipt thereof.
- 2.6 If UTRF shall fail to exercise its OPTION to a NEW INVENTION and associated IP RIGHTS within the OPTION PERIOD, then UTRF's OPTION to license such NEW INVENTION and associated IP RIGHTS under this Section shall automatically expire.
- 2.7 To the extent that any research pertaining to a LICENSED INVENTION has been or is in the future funded in whole or in part by the United States government, the United States government retains certain rights and requires certain obligations concerning such inventions as set forth in 35 U.S.C. §§200-212 and all regulations promulgated thereunder, as amended, and any successor statutes and regulations and applicable policies of such United States government sponsors, including, without limitation, to the extent applicable, the utilization and capability requirements found in the National Institutes of Health (NIH) Grants Policy Statement: "Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts", Federal Register, Vol. 59, No. 215, Tuesday, November 8, 1994, pp. 55674-55679 (collectively, "Federal Policy"). UTRF and OSU acknowledge and shall materially comply with all aspects of Federal Policy applicable to NEW INVENTIONS and shall require that each LICENSE AGREEMENT include a provision requiring the LICENSEE to materially comply with all applicable aspects of Federal Policy. In the event that either party receives notice of any action or notification by the United States government with

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respect to such rights and/or obligations, the party agrees to provide the other prompt written notice of such action or notification.

3. WARRANTIES, INDEMNIFICATION, AND DISCLAIMERS

3.1 OSU represents and warrants that:

- 3.1.1 OSU has the right to enter into this AGREEMENT, to grant the licenses herein and to bind The Ohio State University Research Foundation to the terms of this Agreement in the same manner that The Ohio State University is bound, and hereby binds OSURF thereto;
- 3.1.2 To the best of its knowledge, by entering into and performing under this AGREEMENT, it shall not be in violation of any applicable law, rule, regulation, or contractual obligation owed to any third party, and that it shall have obtained all permits, licenses, or permissions required to comply with such laws, rules, regulations, or obligations;
- 3.1.3 Prior to and at any time during the TERM, it knowingly has not nor will it make any agreements and/or transfer of rights or powers in the LICENSED INVENTIONS or otherwise encumber the LICENSED INVENTIONS or the associated IP RIGHTS in a manner that is inconsistent with or in derogation of the exclusive license or the OPTION granted to UTRF herein, except as permitted und Sections 2 and 3 herein;
- 3.1.4 As of the EFFECTIVE DATE, OSU, to the best of its knowledge, is not aware of any pending or threatened litigation involving the NEW INVENTIONS or associated IP RIGHTS and agrees to notify UTRF in the event it becomes aware of pending or threatened litigation involving any of the NEW INVENTIONS or associated IP RIGHTS thereafter.

3.2 UTRF represents and warrants that:

- 3.2.1 UTRF has the right to enter into this AGREEMENT, to accept and grant the licenses herein.
- 3.2.2 To the best of its knowledge, by entering into and performing under this AGREEMENT, it shall not be in violation of any applicable law, rule, regulation or contractual obligation owed to any third party, and that it shall have obtained all permits, licenses, or permissions required to comply with such laws, rules, regulation, or obligations.

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3.3 EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, EACH PARTY, ITS AFFILIATES, AND THEIR TRUSTEES, DIRECTORS, OFFICERS, EMPLOYEES, AND AGENTS MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OF IP RIGHTS, CLAIMS ISSUED OR PENDING, AND THE ABSENCE OF LATENT OR OTHER DEFECTS, WHETHER OR NOT DISCOVERABLE. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A REPRESENTATION MADE OR WARRANTY GIVEN BY EITHER PARTY THAT THE PRACTICE BY ANY LICENSEE OR SUBLICENSEE OF THE LICENSE GRANTED SHALL NOT INFRINGE THE IP RIGHTS OF ANY THIRD PARTY. NEITHER PARTY SHALL BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING ECONOMIC DAMAGE OR INJURY TO PROPERTY AND LOST PROFITS, REGARDLESS OF WHETHER THE OTHER PARTY IS ADVISED, HAS OTHER REASON TO KNOW, OR IN FACT DOES KNOW OF THE POSSIBILITY.

4. NOTICES

Any notice or other communication required or permitted hereunder (hereinafter "notice") shall be in writing and shall be hand-delivered, sent by overnight courier, mailed by certified United States mail, return receipt requested, or sent by email or facsimile, to the addresses given below or to such other addresses as the parties may hereafter specify in writing. Notice shall be deemed given and received five (5) days after being deposited with the U.S. Postal Service certified mail postage prepaid, or if notice is hand-delivered or sent by overnight courier, upon the date of actual delivery, or if sent by facsimile or email, upon the date the receiving party acknowledges receipt in writing by email or otherwise. An email notice shall be given concurrently to all the email addresses provided by the recipient party and the first acknowledgment of receipt from the recipient party shall establish the date on which such notice is given. Any patent correspondence that is required to be sent shall not be sent via email except where urgent response is required to preserve patent rights of the NEW INVENTION.

UTRF:

If notice is given means other than email, to:

[*]

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If notice is given by email, to:

[*]

OSU:

If notice is given by means other than email, to:

[*]

If notice is given by email, to:

[*]

5. TERMINATION

- 5.1 This AGREEMENT is in full force and effect from the EFFECTIVE DATE and remains in effect for the life of the last-to-expire patent in IP RIGHTS, unless otherwise terminated by mutual written agreement of the parties (the "TERM").
- 5.2 Upon any breach of this AGREEMENT by either party, the other party has the right to terminate this AGREEMENT [*].
- 5.3 The parties acknowledge and agree that any provision that by its nature survives shall survive cancellation or termination of this AGREEMENT.

6. CONFIDENTIALITY

- 6.1 To the extent permitted by law, UTRF and OSU, respectively, shall hold in confidence the TECHNOLOGY, proprietary business information, patent prosecution information or other information related to the NEW INVENTIONS or associated IP RIGHTS of the other party, or any information of or pertaining to a LICENSEE or SUBLICENSEE that has been disclosed to UTRF or OSU agents, personnel or employees (collectively, "PROPRIETARY INFORMATION") using at least the same degree of care as that party uses to protect its own proprietary information of a like nature, but no less than reasonable care, and shall not use or disclose the PROPRIETARY INFORMATION of the disclosing party without the prior written consent of the disclosing party, except as otherwise contemplated by this AGREEMENT. Notwithstanding the foregoing, UTRF and OSU agree that this section does not apply to proprietary business information or other information related to the LICENSED INVENTIONS disclosed by a LICENSEE or SUBLICENSEE to an OSU employee while that employee is acting solely in the capacity as a private consultant or employee of the LICENSEE or SUBLICENSEE. The disclosing party shall label or mark confidential, or as otherwise appropriate, all such PROPRIETARY INFORMATION, provided that the parties agree that all patent

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applications and related patent filings and correspondence shall be and remain PROPRIETARY INFORMATION and covered by the confidentiality provision hereof without any further written notification. If PROPRIETARY INFORMATION is orally disclosed, the disclosing party shall reduce the PROPRIETARY INFORMATION to writing or to some other physically tangible form and deliver it to the receiving party within thirty (30) days of the oral disclosure, marked and labeled as set forth above. Nothing herein shall be construed o such a manner as to preclude UTRF from disclosing PROPRIETARY INFORMATION of OSU to a third party without the prior written consent of OSU for the purpose of marketing, licensing, protecting, or defending LICENSED INVENTIONS or otherwise performing its obligations or exercising its rights as contemplated by this AGREEMENT, provided that such disclosure is made under the same degree of care as UTRF uses to protect its own confidential and proprietary information of a like nature, but with no less than reasonable care and conditions of confidentiality.

6.2 Except as otherwise set forth Section 2, nothing in this AGREEMENT in any way restricts or impairs the right of OSU and UTRF to use, disclose, otherwise deal with any PROPRIETARY INFORMATION that recipient can demonstrate by written records:

- (i) was previously known to it, excluding, however, any PROPRIETARY INFORMATION known to recipient on account of a confidentiality agreement to which it is subject;
- (ii) is now, or becomes in the future, public knowledge other than through acts or omissions of recipient;
- (iii) is lawfully obtained without restrictions by recipient from sources independent of the disclosing party;
- (iv) was made independently without the use of PROPRIETARY INFORMATION received hereunder or under an existing confidentiality agreement; or
- (v) is required by applicable federal, state, or local law or court order to be disclosed.

6.3 In the event one of the parties to this AGREEMENT shall desire to publish or present a manuscript, poster, abstract, presentation, thesis, dissertation, or any other type of public disclosure (together, "Publications") relating to the NEW INVENTIONS, the publishing party shall provide the other party and any LICENSEE or SUBLICENSEE about which the party has received prior notification with a copy of such Publication 60 days prior to submission of such Publication for publication for purposes of protecting PROPRIETARY INFORMATION or associated IP RIGHTS that might be contained in such Publication. Should the receiving party or any LICENSEE or SUBLICENSEE

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identify potentially patentable information in the proposed Publication, the receiving party or any LICENSEE or SUBLICENSEE shall notify the publishing party, and the publishing party agree to delay the submission of the Publication for an additional sixty (60) days to allow for the preparation and filing of a patent application if requested by a party having the right to file a patent application hereunder. The parties agree to cooperate with each other to avoid publication of trade secrets or other sensitive or potentially damaging information of any LICENSEE or SUBLICENSEE.

6.4 The confidentiality obligations of the recipient under these terms will remain in effect as to each item of PROPRIETARY INFORMATION for [*], and such obligations will survive termination of this AGREEMENT should this AGREEMENT terminate prior to completion of the period that the obligations are to remain in effect. Nothing herein shall be construed to abrogate or reduce any existing confidentiality obligations relating to the subject matter hereof.

7. GENERAL

7.1 UTRF and OSU each represent and warrant that they have the full corporate power and authority to enter into this AGREEMENT, and that this AGREEMENT constitutes the binding legal obligation of the parties.

7.2 Other than for the licensing activities contemplated by this AGREEMENT, this AGREEMENT does not confer any right to use any name, trade name, trademark, or other designation of either party to this AGREEMENT (including contraction, abbreviation or simulation of any of the foregoing) in advertising, publicity or other promotional activities.

7.3 This AGREEMENT may not be assigned by UTRF or OSU without the written consent of an authorized representative of the other party, which consent may be granted or withheld in such party's sole and absolute discretion, except that either party may assign this AGREEMENT without consent only (a) along with its ownership of the LICENSED INVENTIONS and associated IP RIGHTS and (b) to a successor that is a university or an organization which has as one of its primary functions the management of LICENSED INVENTIONS (a Bayh-Dole organization). This Agreement shall apply to, inure to the benefit of, and be binding upon, the parties' permitted successors and assigns.

7.4 The scope and validity of any patent or patent application in IP RIGHTS in LICENSED INVENTIONS are governed by applicable laws of the country of that patent or patent application.

7.5 No waiver by either party hereto of any breach or default of any of the covenants or agreements herein set forth may be deemed a waiver as to any subsequent and/or similar

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breach or default.

- 7.6 This AGREEMENT does not confer by implication, estoppel, or otherwise any license or rights under any patents of either party other than the specific LICENSED INVENTIONS and associated IP RIGHTS licensed hereunder regardless of whether such patents are dominant or subordinate to such IP RIGHTS.
- 7.7 This AGREEMENT, including the Attachments and the BRIDGED SARMS INVENTIONS INTER-INSTITUTIONAL AGREEMENT being executed contemporaneously, constitutes the entire agreement, both written and oral between the parties, and it supersedes all prior and contemporaneous agreement between the parties respecting the subject matter of this AGREEMENT, written or oral, expressed or implied. This AGREEMENT shall not be amended or modified except by written instrument that has been duly executed by the signature of an authorized representative of each of the parties. This AGREEMENT may not be amended or modified by conduct manifesting assent and each party is hereby put on notice that any individual purporting to amend or modify this AGREEMENT by conduct manifesting assent is not authorized to do so. In the event this AGREEMENT is modified except as provided in this Section, any party may deem such modification to be voidable at will.
- 7.8 [*]
- 7.9 THE PARTIES INTEND THAT THIS AGREEMENT IS VALID AND SHALL BE ENFORCED AS WRITTEN. In the event any provision of this AGREEMENT shall for any reason be held by a court of law or an agency of the United States government with jurisdiction thereover to be invalid, illegal or unenforceable in any respect (whether on the ground that it is excessively broad or unreasonable as to scope or subject, or otherwise) (“AFFECTED PROVISION”), such AFFECTED PROVISION shall be enforced, modified, or replaced by another equivalent provision, to the extent necessary to render it valid, legal and enforceable under the circumstances and to the extent consistent with applicable law, while reflecting as closely as possible the original intent of the Parties with respect to the AFFECTED PROVISION, as expressed or implied therein. If, however, such enforcement, modification or replacement is not permissible under applicable law, then the AFFECTED PROVISION shall be severed from this AGREEMENT. The invalidity, illegality or unenforceability of the AFFECTED PROVISION, or the enforcement, modification, replacement or severance thereof (as the case may be), shall not affect the validity, legality or enforceability of the other provisions of this AGREEMENT, which shall remain in full force and effect.
- 7.10 To facilitate execution, this AGREEMENT may be executed in as many counterparts as may be required. It shall not be necessary that the signature of or on behalf of each party appears on each counterpart, but it shall be sufficient that the signature of or on behalf of
- [*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**
-

each party appears on one or more of the counterparts. All counterparts shall collectively constitute a single agreement. It shall not be necessary in any proof of this AGREEMENT to produce or account for more than a number of counterparts containing the respective signatures of or on behalf of all of the parties. Further, this AGREEMENT may be executed through the use of facsimile transmission, and a counterpart of this AGREEMENT that contains the facsimile signature of a party shall constitute an executed counterpart of this AGREEMENT.

IN WITNESS WHEREOF, the parties have caused this AGREEMENT to be executed by their respective duly authorized officers or representatives.

UNIVERSITY OF TENNESSEE RESEARCH
FOUNDATION

By: /s/ Fred D. Tompkins

Name: Fred D. Tompkins, Ph.D.

Title: President

Date: 12/23/05

THE OHIO STATE UNIVERSITY

By: /s/ Ellen J. Purpus

Name: Ellen J. Purpus, Ph.D.

Title: Director, Office for Technology Licensing

Date: Jan. 12, 2006

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APPENDIX A to the CONSOLIDATED, AMENDED & RESTATED LICENSE AGREEMENT

[*]

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UNIVERSITY OF TENNESSEE RESEARCH FOUNDATION

and

GTx, INC.

AMENDED AND RESTATED LICENSE AGREEMENT

THIS AMENDED AND RESTATED LICENSE AGREEMENT made and entered into this 24th day of September, 2007, having an effective date of July 24, 1998 (the "Effective Date") by and between University of Tennessee Research Foundation (formerly known as The University of Tennessee Research Corporation), a Tennessee corporation having an office at 1534 White Avenue, Knoxville, Tennessee 37996. (hereinafter "UTRF"), and GTx, Inc. (formerly known as Genotherapeutics, Inc.), a Delaware corporation, located at 3 N. Dunlap St., Memphis, Tennessee 38163 (hereinafter "GTx"), hereinafter sometimes referred to individually as a "Party" and collectively as the "Parties".

RECITALS

WHEREAS, UTRF owns, in whole or in part, certain Licensed Patents (as defined herein) and Licensed Technology (as defined herein), the subject matter of which was initially developed by one or more of the UT Contributors (as defined herein) in the course of their employment with The University of Tennessee ("UT");

WHEREAS, the UT Contributors submitted to UT the invention disclosure form [*] designated by UTRF as file number PD [*] ("Initial SERM Disclosure");

WHEREAS, UTRF and GTx have previously entered into a separate agreement, titled "Amended and Restated Exclusive License Agreement" and made effective as of July 24, 1998, whereby GTx was granted an exclusive license to Licensed Patents (as defined therein) and Licensed Technology (as defined therein) which arose out of the technology described in the Initial SERM Disclosure (the "Prior License Agreement");

WHEREAS, GTx entered into a Collaboration and License Agreement dated September 7, 2006 (the "Ipsen Sublicense") with Ipsen Limited ("Ipsen") to grant Ipsen exclusive rights in the European Territory (as defined in the Ipsen Sublicense) to GTx's product candidate, Acapodene®, and other products containing toremifene citrate, for methods of use that include those encompassed within the Licensed Patents;

WHEREAS, GTx provided UTRF with a copy of the Ipsen Sublicense in accordance with the provisions of the Prior License Agreement;

WHEREAS, the Parties now desire to enter into this "Amended and Restated License Agreement" for the purpose of making certain changes regarding the rights and obligations of the Parties; and

WHEREAS, the Parties intend that this Agreement shall supersede the Prior License Agreement and render it null and void.

NOW, THEREFORE, for and in consideration of the premises and other good and valuable consideration, including a payment in the amount of Two Hundred Ninety Thousand Dollars (\$290,000; the "Consideration Fee"), which is paid by GTx in consideration of UTRF's execution of this Agreement, the Parties hereto expressly agree as follows:

SECTION 1
Definitions

1.1 “Actions” shall have the meaning set forth in Section 17.1 hereof.

1.2 “Active Ingredient” means the material(s) in a pharmaceutical product which provide its pharmacological activity (excluding formulation components such as coatings, stabilizers or controlled release technologies).

1.3 “Affiliate” shall mean any corporation, partnership, or other entity that at any time during the Term of this Agreement, directly or through one or more intermediaries, Controls or is Controlled by or is under common Control with a Party to this Agreement or a Sublicensee, but only for so long as the relationship exists. A corporation or other entity shall no longer be an Affiliate when through loss, divestment, dilution or other reduction of ownership, the requisite Control no longer exists.

1.4 “Agreement” shall mean this Amended and Restated License Agreement.

1.5 “Claims” shall have the meaning set forth in Section 8.1 hereof.

1.6 “Combination Product” means either (i) any pharmaceutical product that consists of at least one SERM and at least one other Active Ingredient that is not a SERM, or (ii) any combination of a SERM and another pharmaceutical product that contains at least one other Active Ingredient that is not a SERM where such products are not formulated together but are sold together as a single product and invoiced as one product.

1.7 “Confidential Information” shall have the meaning set forth in Section 18.2 hereof.

1.8 “Control” or “Controls” or “Controlled” shall mean: (i) in the case of a corporation, ownership or control, directly or indirectly, of at least fifty one percent (51%) of the shares of stock entitled to vote for the election of directors; or (ii) in the case of an entity other than a corporation, ownership or control, directly or indirectly, of at least fifty one percent (51%) of the assets of such entity.

1.9 “Effective Date” shall have the meaning set forth in the introductory paragraph hereof.

1.10 “Federal Policy” shall have the meaning set forth in Section 2.3 hereof.

1.11 “Generic Product” shall mean a product that is derived from, made with, uses, or incorporates, in whole or in part, Licensed Technology, but is not covered or claimed in whole or in part by a Valid Claim of the Licensed Patents in the country of manufacture, use, or sale or import.

1.12 “GTx” shall mean GTx, Inc. and its Affiliate(s) (unless such Affiliates are clearly excluded from the referencing provision(s) at issue), provided that in no instance shall GTx, Inc. be relieved of any duty or obligation hereunder by the inclusion of its Affiliates in the definition of “GTx”.

1.13 “Independent SERM Invention” shall have the meaning set forth in Section 2.8 hereof.

1.14 “Initial SERM Disclosure” shall have the meaning set forth in the Recitals.

1.15 “Ipsen” shall have the meaning set forth in the Recitals.

1.16 “Ipsen Sublicense” shall have the meaning set forth in the Recitals.

1.17 “License Maintenance Fee” shall have the meaning set forth in Section 4.1A. hereof.

1.18 “License Year” shall mean a 12-month period beginning on July 24th of one year and ending on July 23rd of the following year.

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1.19 “Licensed Patent” or “Licensed Patents” shall mean any or all of the (a) the patents set forth on Appendix A, attached hereto and incorporated herein by reference, (b) the patent applications set forth on Appendix A and any patents issuing therefrom, and (c) any other patent applications that may in the future be filed pursuant to Section 6.1 of this Agreement by GTx, whether in the United States of America or any other country, and any patents issuing therefrom, including, as they pertain to patents and patent applications described in (a)-(c) hereof, any and all substitutions for and divisional applications, continuation applications, continuation-in-part applications, provisional applications, and non-provisional applications, renewal applications, reissue applications, any foreign patent applications and divisional, continuation and continuation-in-part applications therefrom or national phase applications which claim priority from any of the pending patent applications set forth on Appendix A.

1.20 “Licensed Product” or “Licensed Products” shall mean any Patented Product or Generic Product, provided that in the case of a Combination Product (as defined under Section 1.6), Licensed Product shall mean only that portion of the Combination Product containing a SERM or SERMS, and Net Sales for such Licensed Product contained within a Combination Product shall be determined as set forth under Section 1.25.

1.21 “Licensed Subject Matter” shall mean Licensed Patents and Licensed Technology.

1.22 “Licensed Technology” shall mean, except to the extent published or otherwise generally known to the public any technology, trade secrets, methods, processes, know-how, show-how, data, information, or results (except technology, trade secrets, methods, processes, know-how, show-how, data, information, or results solely related to Independent SERM Inventions to the extent not published or otherwise generally known to the public) that are (i) developed by any one or more of the UT Contributors in the course of employment by UT or developed by any other UT employee directly from his or her research or clinical investigation of SERMs utilizing any Proprietary SERM Know-How; and (ii) owned solely or in part by UTRF (but, if owned in part by UTRF, only to the extent of the part owned by UTRF); and (iii) necessary or reasonably useful for the practice of any of the Licensed Patent(s), including (for purposes of explaining, and without expanding, the meaning of Sections 1.22 (i) through (iii)) the chemoprevention of prostate cancer and any methods of which the primary purpose is to administer to a subject an effective dose of a chemopreventive agent, toremifene, and analogs or metabolites thereof, to prevent recurrence of, suppress or inhibit prostate carcinogenesis.

1.23 “Major Markets” shall mean and include the United States, Great Britain, France, Germany, and Japan.

1.24 “Negotiation Period” shall have the meaning set forth in Section 2.8D. hereof.

1.25 “Net Sales” shall mean the gross amount actually received by GTx or any Sublicensee for the use, sale or distribution (hereinafter “Sale”) of a Licensed Product (hereinafter “Gross Receipts”), less the following:

- A. refunds, credits, and/or discounts actually given in connection with a particular Sale in amounts customary in the trade for quantity purchases, cash payments, and prompt payments, but only if such refunds, credits, and/or discounts constitute a return of amounts already included in Gross Receipts;
- B. refunds, credits and/or discounts actually given for Licensed Products that are rejected, recalled, returned, or destroyed by customers, but only if such refunds, credits and/or discounts constitute a return of amounts already included in Gross Receipts;
- C. sales, tariff duties and/or use taxes directly imposed and with reference to a particular Sale, to the extent included in Gross Receipts;
- D. outbound transportation expenses (including insurance relating thereto) directly related to a particular Sale, to the extent included in Gross Receipts;

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- E. the cost of export licenses, import duties, value added tax, and prepaid freight directly related to a particular Sale, to the extent included in Gross Receipts;
- F. sales commissions paid by GTx to individuals who are not employees of GTx, a Sublicensee, or their respective Affiliates, to the extent such commissions are directly related to a particular Sale;
- G. out-of-pocket service fees consistent with normal industry practice paid to distributors or wholesalers of drug product in payment for distribution of Licensed Product, provided that (a) such distributors and wholesalers are not Affiliates of GTx; (b) if any such distributor or wholesaler is an Affiliate of a Sublicensee, such fees are no more than that which such distributor/wholesaler actually and contemporaneously charges unaffiliated third party pharmaceutical companies for the same or similar service; (c) such fees may not be deducted more than once; (d) if a Sublicense shall be in effect, the fees paid by a Sublicensee may be deducted from Net Sales under this Agreement only if such fees are deducted from the equivalent of Net Sales under the relevant Sublicense agreement for purposes of calculating the royalty owed to GTx;
- H. retroactive price reductions, chargeback payments and rebates actually granted in connection with a particular Sale to managed health care organizations or to federal, state and local governments, their agencies, purchasers, and reimbursers, but only if such reductions, chargeback payments, and rebates constitute a return of amounts already included in or calculated as part of Gross Receipts; and
- I. [*] of any royalty (including a lump-sum payment) that is paid to a Third Party by GTx pursuant to a patent license agreement between GTx and such Third Party, provided that at the time of such payment (1) such Third Party owns or controls an issued patent containing a Valid Claim that, in the absence of such patent license agreement, would be infringed by the use, sale, or distribution of matter of a SERM licensed to GTx hereunder; and (2) the purpose of such royalty is for licensing of or acquiring such issued patent; and (3) the dollar amount of the [*] deduction for any calendar quarter shall not exceed the dollar amount of Net Sales in the same calendar quarter (computed without the application of this Section 1.25I.) from the use, sale, or distribution of Licensed Products containing such SERM in the country(ies) where such Third Party owns or controls such issued patent, it being agreed, however, that GTx may carry forward to future quarter(s) the amount by which the dollar amount of the [*] deduction exceeds the cumulative dollar amount of the actual deductions taken; and (4) GTx has not entered into such patent license agreement as of the date of execution of this Agreement.

For avoidance of doubt, no deductions shall be made for sales commissions paid to individuals who are employees of GTx, a Sublicensee, or their respective Affiliates, or for cost of collections. Notwithstanding the foregoing, Net Sales shall not include the amount received by GTx for the transfer of Licensed Product to a GTx Affiliate or a Sublicensee or the amount received by a Sublicensee for transfer or distribution of Licensed Product to GTx or a GTx Affiliate. Sales of Licensed Product for use in conducting clinical trials of a Licensed Product candidate in a country shall be excluded from Net Sales calculations for all purposes. Net Sales shall be determined in a consistent manner for all products sold by or on behalf of GTx and its Sublicensees and in accordance with applicable U.S. generally accepted accounting principles for GTx and any U.S. based Sublicensee.

Combination Product. In the event one or more Licensed Products are sold as part of a Combination Product in a particular country, the Net Sales of such Licensed Product(s), for the purposes of determining payments based on Net Sales, shall be determined by multiplying the Net Sales of the Combination Product in such country, during the applicable Net Sales reporting period, by the fraction, $A/(A+B)$, where:

A is the average sale price of the Licensed Product(s) by GTx or Sublicensees when sold separately in finished form in such country and B is the average sale price by GTx or Sublicensees, or, if they have no such right of sale, by a Third Party of the other product(s) included in the Combination Product when sold separately in finished form in such country, in each case during the applicable Net Sales reporting period.

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In the event one or more Licensed Products are sold as part of a Combination Product and are sold separately in finished form in such country, but the other product(s) included in the Combination Product are not sold separately in finished form in such country, the Net Sales of the Licensed Product, for the purposes of determining payments based on Net Sales, shall be determined by multiplying the Net Sales of the Combination Product in such country by the fraction C/D where:

C is the average sale price, in such country, of the Licensed Product(s) contained in such Combination Product when sold separately and D is the average sale price, in such country, for the Combination Product, in each case during the applicable Net Sales reporting period. Under no circumstances can C/D exceed one hundred percent (100%).

In the event that one or more of the Licensed Product(s) are not sold separately in finished form in the country, but all of the other product(s) included in the Combination Product in such country are sold separately, the Net Sales of the Licensed Product, for the purposes of determining payments based on Net Sales, shall be determined by multiplying the Net Sales of the Combination Product in such country by the fraction (D-E)/D, where:

D is the average sale price, in such country, of the Combination Product, and E is the average sale price of the other product(s) included in the Combination Product in finished form in such country, in each case during the applicable Net Sales reporting period.

In the event that the Net Sales of the Licensed Product(s) when included in a Combination Product cannot be determined using the methods above, Net Sales for the purposes of determining payments based on Net Sales shall be calculated by multiplying the Net Sales of the Combination Product by the fraction of F/(F+G) where:

F is the fair market value of the Licensed Product(s) and G is the fair market value of all other pharmaceutical product(s) included in the Combination Product, as reasonably determined in good faith by the Parties.

1.26 "Option" shall have the meaning set forth in Section 2.8 hereof.

1.27 "Option Period" shall have the meaning set forth in Section 2.8A. hereof.

1.28 "Patented Product" shall mean any product whose manufacture, use, sale or import is covered in whole or in part by a Valid Claim of the Licensed Patents in the country of manufacture, use, sale or import.

1.29 "Party" and "Parties" shall have the meaning set forth in the introductory paragraph hereof.

1.30 "Prior License Agreement" shall have the meaning set forth in the Recitals.

1.31 "Proprietary SERM Know-How" shall mean know-how pertaining to a SERM that is obtained from GTx or a UT Contributor and is not published or otherwise generally known to the public.

1.32 "Regulatory Approval" shall mean any approvals granted by a governmental authority in a particular regulatory jurisdiction (with the exception of conditional approvals) that are necessary for the commercial manufacture, use, storage, importation, export, transport or sale of Licensed Products in that regulatory jurisdiction.

1.33 "Running Royalty" shall have the meaning set forth in Section 4.1B. hereof.

1.34 "SERM" or "SERMS" shall mean toremifene, and analogs or metabolites thereof.

1.35 "Sublicense" shall mean a direct grant of right, license, or option to any Licensed Subject Matter from GTx to a GTx Affiliate or a Third Party, including the Ipsen Sublicense, and any further such grant at any tier.

1.36 "Sublicense Revenue" shall mean all payments actually received by GTx pursuant to each Sublicense, including, without limitation, up-front license fees, milestone payments, license maintenance fees, election fees, and all other fees and payments paid to GTx under each Sublicense agreement, excluding running royalties received by GTx that are calculated as a percentage of Sublicensee's Net Sales, and excluding the up-front fee GTx has already received from Ipsen in October 2006 upon its entering into the Ipsen Sublicense. GTx may deduct from Sublicense Revenue attributable to a particular Sublicense agreement payments received by GTx as

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reimbursement for actual, otherwise unreimbursed, out-of-pocket expenses as set out in such Sublicense agreement, provided that only reimbursements for expenses incurred in the development of one or more Licensed Products covered by such Sublicense may be deducted from Sublicense Revenue and then only to the extent of expenses incurred from and after the date of the Sublicense for pre-clinical or clinical research and development, including development of the formulation and manufacturing process, manufacturing of preclinical and clinical supplies and analytical and stability testing as required by the Food and Drug Administration to support a New Drug Application (NDA) filing for the Licensed Product. For the avoidance of doubt, Sublicense Revenue will not include any payments made to Third Parties by or on behalf of a Sublicensee for conducting clinical trials, filing new drug applications, commercially launching a product and/or marketing and selling a product, since these are not payments received by GTx from a Sublicensee on account of the Sublicense.

1.37 “Sublicense Royalty” shall have the meaning set forth in Section 4.1C. hereof.

1.38 “Sublicensee” shall mean and include any recipient of a Sublicense, including Ipsen.

1.39 “Sublicensee Patent Rights” shall have the meaning set forth in Section 6.2 hereof.

1.40 “Term” shall have the meaning set forth in Section 12.1 hereof.

1.41 “Third Party” or “Third Parties” shall mean any person, party or entity other than GTx, its Affiliates, UTRF, or UT.

1.42 “UT” shall mean The University of Tennessee.

1.43 “UT Contributor” and “UT Contributors” shall mean one or more of Mitchell S. Steiner and Sharan Raghov, and any other UT employee who contributed, either before or after the Effective Date, to the development of the Licensed Subject Matter.

1.44 “Valid Claim” shall mean (a) a claim of an issued patent which has not expired and which has not been held revoked, invalid or unenforceable by decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed with the time allowed for appeal having expired, and which has not been admitted to be invalid through reissue or disclaimer or otherwise; or (b) any claim of a pending patent application, which (i) was filed in good faith; and (ii) has not been pending for more than eight (8) years.

SECTION 2

Grant

2.1 During the Term hereof, and subject to the terms and conditions of this Agreement, UTRF hereby grants to GTx for the purpose of developing, making, having made, using, marketing, selling, having sold, importing, distributing, and offering for sale the Licensed Product:

- A. an exclusive, worldwide right and license, with the right to grant Sublicenses, to practice under the Licensed Patents that are owned solely or in part by UTRF; and
- B. an exclusive, worldwide right and license, with the right to grant Sublicenses, to utilize the Licensed Technology.

Subject to the other provisions of this Agreement, the Parties hereby agree that the term “exclusive” means that to the extent of UTRF’s rights in the Licensed Subject Matter and subject to Federal Policy, UTRF shall not grant any other license under Licensed Subject Matter to any Third Party or take any action inconsistent with the rights granted to GTx under this Agreement. The Parties further acknowledge and agree that to the extent UTRF owns any Licensed Subject Matter “in part”, the license herein granted to GTx will not give GTx or its Sublicensees the right to exclude UTRF’s co-owner(s) from exercising any rights attendant to such co-ownership, whether such rights arise by law or contract, provided that UTRF agrees that it will not negotiate or enter into a license agreement or

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sublicense agreement, or otherwise grant any option or licenses or other rights with respect to such Licensed Subject Matter (whether in whole or in part), except as required by Federal Policy. For avoidance of doubt, the exercise by GTx of its right to grant Sublicenses will not serve to restrict GTx's exercising of its right, as granted above, to practice under the Licensed Patents and/or to utilize the Licensed Technology.

2.2 GTx agrees that UT and those persons who, as of the date of signature hereto on behalf of UTRF, are named UT Contributors shall have the royalty-free non-exclusive right to practice under the Licensed Patents and to utilize the Licensed Technology for non-commercial educational, research, and academic purposes only.

2.3 To the extent that any research pertaining to inventions included in Licensed Technology and/or claimed in Licensed Patents has been or is in the future funded in whole or in part by the United States government, the United States government retains certain rights and requires certain obligations concerning such inventions as set forth in 35 U.S.C. §§200-212 and all regulations promulgated thereunder, as amended, and any successor statutes and regulations and applicable policies of such United States government sponsors, including, without limitation, to the extent applicable, the utilization and capability requirements found in the National Institutes of Health (NIH) Grants Policy Statement; "Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts", Federal Register, Vol. 59, No. 215, Tuesday, November 8, 1994, pp. 55675-55679 (collectively, "Federal Policy"). GTx acknowledges that all rights herein granted to GTx may be subject to any such rights held by the United States government and further subject to any restrictions or obligations that may be imposed by the United States government pursuant to such rights. GTx shall materially comply with all aspects of Federal Policy applicable to a licensee pertaining to Licensed Technology and/or Licensed Patents and shall include and require its Sublicensees to include a provision in each Sublicense agreement, at any tier, that requires the Sublicensee to materially comply with all applicable aspects of Federal Policy. In the event UTRF or GTx shall receive notice of any action or notification by the United States government with respect to any rights and/or obligations under Federal Policy pertaining to any rights licensed hereunder to GTx, the Party receiving such notice shall provide prompt written notice thereof to the other Party.

2.4 Intentionally omitted.

2.5 GTx shall have the right to enter into Sublicenses and to permit further sublicensing by Sublicensees through multiple tiers with respect to the Licensed Subject Matter, subject to notifying UTRF of the identity and address of each Sublicensee within thirty (30) days after execution of such agreement by the parties thereto. No GTx Affiliate or Third Party shall have the right to practice under the Licensed Patents or utilize the Licensed Technology to make, have made, use, market, sell, have sold, import, distribute, or offer for sale any Licensed Product in the absence of a written Sublicense agreement. Any grant of rights by GTx or a Sublicensee to practice under the Licensed Patents or to utilize the Licensed Technology to make, have made, use, market, sell, have sold, import, distribute, or offer for sale any Licensed Product shall constitute a Sublicense. All Sublicenses shall be subject to this Agreement in all respects and shall include provisions that such Sublicensee is being granted a license under the Licensed Subject Matter as defined herein and subject to the terms hereof. Notwithstanding anything to the contrary in this Agreement (including, without limitation, this Section 2.5), UTRF hereby agrees that all provisions of the Ipsen Sublicense, as executed on September 7, 2006, are in full compliance with the terms and conditions of this Agreement. GTx agrees that it will not modify or otherwise amend the Ipsen Sublicense in any manner that would deviate from any of the requirements of a Sublicense set forth herein without obtaining UTRF's prior written approval, which approval will not unreasonably be withheld. The Parties agree that unless a modification or amendment shall affect any requirement of a Sublicense as described in the immediately preceding sentence, GTx and Ipsen shall have the right and discretion to negotiate and enter into such amendments and modifications to the Ipsen Sublicense as they shall from time to time determine without first obtaining the approval of UTRF, and GTx will furnish a copy of any such amendment or modification to UTRF within thirty (30) days of the execution of such an instrument as required herein.

2.6 GTx shall be responsible for its Affiliates and Sublicensees and, except as set forth above as it pertains to Ipsen, shall not grant any rights that are inconsistent with the rights granted to and obligations of GTx hereunder. Each Sublicense agreement shall include a requirement that the Sublicensee use its commercially reasonable efforts to bring the subject matter of the Sublicense into commercial use. In addition, each Sublicense agreement shall include an acknowledgement that the ownership of the Licensed Patents are and shall remain in the

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name of UTRF, with the exception of Licensed Patents that are properly assigned to GTx, and, except as set forth in Section 6.2 hereof, an obligation on the part of the Sublicensee to assign, transfer and convey ownership of Licensed Patents to UTRF and/or, as UTRF may direct, to GTx. Upon termination of this Agreement, each Sublicensee's rights under any Sublicense agreement shall also terminate, provided that if UTRF terminates this Agreement for default by GTx, a Sublicensee's rights under a Sublicense agreement shall terminate only if UTRF has given such Sublicensee notice of default at least thirty (30) days prior to the effective date of termination and the Sublicensee shall have failed to cure such default, as provided in Section 12.3. UTRF shall have discharged its obligation to give notice of such default to a Sublicensee by sending (through any means contemplated under Section 15) a copy of GTx's notice of default to the Sublicensee's most recent street address of which UTRF has received written notice from GTx or the Sublicensee. No Sublicense shall relieve GTx of any of its obligations under this Agreement, except that a Sublicensee shall have the right to cure a default of GTx as set out in Section 12.3. GTx shall forward to UTRF a complete copy of each Sublicense agreement (including, without limitation, all amendments and addenda) granted hereunder within thirty (30) days after execution of such agreement by the parties thereto, provided that each such Sublicense agreement (and any amendments and addenda related thereto) shall be deemed GTx's Confidential Information and UTRF shall receive such information and documents in confidence and shall not publicly disclose, discuss or release such information or document to Third Parties (other than such information as may be reasonably necessary to be disclosed to UT Contributors and those persons within UT who have a need to know such information, provided that only such information concerning the Sublicense that is necessary to explain any payments to be made to a UT Contributor will be shared with the UT Contributors) without the prior written approval of GTx except for the purposes of enforcement of UTRF's rights, defense of any claim against UTRF, UT, or UT Contributors, compliance with Federal Policy, or compliance with applicable law, regulation, or court order. GTx shall be responsible for payment of royalties from Sublicensees' Net Sales provided, however, that GTx may arrange for such payments to be made to UTRF by a Sublicensee, with the understanding that the amount paid to UTRF shall not be decreased thereby and that UTRF's acceptance of such payments from a Sublicensee does not relieve GTx of the ultimate responsibility for any other or future payment required hereunder. Each such Sublicense agreement shall include an audit right by UTRF of the same scope as provided in Section 5.1 herein with respect to UTRF's audit of GTx's books of account.

2.7 Any act or omission of an Affiliate or Sublicensee which would constitute a breach of this Agreement if performed by GTx, shall be deemed to be a breach by GTx of this Agreement, subject however to the same cure provisions in favor of GTx, an Affiliate, or Sublicensee as are otherwise provided herein for breach by GTx.

2.8 During the Term hereof, UTRF shall promptly notify GTx in writing upon becoming aware of any SERM invention owned solely or in part by UTRF which is not (a) based on or developed from Proprietary SERM Know-How or (b) developed at UT from grants or research payments made to UT by GTx (each invention described above herein being an "Independent SERM Invention"). Subject to the rights of Third Parties (in the event UTRF co-owns such Independent SERM Invention with a Third Party), GTx will have an exclusive option to acquire, to the extent possible, a worldwide, exclusive (as defined in Section 2.1), royalty-bearing license to such Independent SERM Invention ("Option"), provided that the grant of such Option does not violate Federal Policy and further subject to the following:

- A. The Option shall commence upon UTRF's written notice to GTx of the existence of such Independent SERM Invention and shall terminate upon the earlier of (i) the expiration of six (6) calendar months from the date of such notice; or (ii) the giving of written notice to UTRF by GTx that it does not intend to exercise the Option; or (iii) the termination of this Agreement ("Option Period").
- B. GTx may exercise the Option during the Option Period by giving written notice of same to UTRF, provided that GTx is not then in default or breach of any of its obligations under this Agreement.
- C. Upon proper exercise of the Option by GTx, UTRF and GTx shall negotiate in good faith in an effort to reach agreement on the economic terms of a license to GTx of the Independent SERM Invention that is the subject of such Option, it being the intent that upon agreement of the Parties as to such economic terms, they will be expeditiously incorporated into a new license agreement

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with non-economic terms that are substantially similar to those contained herein, to the extent applicable.

- D. In the event GTx does not exercise the Option for a particular Independent SERM Invention within the Option Period or the Parties do not execute a license agreement within six (6) months after exercise of the Option for a particular Independent SERM Invention by GTx, which time period may be extended by written agreement of the Parties (the "Negotiation Period"), UTRF shall have no further obligation to GTx under this Agreement with regard to such Independent SERM Invention. In the absence of a license agreement granting GTx rights to such Independent SERM Invention, GTx agrees that it will not use such Independent SERM Invention for any commercial or non-commercial purpose.
- E. During the Option Period and the Negotiation Period, if any, UTRF will confer with GTx concerning proper protection of such Independent SERM Invention, but UTRF will have sole authority regarding decisions concerning such protection, including patent activities, provided that if GTx exercises the Option, UTRF shall coordinate all decisions regarding patent protection with GTx and shall take no actions with regard to intellectual property protection for such Independent SERM Invention that are contrary to GTx's advice unless UTRF reasonably believes rights may be lost unless it acts to protect those rights. From and after the commencement of the Option Period, whether or not GTx exercises the Option and whether or not the Parties subsequently execute a license agreement for GTx to secure rights to the Independent SERM Invention prior to the end of the Negotiation Period, GTx shall, within thirty (30) days after receipt of each invoice, reimburse UTRF for all reasonable and documented out-of-pocket expenses incurred by UTRF during the Option Period and the Negotiation Period, if any, for filing, prosecution, and maintenance of United States and foreign patent applications, issued patents, and other forms of intellectual property protection for such Independent SERM Invention, which intellectual property rights shall be assigned solely to UTRF or jointly to UTRF and its co-owner(s), if any, provided that UTRF shall have consulted with GTx regarding such proposed patent protection and UTRF shall have undertaken to make those filings that are reasonably necessary to protect and preserve its rights in the Independent SERM Invention to reasonably minimize the expenses GTx may be required to reimburse in accordance with this Section 2.8E until the Option Period and Negotiation Period shall have expired. If GTx shall fail to enter into a license agreement with UTRF for such Independent SERM Invention, it shall be entitled to receive a dollar for dollar reduction against Running Royalties and/or Sublicense Revenue (to be applied at GTx's sole discretion) for the total amount of costs it shall have reimbursed to UTRF for the expenses incurred by UTRF under this Section 2.8E.

SECTION 3

Diligence

3.1 GTx shall use its commercially reasonable efforts to develop and commercialize Licensed Products through a commercially reasonable program for exploitation of the Licensed Patents and the Licensed Technology.

SECTION 4

Payments and Royalties

4.1 For the rights, privileges and license granted hereunder, GTx shall pay to UTRF, in addition to the Consideration Fee, the following fees and royalties in the manner hereinafter provided until this Agreement expires or is terminated.

- A. License Maintenance Fee. GTx shall pay UTRF a license maintenance fee in the amount of [*] on [*] and on [*] thereafter during the Term of this Agreement ("License Maintenance Fee").

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The License Maintenance Fee actually paid for a particular License Year shall reduce, dollar for dollar, the Running Royalty (defined below) payable in the same License Year. License Maintenance Fees paid in excess of the Running Royalty payable in the same License Year shall not be creditable to the Running Royalty for future years. The Parties acknowledge and agree that there are no License Maintenance Fees due and owing to UTRF by GTx under the Prior License Agreement. The Parties further acknowledge and agree that, prior to the date of execution of this Amended and Restated License Agreement, GTx has paid [*] of the [*] license maintenance fee that was due and owing on [*], and GTx agrees to pay the remaining [*] of the [*] license maintenance fee upon submission of an invoice for same by UTRF.

B. Running Royalty. For the purposes of this Section 4.1B., royalties on Net Sales of all Patented Products and Generic Products incorporated in Combination Products shall be subject to the calculation of Net Sales with respect to Combination Products, as applicable, as set forth in Section 1.25.

- (1) GTx shall pay UTRF [*] of Net Sales of all Patented Products; and
- (2) GTx shall pay UTRF a percentage of Net Sales attributable to the use, sale or distribution of Generic Products, which percentage shall be determined on a Generic Product-by-Generic Product, country-by-country, and calendar quarter-by-calendar quarter basis. In each country the percentage shall be calculated as the [*] during the applicable calendar quarter divided by the [*] during the same calendar quarter [*] (provided that in no event shall the resulting percentage [*]). Furthermore, until such time as this Agreement shall expire in accordance with Section 12.1, should there be no sales in the Major Markets by GTx or Sublicensees of the same Licensed Product covered by a Valid Claim of Licensed Patents during the same calendar quarter, the percentage shall be [*];

(the royalty under 4.1B.(1) and 4.1B.(2) being the "Running Royalty"). Notwithstanding the foregoing, in the event that, for a particular Licensed Product in a given License Year under a specific Sublicense agreement, the running royalty (as a percentage of Net Sales) owed to GTx (including the Running Royalty owed to UTRF, if to be paid by the Sublicensee) is less than [*] of Sublicensee's Net Sales after deduction of running royalties (calculated as a percentage of Net Sales) owed and actually paid by or on behalf of GTx to one or more Third Parties as consideration for the grant by such Third Party(ies) of a license to technology incorporated in such Licensed Product, including the royalty to be paid to Orion to license toremifene, the Running Royalty owed to UTRF shall be [*] of the amount owed to GTx (including the Running Royalty owed to UTRF, if to be paid by the Sublicensee) for that License Year. By way of example only, in the event that during a particular License Year GTx is entitled to receive a running royalty equal to [*] of its Sublicensee's Net Sales of a particular Licensed Product in the EU and is in turn required to pay, and does actually pay, [*] of Sublicensee's Net Sales of that Licensed Product in the EU to a Third Party, then UTRF's Running Royalty would be [*] of Sublicensee's Net Sales of that Licensed Product in the EU.

C. Sublicense Royalty. GTx shall pay UTRF [*] of Sublicense Revenue ("Sublicense Royalty")

4.2 In the event that any taxes are required by law or regulation to be levied in any foreign country by a foreign taxing authority on any Running Royalty or Sublicense Royalty payable in UTRF's name under this Agreement and GTx determines in good faith that it or its Sublicensee must withhold such taxes:

- A. GTx or its Sublicensee shall have the right to withhold and pay such taxes withheld on the Running Royalty and/or Sublicense Royalty to the local tax authorities in UTRF's name;
- B. GTx or its Sublicensee shall pay the net amount of Running Royalty and/or Sublicense Royalty due after reduction by the amount of such taxes that are actually withheld and paid;

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- C. GTx or its Sublicensee shall provide UTRF with appropriate documentation and receipts supporting such withholding; and
- D. GTx or its Sublicensee shall inform UTRF in writing within thirty (30) days of being notified that taxes will be or have been required by a taxing authority to be withheld on the Running Royalty and/or Sublicense Royalty.

4.3 In the event that a Running Royalty is payable to UTRF on the same Net Sales revenue or a Sublicense Royalty is payable to UTRF on the same Sublicense Revenue under this Section 4 and under one or more other UTRF/GTx license agreements, GTx shall only be required to pay UTRF such royalty under one such license agreement, subject to the provisions of Section 5.2 and provided that if the amount due varies from one such license agreement to another, GTx shall pay the highest amount.

4.4 Within [*] following the close of each calendar quarter in which Net Sales revenue is received by GTx or a Sublicensee, or Sublicense Revenue is received by GTx, payment of all amounts due to UTRF, including but not limited to Running Royalty and Sublicense Royalty, shall be made to UTRF or its designee in United States dollars in Knoxville, Tennessee, or at such other place as UTRF may reasonably designate consistent with the laws and regulations controlling in any foreign country, provided that the [*] period may be extended for up to [*] after the close of each calendar quarter if a Sublicensee under a Sublicense requires more time than [*] to make its sales and royalty calculation and its royalty payment available to GTx. In the event GTx arranges for any payment under this Section 4.4 to be made to UTRF by a Sublicensee pursuant to Section 2.6, if such payment is not received by UTRF within the [*] period set forth herein (or within up to the [*] extension period as stated above, or [*]), GTx shall be deemed to be in breach of this Agreement, subject to the same cure provisions in favor of GTx as set forth in Section 12. If any currency conversion shall be required in connection with the payment of royalties hereunder, such conversion shall be made by using the exchange rate procedure listed in a Sublicense, if applicable, or in the absence of an applicable Sublicense provision addressing this issue, using the exchange rate listed in the Wall Street Journal for major New York banks on the last business day of the calendar quarter during which the royalty-bearing revenue was received by GTx or its Sublicensees, as the case may be.

SECTION 5

Reports and Records

5.1 No more often than once each License Year, UTRF or its accounting agents shall have the right to inspect the books of account of GTx. GTx shall keep full, true and accurate books of account containing all particulars that may be necessary for the purpose of showing the amounts payable to UTRF hereunder. Said books of account shall be kept at GTx's principal place of business or the principal place of business of the appropriate division of GTx to which this Agreement relates. Said books and the supporting data shall be open at all reasonable times for [*] following the end of the License Year to which they pertain, to the inspection of UTRF or its accounting agents for the purpose of verifying GTx's royalty statements. If any examination reveals a shortage in amounts paid to UTRF, GTx shall promptly reimburse UTRF for the shortage, together with interest thereon as provided in Section 5.4, and if the shortage is equal to or greater than [*] of the total amount due in the period under audit, GTx shall reimburse UTRF for the cost of the examination as well. If the examination reveals an overpayment to UTRF, GTx may deduct the amount of such overpayment from future amounts owed to UTRF hereunder.

5.2 GTx shall deliver to UTRF true and accurate reports to confirm a royalty accounting hereunder within [*] after the close of each calendar quarter (provided that the [*] period may be extended for up to [*] after the close of each calendar quarter if a Sublicensee under a Sublicense requires more time than [*] to make such information and its royalty payment available to GTx) and a summary of GTx's activities during such quarter to develop and commercialize Licensed Products. These reports shall be deemed GTx's Confidential Information and shall include at least the following, on a Licensed Product-by-Licensed Product, country-by-country, and Sublicensee-by-Sublicensee basis:

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- A. The number/amount of Licensed Product used, sold, or imported by and/or for GTx and Sublicensees and other information that is reasonably necessary to allow UTRF to properly calculate royalties due;
- B. The total amounts invoiced and received by GTx and Sublicensees for Licensed Products used or sold by GTx and/or Sublicensees including (i) an accounting of Net Sales for Running Royalty payments due to UTRF under Section 4.1B. above, with separate calculations for Patented Products, Generic Products, and Combination Products reflecting the type and amount of all deductions from Gross Receipts; and (ii) an accounting of Sublicense Revenue for Sublicense Royalty payments due to UTRF under Section 4.1C above reflecting the type and amount of all amounts deducted or excluded from Sublicense Revenue;
- C. The Running Royalty and Sublicense Royalty due, showing the application of any reduction pursuant to Section 2.8E., if applicable;
- D. For all royalties due to UTRF pursuant to Section 4.1, the report shall include (i) the manner in which such royalties were calculated and the amount allocable to each Licensed Product; and (ii) if any such royalties are payable to UTRF under this Agreement and under one or more other UTRF/GTx license agreements, GTx shall set out in its report the amount of such royalties covered by multiple license agreements and identify all such license agreements to which such royalties apply, notwithstanding that GTx is required to pay such royalties under only one such license agreement;
- E. The names and addresses of all Sublicensees for or on whose account royalty payments are being made in accordance with the terms hereof; and
- F. Upon request by UTRF, any other information that may be necessary for the purpose of showing the amounts payable to UTRF hereunder or compliance by GTx with the diligence provisions of Section 3.

5.3 With each such report submitted, GTx shall pay to UTRF the royalties due and payable under this Agreement. If no royalties shall be due, GTx shall so report.

5.4 Any amount owed by GTx under this Agreement that is not received by UTRF on or before the date due shall bear interest at a per annum rate [*] above the prime rate quoted in the Wall Street Journal for major New York banks on the date due, or if not quoted on the date due, the rate quoted on the first business day after the date due. GTx shall also pay all reasonable collection costs at any time incurred by UTRF in obtaining payment of amounts past due, including reasonable attorneys fees. If the transfer or the conversion into United States Dollar equivalents in any such instance is not lawful or possible, the payment of such part of the royalties as is necessary shall be made by the deposit thereof, in the currency of the country where the sales were made on which the royalty was based, to the credit and account of UTRF or its nominee in any commercial bank or trust company of its choice located in that country, prompt notice of which shall be given by GTx to UTRF.

SECTION 6

Patent Prosecution

6.1 During the Term and subject to the terms hereof, GTx shall have (a) complete control of the prosecution of the Licensed Patents listed on Appendix A and will be responsible for maintaining any patents issuing therefrom and (b) the exclusive right and responsibility to prepare, file, prosecute and maintain all patent applications and patents claiming (i) inventions solely owned by UTRF that are described in the Initial SERMS Disclosure; and (ii) Licensed Technology defined in Section 1.22, and such patent applications and patents shall be added to Appendix A. GTx shall use patent counsel of its own choice, at its own expense. GTx agrees to pay all costs incident to the United States and foreign applications, patents and like protection relating to the Licensed Subject Matter, including all costs incurred for filing, prosecution, issuance and maintenance fees as well as any costs incurred in filing continuations, continuations-in-part, divisionals or related applications and any re-examination, reissue, opposition, or interference proceedings. Subject to the provisions of Section 6.4, GTx shall file and maintain patent applications claiming Licensed Technology defined in Section 1.22 in such countries as

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GTx in its sole discretion shall select. Except for Licensed Patents listed on Appendix A that are assigned to GTx or Sublicensee Patent Rights as described in Section 6.2, UTRF shall have the sole and exclusive right, title and ownership in and to all Licensed Patents, including Licensed Patents claiming Licensed Technology defined in Section 1.22 which now exist or may exist in the future, including all United States and foreign patent applications filed and patents issued pursuant to this Section 6, except Licensed Patents claiming invention(s) made in whole or in part by one or more Third Parties as determined in accordance with applicable patent laws, ownership of which shall be subject to the provisions of Section 6.2.

6.2 GTx and its Sublicensees shall assign, transfer and convey to UTRF all right, title and interest in and to all Licensed Patents, except (i) those claiming invention(s) made in whole or in part by one or more Third Parties, which Licensed Patents are to be assigned, in whole or in part, as the case may be, in accordance with the instructions of such Third Party(ies); and (ii) those listed on Appendix A that, as of the Effective Date, have been assigned to GTx. GTx shall be responsible for recording an assignment, as appropriate, to UTRF and/or to such individual(s) or entity(ies) as such Third Party(ies) may direct, of patent applications filed pursuant to this Section 6 with the United States Patent and Trademark Office and with each foreign Patent Office in which such applications are filed. Notwithstanding the foregoing, GTx may permit its Sublicensees to retain ownership of patent applications or patents claiming invention(s) made by employee(s) or agent(s) of such Sublicensee which result from the Licensed Subject Matter ("Sublicensee Patent Rights"), provided that the pertinent Sublicense agreement shall include provision(s) granting to UTRF and UT a perpetual worldwide non-exclusive royalty-free right to practice, for non-commercial educational, research and academic purposes only (such right to exclude the practice of Licensed Patents for any fee-for-services arrangement or for sponsored research on behalf of any commercial entity), under Sublicensee Patent Rights claiming inventions necessary or reasonably useful in the practice of the Licensed Patents.

6.3 GTx agrees to provide UTRF with reasonable (which the Parties agree generally means not less than two weeks) advance notice prior to filing of new patent applications containing new subject matter, including, without limitation, continuation-in-part applications, within Licensed Patents. Copies of applications that are divisional or continuation applications of Licensed Patents shall be furnished to UTRF within thirty (30) days of their being initially filed with an appropriate patent office. GTx shall keep UTRF informed, at GTx's expense, of filing, prosecution, maintenance, and abandonment of applications and issued patents within Licensed Patents pursuant to this Section 6, including submitting to UTRF copies of all patent applications in accordance with the previous sentence, and submitting to UTRF copies of material, official actions and responses thereto, and other material written communications it or its patent counsel receives from or files with the U.S. Patent and Trademark Office and the equivalent foreign offices within forty-five (45) days of filing or receipt, as the case may be. GTx shall consult with UTRF prior to the abandonment of applications or issued patents with the Licensed Patents.

6.4 UTRF agrees to reasonably cooperate with GTx, at GTx's request and expense, to whatever extent is reasonably necessary, to procure patent protection for Licensed Technology, including execution of all appropriate documents to provide GTx the full benefit of the licenses granted herein.

6.5 In the event that GTx decides not to continue prosecution of any United States or foreign patent application within Licensed Patents to issuance or not to maintain any United States or foreign patent within Licensed Patents in a particular jurisdiction, GTx shall timely notify UTRF in writing in order that UTRF may continue said prosecution or maintenance of such patent applications or patents at its option and at its own expense in such jurisdiction. GTx's right under this Agreement to practice the invention(s) under such patents and patent applications shall immediately terminate in such jurisdiction upon UTRF's assuming said costs provided that the application for which GTx decides not to continue prosecution, or the patent which GTx decides not to maintain, is before the patent office of a country that is a Major Market. GTx shall not be considered in default and this Agreement shall not terminate as to any particular jurisdiction merely due to the fact that GTx decides not to continue prosecution of a patent application to issuance, or not to maintain any patent in any country that is not a Major Market. If GTx fails to notify UTRF in sufficient time for UTRF to reasonably continue prosecution, or the maintenance of, a patent or patent application in a Major Market, GTx shall be considered in default of this Agreement.

6.6 *Intentionally Omitted.*

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6.7 *Intentionally Omitted.*

6.8 *Intentionally Omitted.*

6.9 GTx and all its Sublicensees shall mark all products covered by Licensed Patents with patent numbers in accordance with the statutory requirements in the country(ies) of manufacture, use, and sale.

6.10 UTRF and GTx agree that one or more senior administrators representing each of the Parties will meet at least on a semi-annual basis at a mutually agreeable time and place so that GTx may provide UTRF with an oral update on the current development, licensing, regulatory, and commercialization status of Licensed Products and to discuss any issues raised by either UTRF or GTx arising out of, under, or in connection with this Agreement.

SECTION 7

Infringement

7.1 GTx shall inform UTRF and UTRF shall inform GTx promptly in writing of any alleged assertion and/or claim of infringement of the Licensed Patents by a Third Party and of any available evidence thereof.

7.2 GTx shall have the first, sole and exclusive right, but shall not be obligated, to prosecute or defend at its own expense all infringements or opposition, interference and ex parte proceedings of the Licensed Patents, including prosecuting for any misappropriation of Licensed Technology or Licensed Products. The Parties acknowledge that as to Licensed Patents that UTRF owns "in part", such right on the part of GTx shall not preclude UTRF's co-owner(s) from taking any action they may have available to them in law or by contract. In furtherance of such right granted to GTx, UTRF hereby agrees that GTx may include UTRF as a party plaintiff in any such suit, without expense to UTRF. The total cost of any such infringement action commenced or defended by GTx shall be borne by GTx. No settlement, consent judgment, or other voluntary final disposition of such suits may be entered into without the consent of UTRF, provided that such consent shall not be unreasonably withheld and that UTRF shall not condition such consent on an increase in payments to UTRF hereunder.

7.3 If within six (6) months after having been notified of an alleged infringement by a Third Party, GTx has not brought or is not diligently prosecuting an infringement action, or if GTx has notified UTRF at any time prior thereto of its intention not to bring suit against any alleged infringement of the Patents, then, and in those events only, UTRF shall have the right, but shall not be obligated, to prosecute at its own expense any infringement of the Licensed Patents, and UTRF may, for such purposes, use the name of GTx as party plaintiff. No settlement, consent judgment, or other voluntary final disposition of the suit may be entered into without the consent of GTx, which consent shall not unreasonably be withheld. After deduction of outstanding expenses of UTRF, including attorney fees, and any expenses of GTx, including attorney fees incurred prior to UTRF's pursuit of such infringement, the balance remaining from any such recovery shall be divided equally between GTx and UTRF.

7.4 *Intentionally Omitted.*

7.5 In the event that GTx undertakes the enforcement and/or defense of the Licensed Patents by litigation, opposition, interference or ex parte proceedings or an *inter partes* proceeding (including the defense of a declaratory judgment action pursuant to Section 7.6) in the United States or a foreign country against a Third Party, GTx may withhold up to [*] of the payments otherwise thereafter due UTRF under Section 4 that are attributable to sales of Licensed Products in the country where such litigation or *inter partes* proceeding takes place and apply the same toward reimbursement of up to [*] of GTx's expenses, including reasonable attorneys' fees, in connection therewith. GTx may not withhold any portion of the payments due UTRF under Section 4 in the event that GTx undertakes the enforcement and/or defense of the Licensed Patents by litigation or an *inter partes* proceeding in the United States or a foreign country against an Affiliate or Sublicensee. Any recovery of damages by GTx resulting from each such suit or *inter partes* proceeding shall be applied first in satisfaction of any unreimbursed expenses and legal fees of GTx relating to such suit, and next toward reimbursement of any unreimbursed expenses and legal fees of UTRF relating to such suit, and next toward reimbursement of UTRF for any payments under Section 4 withheld and applied pursuant to this Section 7.5, and the remaining balance, if any, shall be divided equally between GTx and UTRF unless the damage award is identified by judgment of the court or in a settlement in such suit as compensating GTx for loss of sales revenue for Licensed Product on account of such Third Party's unlicensed or

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illegal actions, in which event (instead of dividing the remaining balance equally between the Parties), GTX shall pay to UTRF an amount equal to the lesser of: (i) [*] the remaining balance; or (ii) [*] of the equivalent of the lost Net Sales upon which such judgment or settlement award is based, and GTX shall retain the rest. For sake of clarity, any recovery attributable to loss or diminution of the value of Licensed Patents shall be divided equally between UTRF and GTX. As to a settlement of such claim or suit, the rebuttable presumption shall be that any payment to be made to GTX under the settlement agreement is not attributable to lost sales revenue and GTX shall have the burden of proof to reasonably establish that the recovery of damages resulting from such settlement represents compensation for loss of sales revenue (i.e., the equivalent of lost Net Sales hereunder).

7.6 In the event that a declaratory judgment action alleging invalidity or noninfringement of any of the Licensed Patents shall be brought against UTRF, GTX at its option shall have the right, within thirty (30) days after commencement of such action, to intervene and take over the sole defense of the action against UTRF at its own expense, provided that GTX may not enter into a settlement, consent judgment, or other voluntary final disposition of the matter without the prior written approval of UTRF, which approval shall not be unreasonably withheld.

SECTION 8

Liability and Indemnification

8.1 GTX shall at all times during the Term of this Agreement, indemnify, defend and hold UTRF, UT, and their respective trustees, directors, officers, employees and Affiliates, harmless against all claims, proceedings, demands and liabilities of any kind whatsoever, including legal expenses and reasonable attorneys fees (collectively, "Claims"), arising out of the death of or injury to any person or persons or out of any damage to property, to the extent resulting from the production, manufacture, sale, use, lease, or consumption of the Licensed Products, Licensed Technology, or associated intellectual property rights, including Licensed Patents, or arising from any obligation or act of GTX hereunder, except, as to UTRF and UT, for Claims arising (i) out of the use or practice of Licensed Subject Matter by UT as described in Section 2.2 or (ii) from the willful misconduct or misrepresentation by UTRF, UT, or their respective trustees, directors, officers, employees or Affiliates; or (iii) breach of this Agreement by UTRF. Infringement of a Third Party patent by GTX, a GTX Affiliate, or a Sublicensee shall not be deemed for purposes of this Agreement an improper action, omission, or negligent act on the part of UTRF, UT, or their respective trustees, directors, officers, employees or Affiliates.

8.2 GTX shall obtain and carry in full force and effect from the first manufacture, use or sale of the Licensed Products or Licensed Technology to [*] after such manufacturing, use or sales cease, commercial, general liability insurance which shall protect GTX, UTRF, UT, and their respective trustees, directors, officers, employees and Affiliates with respect to events covered by Section 8.1 above. Such insurance shall be written by a reputable insurance company, reasonably acceptable to UTRF, shall list UTRF as an additional named insured, shall be endorsed to include product liability coverage and shall require thirty (30) days written notice to be given to UTRF prior to any cancellation or material change thereof. The limits of such insurance shall not be less than [*] per occurrence with an aggregate of [*] for personal injury or death. Upon the request of UTRF, GTX shall provide UTRF with Certificates of Insurance evidencing the same.

8.3 GTX, UTRF, UT, AND THEIR RESPECTIVE TRUSTEES, DIRECTORS, OFFICERS, EMPLOYEES, AND AFFILIATES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR THE ABSENCE OF LATENT OR OTHER DEFECTS, WHETHER OR NOT DISCOVERABLE, IN ANY LICENSED PRODUCT, LICENSED TECHNOLOGY OR LICENSED PATENT. SUBJECT TO THE PROVISIONS OF SECTION 8.1 AND EXCEPT FOR A BREACH OF SECTION 18, IN NO EVENT SHALL GTX, UTRF, UT, OR THEIR RESPECTIVE TRUSTEES, DIRECTORS, OFFICERS, EMPLOYEES OR AFFILIATES BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING, WITHOUT LIMITATION, ECONOMIC DAMAGE, INJURY TO PROPERTY OR LOST PROFITS, REGARDLESS OF WHETHER GTX, UTRF, OR UT SHALL BE ADVISED, SHALL HAVE OTHER REASON TO KNOW, OR IN FACT SHALL KNOW OF THE POSSIBILITY OF ANY OF THE FOREGOING. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS:

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- A. A REPRESENTATION MADE OR WARRANTY GIVEN BY UTRF THAT THE PRACTICE BY GTX OF ANY LICENSE OR SUBLICENSE GRANTED HEREUNDER SHALL NOT INFRINGE THE PATENTS OF ANY THIRD PARTY;
- B. A REPRESENTATION MADE OR WARRANTY GIVEN BY UTRF THAT ANY PATENT APPLICATION INCLUDED IN THE PATENTS WILL ULTIMATELY ISSUE AS A PATENT;
- C. A REPRESENTATION MADE OR WARRANTY GIVEN THAT GTX SHALL HAVE THE RIGHT TO USE ANY PORTION OF THE LICENSED PATENTS THAT IS CLAIMED IN A PATENT OF ANY THIRD PARTY;
- D. A REQUIREMENT THAT UTRF SHALL BE RESPONSIBLE FOR THE EXPENSES OF FILING OR PROSECUTING ANY PATENT APPLICATION OR MAINTAINING ANY LICENSED PATENTS IN FORCE;
- E. AN OBLIGATION ON THE PART OF UTRF TO BRING OR PROSECUTE ACTIONS OR SUITS AGAINST THIRD PARTIES FOR INFRINGEMENT OF THE LICENSED PATENTS OR FOR UNAUTHORIZED USE OF THE PATENTS OR MISAPPROPRIATION OF THE LICENSED TECHNOLOGY;
- F. AN OBLIGATION ON THE PART OF UTRF TO DEFEND ANY ACTION OR SUIT BROUGHT BY ANY THIRD PARTY;
- G. A REPRESENTATION MADE OR WARRANTY GIVEN BY UTRF AS TO THE SAFETY, RELIABILITY OR EFFICACY OF: 1) THE LICENSED TECHNOLOGY OR THE INVENTIONS COVERED BY THE LICENSED PATENTS; OR 2) ANY LICENSED PRODUCT; OR
- H. A REPRESENTATION MADE OR WARRANTY GIVEN BY UTRF THAT ANY OF THE UT CONTRIBUTORS WILL AGREE TO PROVIDE TECHNICAL ASSISTANCE OR CONSULTATION TO GTX, OR THAT SUCH TECHNICAL ASSISTANCE OR CONSULTATION, IF PROVIDED, WOULD BE SUFFICIENT TO ENABLE GTX TO SUCCESSFULLY EXPLOIT THE LICENSED TECHNOLOGY OR THE LICENSED PATENTS.

8.4 UTRF represents and warrants that to the best of its actual knowledge as of the Effective Date: (i) it has the full corporate power and authority to enter into this Agreement, to carry out the provisions of this Agreement, and to grant the rights granted to GTX herein; (ii) it has not previously granted and shall not grant to any Third Party any rights which are inconsistent with the rights granted to GTX herein; (iii) it is the owner of the entire right, title, and interest in and to the Licensed Patents and Licensed Technology except for such rights held by GTX, UT, the United States government, Sublicensees, and/or their respective designees and/or assignees, if any; and (iv) it has fully complied with all requirements of 35 U.S.C. § 200 *et seq.* and all implementing regulations necessary to perfect title to the rights and license granted to GTX herein.

8.5 UTRF acknowledges and understands that Dr. Mitchell S. Steiner is an employee of UT and that as of the Effective Date, he is the Chief Executive Officer of GTX.

8.6 GTX represents that: (i) it has full corporate power and authority to enter into this Agreement and carry out all the provisions of this Agreement; (ii) it is authorized to execute this Agreement on its behalf; (iii) the person executing this Agreement is duly authorized to do so; and (iv) no consent, approval or authorization of any Third Party is required. GTX further represents and warrants that it shall not deny, contest (through declaratory judgment action or otherwise), or take any action inconsistent with UTRF's ownership in or the validity or enforceability of any of the Licensed Patents associated with or arising from the Licensed Subject Matter except those Licensed Patents listed on Appendix A that are assigned to GTX.

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SECTION 9

Export Controls

9.1 GTx acknowledges that the export of goods and/or technical data from the United States may require some form of export control license from the United States Government. GTx agrees that neither it nor its Sublicensees will disclose, export or re-export any materials or technical data received under this Agreement to any countries for which the U.S. Government requires an export license, unless GTx or its Sublicensees have obtained prior written authorization from the U.S. Department of State, Directorate of Defense Trade Controls, Department of Commerce, U.S. Bureau of Industry and Security or other authority responsible for such matters. GTx agrees that it or its Sublicensees are responsible for any fees or expenses associated with obtaining an export license, if required, and acknowledges that failure to obtain such export control license may result in criminal liability. UTRF neither represents that a license shall not be required nor that, if required, it shall be issued.

SECTION 10

Non-Use of Names

10.1 GTx shall not use the names or trademarks of UTRF or UT, or any adaptation thereof, in any advertising, promotional or sales literature without prior written consent obtained from UTRF or UT, as the case may be, except that GTx may state that it has licensed the Licensed Patents and Licensed Technology from UTRF.

10.2 Neither UTRF nor UT shall use the names or trademarks of GTx, or any adaptation thereof, in any advertising, promotional or sales literature without prior written consent obtained from GTx, except that UTRF may state that it has licensed the Licensed Patents and Licensed Technology to GTx.

SECTION 11

Dispute Resolution

11.1 Except for the right of either party to apply to a court of competent jurisdiction for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or to prevent irreparable harm, any and all claims, disputes or controversies arising under, out of, or in connection with this Agreement, shall be resolved upon thirty (30) days written notice of either party to the other by final and binding arbitration in Knoxville, Tennessee under the Commercial Arbitration Rules of the American Arbitration Association, or the Patent Arbitration Rules if applicable, then in effect. The arbitrator(s) shall have no power to add to, subtract from or modify any of the terms or conditions of this Agreement, nor to award punitive damages. The prevailing party in any such arbitration shall, in addition to recovering reasonable out-of-pocket costs of the arbitration, be entitled to an award of reasonable attorneys fees incurred in connection with the arbitration, with any action necessary to perfect the arbitration award as a judgment, and for any collection action required to secure payment of any arbitration award. Any award rendered in such arbitration may be entered and enforced by either party in either the courts of the State of Tennessee or in the United States District Court for the Eastern District of Tennessee, to whose jurisdiction for such purposes UTRF and GTx each hereby irrevocably consents and submits, or in any other United States court having jurisdiction.

11.2 Notwithstanding the foregoing, nothing in this Section shall be construed to waive any rights or timely performance of any obligations existing under this Agreement.

SECTION 12

Term of Agreement and Termination

12.1 This Amended and Restated License Agreement shall take effect for all purposes upon the date of execution by the Parties, and unless earlier terminated in accordance with the provisions of this Section 12, shall continue in full force and effect on a country-by-country basis for the longer of (i) a period of twenty (20) years from the Effective Date, or (ii) in each country in which a Valid Claim for any Licensed Patent shall continue to

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exist, until the last Valid Claim for any Licensed Patent shall expire in the country, at which time this Agreement shall expire as to such country (“Term”).

12.2 After expiration of the Term in a country, GTx shall have a perpetual, fully paid, royalty-free license to the Licensed Patents and Licensed Technology in such country, such license being of no greater scope than that granted hereunder. GTx shall continue to be obligated to pay (i) Running Royalties on account of Licensed Product used, marketed, sold, manufactured or distributed in or imported from any country for which the Term shall not have expired; and (ii) Sublicense Royalties on Sublicense Revenue generated under any Sublicense that includes a grant of rights in any Major Country for which the Term shall not have expired; and (iii) the License Maintenance Fee as long as there is at least one Major Country for which the Term shall not have expired. GTx shall continue to enjoy the rights and license to the Licensed Subject Matter granted hereunder in each country for which the Term shall not have expired.

12.3 In the event of default or failure by GTx to perform any of the terms, covenants or provisions of this Agreement (hereinafter, “default”), GTx shall have thirty (30) days to cure such default after the giving of written notice of such default by UTRF. In accordance with Section 2.6, no Sublicensee’s rights under a Sublicense shall terminate on account of a default by GTx unless UTRF shall have given written notice of such default to the Sublicensee and the Sublicensee shall have failed to cure or have cured such default within thirty (30) days of such notice. If such default is not cured by GTx, its Affiliates, and/or its Sublicensees within the said thirty (30) day period, UTRF shall have the right, at its option, to terminate this Agreement. The failure of UTRF to exercise such right of termination for non-payment of royalties or otherwise shall not be deemed to be a waiver of any right UTRF might have, nor shall such failure preclude UTRF from exercising or enforcing said right upon any subsequent failure by GTx.

12.4 UTRF shall have the right, at its option, to terminate this Agreement in the event that GTx is finally declared bankrupt, or is placed in receivership pursuant to proceedings affecting the operation of its business. In the event of termination of this Agreement pursuant to Sections 12.3 or 12.4 hereof, all rights to the Licensed Patents and Licensed Technology granted to GTx herein shall revert to UTRF, except as otherwise provided in Section 2.6.

12.5 Upon termination of this Agreement for any reason, nothing herein shall be construed to release either party from any obligation that matured prior to the effective date of such termination; and Sections 1, 4.4, 5, 8, 9-12, 14, 18, 20, and 21 shall survive any such termination.

12.6 No termination of this Agreement shall constitute a termination or a waiver of any rights of either Party against the other Party accruing at or prior to the time of such termination.

12.7 GTx shall have the right to terminate this Agreement at any time on three (3) months notice to UTRF and upon payment of all amounts due UTRF through the effective date of the termination.

SECTION 13

Assignability

13.1 This Agreement shall be binding upon and shall inure to the benefit of UTRF and its assigns and successors, and shall be binding upon and shall inure to the benefit of GTx and its assigns provided that prior written approval by UTRF is first obtained, which approval shall not be unreasonably withheld. Notwithstanding the foregoing, no prior written approval from UTRF shall be required for any assignment by GTx to (i) an Affiliate of GTx (or any entity into which GTx shall have been merged or consolidated, provided that at least 51% of such merged or consolidated entity is owned by shareholders holding at least 51% of GTx immediately prior to such merger or consolidation) or (ii) a Third Party which acquires all or substantially all of GTx’s assets or a Controlling interest in the business to which this Agreement relates if, but only if, the Third Party can reasonably demonstrate a financial net worth or market cap equal to or better than the financial net worth of GTx existing prior to the acquisition, but not less than a net worth of One Hundred Million Dollars (\$100,000,000) or a market cap of Five Hundred Million Dollars (\$500,000,000). No assignment shall be deemed effective unless such assignee has agreed in writing to be bound by the terms and provisions of this Agreement. Any attempt to assign or assignment made in

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violation of this Section 13.1 shall be void *ab initio*. GTx shall give notice to UTRF of any assignment of this Agreement within thirty (30) days thereafter, such notice to include a copy of assignee's written agreement to be bound by the terms and provisions of this Agreement.

SECTION 14
Governmental Compliance

14.1 GTx shall at all times during the Term of this Agreement and for so long as it shall develop, make, have made, use, market, sell, have sold, import, distribute, or offer to sell Licensed Products or Licensed Technology comply and cause its Sublicensees to comply with all laws that may control the import, export, manufacture, use, sale, marketing, distribution and other commercial exploitation of Licensed Products, Licensed Technology, or Licensed Patents or any other activity undertaken pursuant to this Agreement.

SECTION 15
Notices

15.1 Any notice or other communication required or permitted hereunder (hereinafter "notice") shall be in writing and shall be hand-delivered, sent by overnight courier, mailed by certified United States mail, return receipt requested, or sent by email, to the addresses given below or to such other addresses as the parties may hereafter specify in writing. Notice shall be deemed given and received five (5) days after being deposited with the U.S. Postal Service with sufficient postage, or if notice is hand-delivered or sent by overnight courier, upon the date of actual delivery, or if sent by email, upon the date the receiving party acknowledges receipt. An email notice shall be given concurrently to all the email address(es) provided by the recipient party and the first acknowledgment of receipt from the recipient party shall establish the date on which such notice is given.

UTRF:

If notice is given by means other than email, to:

University of Tennessee Research Foundation
1534 White Avenue, Suite 403
Knoxville, Tennessee, U.S.A. 37996-1527
Attn: President

With a copy to:

University of Tennessee Research Foundation
920 Madison, Suite 515
Memphis, TN 38163

If notice is given by email, to:

rmagid1@utmem.edu
jlsnider@utk.edu
vhunley@tennessee.edu

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GTx:

If notice is given by means other than email, to:

GTx, Inc.
3 N. Dunlap Street, 3rd Floor
Memphis, Tennessee 38163
Attn: Dr. Mitchell Steiner, CEO

With a copy to:

GTx, Inc.
3 N. Dunlap Street, 3rd Floor
Memphis, TN 38163
Attn: Henry P. Doggrell, Vice President, General Counsel

If notice is given by email, to:

msteiner@gtxinc.com
hdoggrell@gtxinc.com

SECTION 16
Severability of Provisions

16.1 If any provision of this Agreement shall be declared by a court of competent jurisdiction to be invalid, illegal or incapable of being enforced in whole or in part, the remaining conditions and provisions or portions thereof shall nevertheless remain in full force and effect and enforceable to the extent they are valid, legal and enforceable, and no provision shall be deemed dependent upon any other covenant or provision unless so expressed herein.

SECTION 17
Governing Law

17.1 This Agreement shall be deemed to be subject to, and have been made under, and shall be construed and interpreted in accordance with the laws of the State of Tennessee. This Agreement is expressly acknowledged to be subject to all applicable federal laws. No conflict-of-laws rule or law that might refer such construction and interpretation to the laws of another state, republic, or country shall be considered. The Parties irrevocably and unconditionally agree that the exclusive place of jurisdiction for any action, suit or proceeding for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or to prevent irreparable harm, arising under, out of, or in connection with this Agreement (“Actions”), shall be in the courts of the United States of America sitting in the city, state and country of State of Tennessee, or, if such courts shall not have jurisdiction over the subject matter thereof, in the courts of the State of Tennessee sitting therein, and each such party hereby irrevocably and unconditionally agrees to submit to the jurisdiction of such courts for the purposes of any such Actions. If any such State court also does not have jurisdiction over the subject matter thereof, then such an Action may be brought in the federal or state courts located in the states of the principal place of business of any Party hereto.

SECTION 18
Confidentiality

18.1 Nothing herein shall preclude a Party from disclosing the existence of this Agreement and the general scope of the license granted hereunder. However, neither Party shall disclose the economic terms of this Agreement except that UTRF may disclose such economic terms to the UT Contributors and UT, or as required by Federal Policy.

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18.2 Subject to the exceptions set forth herein, all information or material disclosed pursuant to this Agreement and/or related to the Licensed Patents, Licensed Products, Licensed Technology, and Independent SERM Inventions shall be confidential (“Confidential Information”). Recipient (the “Receiving Party”) of another Party’s Confidential Information (the “Providing Party”) agrees to hold in confidence, and not to distribute or disseminate to any person or entity, for any reason for a period of seven (7) years after receipt, any Confidential Information received, under or relating to this Agreement, except for Confidential Information of the Providing Party which:

- A. was known or used by the Receiving Party prior to the date of disclosure to the Receiving Party as evidenced by written records; or
- B. either before or after the date of disclosure is lawfully disclosed to the Receiving Party by sources other than the Providing Party which are rightfully in possession of the Confidential Information and not subject to any obligation of confidentiality, as evidenced by written records; or
- C. either before or after the date of disclosure to the Receiving Party becomes published, through no fault or omission on the part of the Receiving Party; or
- D. is independently developed by or for the Receiving Party without reference to, knowledge of, or reliance upon the Confidential Information as evidenced by written records; or
- E. is required to be disclosed by the Receiving Party to comply with applicable laws or court order, to defend or prosecute litigation or arbitration or to comply with governmental regulations or Federal Policy, provided that the Receiving Party provides prior written notice of such disclosure to the Providing Party and takes reasonable and lawful actions to avoid and/or minimize the degree of such disclosure, and further provided that specific information shall not be deemed to be within any of these exclusions merely because it is embraced by more general information falling with these exclusions; or
- F. is disclosed by UTRF to UT, the UT Contributors, or the State of Tennessee, such disclosure being subject to the provisions of Section 2.6, if and as applicable.

All information concerning (i) Licensed Patents and/or Licensed Technology owned solely or partly by UTRF and (ii) Independent SERM Inventions shall be deemed Confidential Information of UTRF. Disclosures of Confidential Information to GTx concerning (i) and (ii), including, without limitation, disclosures that are made to GTx by UT Contributors, shall be deemed, for purposes of this Section, to be disclosures made by UTRF. Nothing herein shall be construed in such a manner as to permit UTRF, UT, or any UT Contributor to take any action with regard to Licensed Patents, Licensed Technology, or Independent SERM Inventions that is contrary to the rights herein granted to GTx or to permit UTRF, UT, or any UT Contributor to include any Confidential Information of GTx in any patent application or regulatory filing or application without obtaining GTx’s prior written approval except to the extent such activity falls within the exceptions to confidentiality set forth in Sections 18.2A through F.

18.3 GTx recognizes that under UTRF and UT policy, research results must be publishable and agrees that researchers engaged in such research shall have the right, with regard to the Licensed Subject Matter, to present at symposia, professional meetings and to publish in journals, theses or dissertations, or otherwise of their own choosing (“Publications”) provided that UTRF shall provide to GTx a copy of a draft of such Publication, if received by UTRF in draft form, or a copy of the final Publication, if first received by UTRF in that form, in either case promptly upon receipt and in the manner and form in which received in order that GTx may review the Publication to identify and protect any Confidential Information of GTx that may be contained therein and to allow for the preparation and filing of a patent application by GTx or Sublicensees. UTRF shall not be deemed in breach or default of this Agreement merely due to a Publication that UTRF does not receive prior to publication.

18.4 *Intentionally Omitted.*

18.5 The Parties agree that counsel of the Parties, who have a duty of confidentiality to the respective Parties, may receive Confidential Information.

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SECTION 19
Reformation

19.1 All Parties hereby agree that neither Party intends to violate any public policy, statutory or common law, rule, regulation, treaty or decision of any government agency or executive body thereof of any country or community or association of countries; that if any word, sentence, paragraph or clause or combination thereof of this Agreement is found, by a court or executive body with judicial powers having jurisdiction over this Agreement or any of its Parties hereto, in a final unappealed order to be in violation of any such provision in any country or community or association of countries, such words, sentences, paragraphs or clauses or combination shall be inoperative in such country or community or association of countries, and the remainder of this Agreement shall remain binding upon the Parties hereto.

SECTION 20
Non-Waiver

20.1 The Parties covenant and agree that if a Party fails or neglects for any reason to take advantage of any of the terms provided for the termination of this Agreement or if a Party, having the right to declare this Agreement terminated, shall fail to do so, any such failure or neglect by such Party shall not be a waiver or be deemed or be construed to be a waiver of any cause for the termination of this Agreement subsequently arising, or as a waiver of any of the terms, covenants or conditions of this Agreement or of the performance thereof. None of the terms, covenants and conditions of this Agreement may be waived by a Party except by its written consent.

SECTION 21
Entire Agreement

21.1 This Agreement, as amended and restated herein, contains the entire agreement and understanding of the parties as of the Effective Date with respect to the subject matter hereof, supersedes any prior agreements and understandings with respect thereto, including, without limitation, the Prior License Agreements, and cannot be modified, amended or waived, in whole or in part, except in writing signed by the Party to be charged. Any such purported non-written modification, amendment, or waiver shall be null and void. A discharge of the terms of this Agreement shall not be deemed valid unless by full performance of the Parties hereto or by writing signed by the Parties hereto. A waiver by UTRF of any breach by GTx of any provision or condition of this Agreement to be performed by GTx shall not be deemed a waiver of similar or dissimilar provisions or conditions at the same or any prior or subsequent time.

SECTION 22
Effect of Agreement

22.1 This Amended and Restated License Agreement shall supersede and render null and void the Prior License Agreements.

IN WITNESS WHEREOF, the Parties hereto have executed and delivered this Agreement in multiple originals by their duly authorized officers and representatives on the respective dates shown below. The undersigned representative of UTRF is authorized to execute this Agreement on its behalf and bind UTRF to the terms and conditions set forth herein, and the undersigned representative of GTx is authorized to execute this Agreement on its behalf and bind GTx to the terms and conditions set forth herein.

UNIVERSITY OF TENNESSEE RESEARCH
FOUNDATION (UTRF)

GTx, INC. (GTx)

By: /s/ Fred D. Tompkins
Name: Fred D. Tompkins
Title: President

By: /s/ Henry P. Doggrell
Name: Henry P. Doggrell
Title: Vice President, General Counsel & Secretary

Date: 9/26/07

Date: Sept. 26, 2007

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APPENDIX A AMENDED & RESTATED LICENSE AGREEMENT

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CHIEF EXECUTIVE OFFICER CERTIFICATION

I, Mitchell S. Steiner, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of GTx, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2007

/s/ Mitchell S. Steiner

Mitchell S. Steiner, M.D., F.A.C.S.

Chief Executive Officer and

Vice-Chairman of the Board of Directors

CHIEF FINANCIAL OFFICER CERTIFICATION

I, Mark E. Mosteller, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of GTx, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2007

/s/ Mark E. Mosteller

Mark E. Mosteller, CPA

Vice President and Chief Financial Officer

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

In connection with the Quarterly Report of GTx, Inc. (the "Company") on Form 10-Q for the three months ended September 30, 2007, 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.

Date: November 9, 2007

/s/ Mitchell S. Steiner

Mitchell S. Steiner, M.D., F.A.C.S.

Chief Executive Officer and

Vice-Chairman of the Board of Directors

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

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

In connection with the Quarterly Report of GTx, Inc. (the "Company") on Form 10-Q for the three months ended September 30, 2007, 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.

Date: November 9, 2007

/s/ Mark E. Mosteller

Mark E. Mosteller, CPA

Vice President and Chief Financial Officer

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