



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 March 31, 2004

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 005-79588

**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, 3rd Floor  
Van Vleet Building  
Memphis, Tennessee 38163**  
(Address of principal executive offices)

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

**Not Applicable**  
(Former Name, Former Address and Former Fiscal Year,  
if Changed Since Last Report)

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 an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes  No

Indicate the number of shares outstanding of each of the Issuer's classes of common stock, as of the latest practicable date.

As of May 7, 2004, 24,656,923 shares of the Registrant's Common Stock were outstanding

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**PART I  
FINANCIAL INFORMATION**

**GTx, Inc.**

**CONDENSED BALANCE SHEETS  
(in thousands, except share data)**

	March 31, 2004	December 31, 2003
	(unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 80,620	\$ 14,769
Inventory	69	194
Other receivables	6,782	–
Prepaid expenses	1,052	61
Total current assets	88,523	15,024
Property and equipment, net	799	815
Deferred initial public offering costs	–	1,471
Total assets	\$ 89,322	\$ 17,310
<b>LIABILITIES, CUMULATIVE REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 1,098	\$ 461
Accrued expenses	1,734	1,788
Deferred revenue	1,337	–
Total current liabilities	4,169	2,249
Deferred revenue	5,298	–
Cumulative redeemable convertible preferred stock	–	165,292
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value 5,000,000 shares authorized, none issued or outstanding	–	–
Common stock, \$0.001 par value: 60,000,000 shares authorized; 24,656,923 shares issued and outstanding at March 31, 2004 and 7,735,848 shares issued and outstanding at December 31, 2003	25	8
Deferred stock compensation	(3,255)	(3,505)
Additional paid-in capital	223,988	5,018
Accumulated deficit	(140,903)	(151,752)
Total stockholders' equity (deficit)	79,855	(150,231)
Total liabilities and stockholders' equity (deficit)	\$ 89,322	\$ 17,310

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 March 31,	
	2004	2003
Revenue	\$ 52	\$ —
Operating expenses:		
Research and development	4,336	2,113
General and administrative	1,600	610
Depreciation	87	87
Total operating expenses	6,023	2,810
Loss from operations	(5,971)	(2,810)
Interest income	150	29
Net loss	(5,821)	(2,781)
Accrued preferred stock dividends	(455)	(683)
Adjustments to preferred stock redemption value	17,125	(73)
Net income (loss) attributable to common stockholders	\$ 10,849	\$ (3,537)
Net income (loss) per share attributable to common stockholders:		
Basic	\$ 0.60	\$ (0.46)
Diluted	\$ (0.26)	\$ (0.46)
Weighted average shares used in computing net loss per share attributable to common stockholders:		
Basic	17,962,871	7,734,998
Diluted	22,456,489	7,734,998

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

## GTx, Inc.

**CONDENSED STATEMENTS OF CASH FLOWS**  
**(in thousands)**  
**(unaudited)**

	Three Months Ended March 31,	
	2004	2003
<b>Cash flows from operating activities:</b>		
Net loss	\$ (5,821)	\$ (2,781)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	87	87
Stock-based compensation expense	250	—
Changes in assets and liabilities:		
Inventory	125	—
Prepaid expenses	(991)	—
Other receivables	(6,782)	(2)
Accounts payable	650	(226)
Accrued expenses	366	293
Deferred revenue	6,635	—
Net cash used in operating activities	<u>(5,481)</u>	<u>(2,629)</u>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(71)	(3)
Net cash used in investing activities	<u>(71)</u>	<u>(3)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from initial public offering	71,403	—
Net cash provided by financing activities	<u>71,403</u>	<u>—</u>
Net increase in cash and cash equivalents	65,851	(2,632)
Cash and cash equivalents, beginning of period	14,769	8,925
Cash and cash equivalents, end of period	<u>\$80,620</u>	<u>\$ 6,293</u>
<b>Supplemental schedule of non-cash investing and financing activities:</b>		
Preferred stock dividends	\$ 455	\$ 683
Preferred stock adjustment to redemption value	<u>\$17,125</u>	<u>\$ (73)</u>
Deferred initial public offering costs reclassified to additional paid-in capital	<u>\$ 1,471</u>	<u>\$ —</u>

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

**GTx, Inc.**

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**  
**(in thousands, except share and per share data)**

**NOTE 1— BUSINESS AND BASIS OF PRESENTATION**

Business – GTx, Inc. (the “Company” or “GTx”) is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics primarily related to the treatment of serious men’s health conditions. GTx’s drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens.

Basis of Presentation – The accompanying unaudited condensed financial statements reflect, in the opinion of management, all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation of GTx’s financial position, results of operations and cash flows for each period presented in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted from the accompanying statements. These interim financial statements should be read in conjunction with the audited financial statements and related notes thereto, which are included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2003. Operating results for the three month period ended March 31, 2004 are not necessarily indicative of future results that may be expected for the year ending December 31, 2004.

Prior to March 2004, the Company operated as a development-stage company and did not generate any revenue. Effective March 2004, the Company exited the development stage when it entered into a joint collaboration and license agreement with Ortho Biotech Products L.P., a wholly owned subsidiary of Johnson & Johnson.

**NOTE 2—STOCK COMPENSATION**

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

SFAS 123 requires pro forma disclosure of net loss attributable to common stockholders, assuming all stock options were valued on the date of grant using the minimum value option pricing model for stock options granted prior to the Company’s initial public offering in February 2004 and using the Black-Scholes option-pricing model for stock options granted after the IPO. The following weighted average assumptions were used for 2004 and 2003, respectively: risk free interest rates of 3.8% and 3.2%, expected volatility of 60.6% and 0.0%, no expected

## GTx, Inc.

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**  
**(in thousands, except share and per share data)**

dividend yield, and expected option life of 6 years and 8 years. If compensation cost for stock-based compensation plans had been determined under SFAS 123, the Company's net income (loss) and income (loss) attributable to common stockholders would have been the pro forma amounts indicated as follows:

	Three Months Ended March 31,	
	2004	2003
Net income (loss) attributable to common stockholders, as reported	\$10,849	\$(3,537)
Add: Deferred compensation amortization included in reported net income	250	—
Deduct: Stock-based employee compensation determined under fair value based method for all awards	(277)	(32)
Pro forma net loss attributable to common stockholders	<u>\$10,822</u>	<u>\$(3,569)</u>
Pro forma SFAS 123 disclosure:		
Net income (loss) per share attributable to common stockholders as reported:		
Basic	<u>\$ 0.60</u>	<u>\$ (0.46)</u>
Diluted	<u>\$ (0.26)</u>	<u>\$ (0.46)</u>
Net income (loss) per share attributable to common stockholders pro forma:		
Basic	<u>\$ 0.60</u>	<u>\$ (0.46)</u>
Diluted	<u>\$ (0.26)</u>	<u>\$ (0.46)</u>

**NOTE 3—INITIAL PUBLIC OFFERING**

On February 6, 2004, GTx successfully completed an initial public offering (IPO) of 5.4 million shares of common stock at an offering price to the public of \$14.50 per share, resulting in net proceeds of \$70,365. Upon the closing of the IPO, all outstanding shares of preferred stock, and accrued dividends thereon, were converted into 11,521,075 shares of common stock. At March 31, 2004, GTx had outstanding 24,656,923 shares of common stock.

**NOTE 4—ADJUSTMENT TO PREFERRED STOCK REDEMPTION VALUE**

The Company's preferred stock was recorded at its redemption value. The per share redemption price was equal to the greater of liquidation value, which included accrued dividends, or the fair value calculated on an as-if converted to common stock basis. At December 31, 2003, the per share redemption value was determined based on the estimated projected midpoint on the range of the Company's initial public offering price per common share of approximately \$14.50 per share. At February 6, 2004, the date of the closing of the Company's IPO and automatic conversion of all outstanding preferred stock, and accrued dividends thereon, into common stock, (see Note 3), the market price for the Company's common stock was \$12.90 per share. Prior to conversion into common stock, the carrying value of the preferred stock and accrued dividends was adjusted to reflect the per share redemption value on the date of conversion resulting in a decrease in the carrying value of preferred stock of \$17,125 and an offsetting increase in stockholders' equity. The changes in redemption value affect the income (loss) attributable to common stockholders.



**GTx, Inc.**

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**  
**(in thousands, except share and per share data)**

**NOTE 5—COLLABORATION, LICENSE AND CO-PROMOTION AGREEMENT**

In March 2004, the Company entered into a joint collaboration and license agreement with Ortho Biotech Products L.P., a wholly owned subsidiary of Johnson & Johnson. Under the agreement, the Company received in April 2004 an upfront licensing fee of \$6,000 and reimbursement for development expenses of approximately \$687 for its recently completed Phase Id clinical trial for andarine and will receive additional licensing fees and milestone payments of up to \$82,000 based on andarine and up to \$45,000 for each additional licensed compound achieving specific clinical development decisions or obtaining regulatory approvals. Johnson & Johnson Pharmaceutical Research & Development will be responsible for further clinical development and related expenses for andarine and other licensed SARM compounds. Ortho Biotech will be responsible for commercialization and related expenses for andarine and other licensed SARM compounds. If andarine is approved for commercial sale, Ortho Biotech will exclusively market andarine in the United States and in markets outside the United States. Under the agreement, the Company has the option to co-promote andarine and the other licensed SARM compounds to urologists in the United States for indications specifically related to men's health. GTx will receive up to double digit royalties on all worldwide sales, as well as additional royalty payments in excess of 20% on all co-promoted sales generated from urologists in the United States.

The upfront licensing fee and reimbursement of Phase Id clinical trial expenses for andarine totaling \$6,687 are expected to be amortized into revenue on a straight-line basis through March 2009. The Company recognized revenue of \$52 for the three months ended March 31, 2004 from the amortization of the upfront license fee and expense reimbursement.

**NOTE 6—BASIC AND DILUTED NET INCOME (LOSS) PER SHARE**

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

## GTx, Inc.

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**  
**(in thousands, except share and per share data)**

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

	Three Months Ended March 31,	
	2004	2003
Basic net income (loss) per share		
Numerator:		
Net income (loss) attributable to common stockholders	\$ 10,849	\$ (3,537)
Denominator:		
Common stock outstanding at beginning of period	7,735,848	7,734,998
Conversion of preferred stock to common stock	6,963,287	-
Issuance of common stock in initial public offering	3,263,736	-
Weighted average shares used in computing basic net income (loss) per share	<u>17,962,871<sup>(1)</sup></u>	<u>7,734,998</u>
Basic net income (loss) per share attributable to common stockholders	<u>\$ 0.60</u>	<u>\$ (0.46)</u>

(1) The weighted average shares used in computing basic net income per share attributable to common stockholders for the three months ended March 31, 2004 include 3,263,736 shares, which represent the weighted average effect during the quarter of the issuance of 5.4 million shares of common stock for the Company's IPO on February 6, 2004, and 6,963,287 shares, which represent the weighted average effect during the quarter of the issuance of 11,521,075 shares for the conversion of all preferred stock, and accrued dividends thereon, into common stock at the closing of the IPO. At March 31, 2004, the Company had outstanding 24,656,923 shares of common stock.

	Three Months Ended March 31,	
	2004	2003
Diluted net loss per share		
Numerator:		
Net loss	\$ (5,821) <sup>(2)</sup>	\$ (3,537)
Denominator:		
Common stock outstanding at beginning of period	7,735,848	7,734,998
Conversion of preferred stock to common stock	11,456,905	-
Issuance of common stock in initial public offering	3,263,736	-
Weighted average shares used in computing diluted net loss per share	<u>22,456,489<sup>(2)</sup></u>	<u>7,734,998<sup>(3)</sup></u>
Diluted net loss per share attributable to common stockholders	<u>\$ (0.26)</u>	<u>\$ (0.46)</u>

(2) Diluted net loss per share attributable to common stockholders for the three months ended March 31, 2004 is calculated as if the conversion of all preferred stock, and accrued dividends thereon, into shares of common stock occurred on January 1, 2004. As a result, diluted net loss per share attributable to common stockholders for the quarter ended March 31, 2004 does not include accrued preferred stock dividends or the adjustments to preferred stock redemption value. In addition, the weighted average shares used in computing diluted net loss per share attributable to common stockholders for the three months ended March 31, 2004 include an additional 11,456,905 shares to reflect the assumed conversion of preferred stock, and accrued dividends thereon, into common stock and 3,263,736 shares to reflect the weighted average effect during the quarter of 5.4 million shares issued in the IPO. Outstanding options to purchase 904,750 shares of common stock were excluded from the calculation of diluted net

GTx, Inc.

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**  
**(in thousands, except share and per share data)**

loss per share attributable to common stockholders for the three months ended March 31, 2004, as inclusion of the options would have an anti-dilutive effect on net loss for the period.

(3) Outstanding options to purchase 363,375 shares of common stock and 8,247,984 shares of common stock issuable upon the conversion of convertible preferred stock were excluded from the calculation of diluted earnings per share attributable to common stockholders for the three months ended March 31, 2003, as inclusion of the options and convertible preferred stock would have an anti-dilutive effect on the net loss for the period.

**NOTE 7—COMPREHENSIVE LOSS**

The Company has adopted the provisions of SFAS No. 130, *Comprehensive Income*. SFAS 130 establishes standards for the reporting and display of comprehensive loss and its components for general purpose financial statements. For all periods presented, there were no differences between net loss and comprehensive loss.

**NOTE 8—RECENT ACCOUNTING PRONOUNCEMENTS**

In January 2003, the FASB issued FASB Interpretation No. 46 ("FIN 46"), *Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51*. FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period ending after March 15, 2004. The Company does not have any ownership in any variable interest entities as of March 31, 2004. The Company will apply the consolidation requirement of FIN 46 in future periods if it should own any interest in a variable interest entity.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments With Characteristics of both Liabilities and Equity*. SFAS No. 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liability and equity. SFAS No. 150 is effective for the Company's financial instruments entered into or modified after May 31, 2003, and otherwise is effective on July 1, 2003. The Company has evaluated the impact of SFAS No. 150 and has determined that its financial instruments will not be affected.

**NOTE 9—STOCK SPLIT**

On January 14, 2004, the Company effected an 8.5-for-1 stock split of its common stock in the form of a stock dividend. All common stock share and per share amounts in these condensed financial statements have been adjusted retroactively to reflect the stock split.

**NOTE 10—2004 OPTION PLANS**

On January 14, 2004, the Company adopted its 2004 Equity Incentive Plan and 2004 Non-Employee Directors' Stock Option Plan, both of which became effective upon consummation of the Company's initial public offering of its common stock. The Company may issue awards for up to 1,500,000 shares of common stock under the 2004 Equity Incentive Plan, which amount may be increased annually on January 1<sup>st</sup> of each year, from 2005 until 2013, by the lesser of five percent of the number of shares of common stock outstanding on such date or an amount

**GTx, Inc.**  
**(in thousands, except share and per share data)**

designated by the Company's Board of Directors. The Company may issue options for up to 200,000 shares of common stock under the 2004 Non-Employee Directors' Stock Option Plan, which amount may be increased annually on January 1<sup>st</sup> of each year, from 2005 until 2013, by the lesser of the number of shares of options granted during the prior Calendar Year or such amount designated by the Company's Board of Directors.

**GTx, Inc.**  
**(in thousands, except share and per share data)**

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

**Forward-Looking Information is Subject to Risk and Uncertainty**

This Quarterly Report on Form 10-Q contains forward-looking statements, including, without limitation, statements related to potential future licensing fees and milestone and royalty payments and GTx's current and anticipated clinical trials and research and development programs. These forward-looking statements are based upon GTx's current expectations. Forward-looking statements involve risks and uncertainties. GTx's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks that neither GTx nor its collaboration partners will be able to commercialize its product candidates if preclinical studies do not produce successful results or clinical trials do not demonstrate safety and efficacy in humans; if third parties do not manufacture the Company's product candidates in sufficient quantities and at an acceptable cost, clinical development and commercialization of its product candidates would be delayed; use of third-party manufacturers may increase the risk that the Company will not have adequate supplies of its product candidates; if third parties on whom the Company relies do not perform as contractually required or expected, the Company may not be able to obtain regulatory approval for or commercialize its product candidates; the Company is dependent upon collaborative arrangements to complete the development and commercialization of some of its product candidates, and these collaborative arrangements may place the development of its product candidates outside its control, may require it to relinquish important rights or may otherwise be on terms unfavorable to the Company; and if the Company is not able to obtain required regulatory approvals, the Company will not be able to commercialize its product candidates. You should not place undue reliance on these forward looking statement, which apply only as of the date of this Quarterly Report of Form 10-Q. The annual report filed on Form 10-K with the U.S. Securities and Exchange Commission on March 26, 2004 contains under the heading "Additional Factors That Might Affect Future Results" a more comprehensive description of these and other risks to which GTx is subject. GTx expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

**OVERVIEW**

GTx is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics primarily related to the treatment of serious men's health conditions. Our drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens. We currently have two product candidates that are in human clinical trials. We are currently conducting clinical trials on ACAPODENE™, our most advanced product candidate, for two separate indications: (i) a Phase IIb clinical trial to assess the effect of ACAPODENE™ in the reduction in the incidence of prostate cancer in men with precancerous prostate lesions and (ii) a pivotal Phase III clinical trial to assess the effect of ACAPODENE™ in the treatment of serious side effects of androgen deprivation therapy for advanced prostate cancer. We are developing a second product candidate, andarine, and other specified backup compounds, with our collaboration partner, Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson. Andarine will be entering a planned Phase II clinical trial this year. We retain all rights to the discovery, development, and commercialization of the rest of our selective androgen receptor modulator (SARM) program, including our other specific product candidates ostarine and prostarine, and our anti-cancer compound, andromustine.

**GTx, Inc.**  
**(in thousands, except share and per share data)**

On February 6, 2004, we successfully completed an initial public offering (IPO) of 5.4 million shares of common stock at an offering price to the public of \$14.50 per share resulting in net proceeds of \$70,365. Upon the closing of the IPO, all outstanding shares of preferred stock, and accrued dividends thereon, were converted into 11,521,075 shares of common stock. At March 31, 2004, we had outstanding 24,656,923 shares of common stock.

In March 2004, we entered into a joint collaboration and license agreement with Ortho Biotech Products L.P., a wholly owned subsidiary of Johnson & Johnson. In accordance with the agreement, we received in April 2004 an upfront licensing fee of \$6,000, and reimbursement for development expenses of approximately \$687 for our recently completed Phase I clinical trial for andarine and will receive additional licensing fees and milestone payments of up to \$82,000 based on andarine and up to \$45,000 for each additional licensed compound achieving specific clinical development decisions or obtaining regulatory approvals. Johnson & Johnson Pharmaceutical Research & Development will be responsible for further clinical development and related expenses for andarine and other licensed SARM compounds. We anticipate initiating the Phase II clinical trial for andarine in 2004. Ortho Biotech will be responsible for commercialization and related expenses for andarine and other licensed SARM compounds. If andarine is approved for commercial sale, Ortho Biotech will exclusively market andarine in the United States and in markets outside the United States. Under the agreement, we have the option to co-promote andarine and the other licensed SARM compounds to urologists in the United States for indications specifically related to men's health. We will receive up to double digits royalties on all worldwide sales, as well as additional royalty payments in excess of 20% on all co-promoted sales generated from urologists in the United States.

The upfront licensing fee and reimbursement of Phase I clinical trial expenses for andarine totaling \$6,687 is expected to be amortized into revenue on a straight-line basis through March 2009. We recognized revenue of \$52 for the three months ended March 31, 2004 from the amortization of the upfront license fee and expense reimbursement.

On April 22, 2004, we entered into a collaboration with Hybritech, Inc., a wholly owned subsidiary of Beckman Coulter, Inc. Under the terms of the agreement, we will provide clinical samples from our Phase IIb clinical trial program evaluating ACAPODENE™ for the reduction in the incidence of high grade prostatic intraepithelial neoplasia (PIN), a premalignant lesion that has the potential to progress to prostate cancer. Information resulting from this collaboration will be evaluated for use by Beckman Coulter to determine its usefulness in research, development and evaluation of assays for prostate diseases.

## **CRITICAL ACCOUNTING POLICIES**

### ***Use of Estimates***

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

**GTx, Inc.**  
**(in thousands, except share and per share data)**

***Revenue Recognition***

Non-refundable, up-front payments received in connection with research collaboration and license agreements are deferred and recorded as deferred revenue in the balance sheet and recognized as revenue in the statement of operations on a straight-line basis over the relevant periods specified in the agreement, generally the development period. The estimated development period is based on the attainment of a particular development goal and is determined based on the estimated time required to achieve that goal considering experience with similar projects, the level of effort and the development stage of the project. The basis of the revenue recognition is reviewed and adjusted based on the status and progress of the project as measured against the estimated timeline as additional information becomes available. Changes in estimates of development terms can cause an acceleration or delay in revenue recognition.

***Research and Development Costs***

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

***Preferred Stock Redemption Value***

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

***Stock Compensation***

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

**GTx, Inc.**  
**(in thousands, except share and per share data)**

***Deferred Stock Compensation***

In connection with the grant of stock options to employees, we recorded deferred stock compensation totaling \$4,055 in 2003, and are amortizing the related expense over the service period, which is generally five years. Deferred stock compensation for options granted to employees has been determined as the difference between the deemed fair value of our common stock for financial reporting purposes on the date such options were granted and the applicable exercise price. Such amount is included as a reduction of stockholders' equity and is being amortized on the straight-line basis. We recorded amortization of deferred stock compensation of approximately \$250 for the three months ended March 31, 2004. Of that amount, \$133 was included in research and development expenses and \$117 was included in general and administrative expenses in our statement of operations. No amortization of deferred stock compensation was recorded for the three months ended March 31, 2003. At March 31, 2004, we had approximately \$3,255 to be amortized over the remaining vesting periods of the stock options.

**Results of Operations**

**Three Months Ended March 31, 2004 and 2003**

**Revenues**

We recognized revenue of \$52 for the three months ended March 31, 2004 from the amortization of the upfront license fee and expense reimbursement, which we received in April 2004 in connection with the collaboration and license agreement with Ortho Biotech Products L.P. No revenue was recognized for the three months ended March 31, 2003.

**Research and Development**

Research and development expenses increased 105% to \$4,336 for the three months ended March 31, 2004 from \$2,113 for the three months ended March 31, 2003. The increase in research and development expenses included planned increased expenditures of approximately \$952 related to the pivotal Phase III clinical trial of ACAPODENE™ (Toremifene Citrate) tablets for the treatment of side effects of androgen deprivation therapy. In addition, we incurred additional expenses of \$1,153 related to the completion of Phase I clinical trials for andarine and the continued development of andarine and other product candidates in our SARM program. We also increased research and development spending on other product candidates by approximately \$311. These increases were offset by a reduction in clinical trial expenses for the Phase IIb clinical trial for the reduction in the incidence of prostate cancer in men with high grade PIN of approximately \$193.

We expect that research and development expenditures will continue to increase during the remainder of the year and in subsequent years due to (1) the pivotal Phase III clinical trial of ACAPODENE™ (Toremifene Citrate) tablets for the treatment of side effects of androgen deprivation therapy, (2) the completion of the current Phase IIb clinical trial of ACAPODENE™ for reduction of prostate cancer incidence in men with high grade PIN in 2004 and the planned commencement of a pivotal Phase III clinical trial of ACAPODENE™ for reduction of prostate cancer incidence in men with PIN, (3) the continued preclinical development of other product candidates in the company's SARM program that are not included in our collaboration with Ortho Biotech, and (4) the increase in research and development personnel. Under the terms of our collaboration with Ortho Biotech, Johnson & Johnson Pharmaceutical Research and Development will be responsible for future clinical development and expenses of andarine. We expect to expand the scope of our drug discovery and development programs in future periods, which may result in substantial increases in research and development expenses.



**GTx, Inc.**  
**(in thousands, except share and per share data)**

**General and Administrative**

General and administrative expenses increased 162% during the quarter to \$1,600 from \$610 for the first quarter of 2003, primarily as a result of increases in personnel and insurance costs, as well as increased professional fees resulting from reporting obligations applicable to public companies.

General and administrative expenses consist primarily of salaries and other related costs for personnel serving executive, finance, legal, human resources, information technology, and public relations functions. Other costs include facility costs not otherwise included in research and development expense and professional fees for legal, accounting, and public relations services. We expect that our general and administrative expenses will increase as we add personnel, comply with the reporting obligations applicable to public companies and develop our sales and marketing functions

**Interest Income**

Interest income increased to \$150 for the three months ended March 31, 2004 from \$29 for the three months ended March 31, 2003. The increase was attributable to higher average cash and cash equivalents balances during the three months ended March 31, 2004 as compared to the three months ended March 31, 2003 resulting from the IPO net proceeds of \$70,365 received on February 6, 2004 and the net proceeds of \$19,986 received in August 2003 from the issuance of Series E preferred stock.

**Adjustment to Preferred Stock Redemption Value**

The adjustment to the preferred stock redemption value for the three months ended March 31, 2004 was an increase to net income attributable to common stockholders of \$17,125 as compared to an increase to net loss attributable to common stockholders for the three months ended March 31, 2003 of \$73. Our preferred stock was recorded at its redemption value. The per share redemption price was equal to the greater of liquidation value, which included accrued dividends, or the fair value calculated on an as-if converted to common stock basis. At December 31, 2003, the per share redemption value was determined based on the estimated projected midpoint on the range of our initial public offering price per common share of approximately \$14.50 per share. At February 6, 2004, the date of the closing of the Company's IPO and automatic conversion of all outstanding preferred stock, and accrued dividends thereon, into common stock, the market price for our common stock was \$12.90 per share. Prior to conversion into common stock, the carrying value of the preferred stock and accrued dividends was adjusted to reflect the per share redemption value on the date of conversion resulting in a decrease in the carrying value of preferred stock of \$17,125 and an offsetting increase in stockholders' equity.

**Liquidity and Capital Resources**

At March 31, 2004, we had cash and cash equivalents of \$80,620, compared to \$14,769 at December 31, 2003. On February 6, 2004, we completed an initial public offering of 5.4 million shares of common stock at a price of \$14.50 per share, resulting in net proceeds of \$70,365.

Net cash used in operating activities was \$5,481 and \$2,629 for the three months ended March 31, 2004 and 2003, respectively. The use of cash in both periods resulted primarily from funding our net losses.

Net cash used in investing activities was \$71 and \$3 for the three months ended March 31, 2004 and 2003, respectively. The use of cash in both periods was primarily for the purchase of office and research and development equipment. We currently expect to make expenditures for capital equipment and leasehold improvements of up to \$3,258 in 2004.

**GTx, Inc.**  
**(in thousands, except share and per share data)**

Net cash provided by financing activities, was \$71,403 and \$-0- for the three months ended March 31, 2004 and 2003, respectively. Net cash provided by financing activities for the three months ended March 31, 2004 reflected the proceeds from the Company's IPO which closed February 6, 2004 less underwriters commission and offering expenses paid during the period and did not include offering expenses paid in 2003 of \$1,038.

We believe that the net proceeds from our initial public offering, our current cash resources and interest on these funds, and committed payments under our research collaborative agreement will be sufficient to meet our projected operating requirements through at least the end of 2005. This estimate does not include payments that we may receive as milestone payments under our joint collaboration and license agreement with Ortho Biotech.

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 in the "Additional Factors That May Affect Future Results" section of the annual report filed on Form 10-K with the U.S. Securities and Exchange Commission on March 26, 2004. 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 terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the achievement of certain milestone events under our joint collaboration and license agreement with Ortho Biotech;
- the cost and timing of regulatory approvals;
- 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.

**GTx, Inc.**  
**(in thousands, except share and per share data)**

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

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our exposure to market risk for changes in interest rates relates to our cash equivalents on deposit in highly liquid money market funds. The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. We do not use derivative financial instruments in our investment portfolio. Our cash and investments policy emphasizes liquidity and preservation of principal over other portfolio considerations.

We have operated primarily in the United States. Accordingly, we do not have any material exposure to foreign currency rate fluctuations. However, if we are successful in our efforts to commercialize Acapodene, our exposure to foreign currency rate fluctuations may increase because we are obligated to pay Orion, our supplier of Acapodene, in Euros.

**ITEM 4. EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES**

We maintain disclosure controls and procedures, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities 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 timely decisions regarding required disclosure. Our Chief Executive Officer and Chief Financial Officer carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the evaluation of these disclosure controls and procedures, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective. It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system are met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of future events. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

**GTx, Inc.**  
**(in thousands, except share and per share data)**

**PART II**  
**OTHER INFORMATION**

**ITEM 2. CHANGES IN SECURITIES, USE OF PROCEEDS AND ISSUER PURCHASES OF EQUITY SECURITIES**

The Company's common stock began trading on The Nasdaq National Market under the trading symbol "GTXI" on February 3, 2004. The Company sold 5,400,000 shares of common stock in our initial public offering at \$14.50 per share. The offering terminated after the sale of all of the securities registered on the registration statement and the expiration of the underwriters' over-allotment option. The aggregate gross proceeds from the shares of common stock sold were \$78,300. The Company paid the underwriters a commission of \$5,481 and incurred offering expenses of \$2,454. The offering expenses included approximately \$98 in lease payments paid to Pittco Management, Inc., an affiliate of Mr. Hyde, one of our directors, for the rental of Pittco Management Inc.'s airplane during the IPO road show. The Company was reimbursed \$39 of the \$98 from the underwriters. Other than the fees paid to Pittco Management, Inc., none of the IPO expenses were paid directly or indirectly to our directors, officers or persons owning 10% or more of our common stock. After deducting the underwriters' commission and the offering expenses, the Company received net proceeds of \$70,365. We invested the net proceeds in short-term securities and expect to use the net proceeds to fund our clinical trials and other research and development activities and for general corporate purposes. In addition, we may use a portion of the net proceeds to acquire equipment, products, technologies or businesses, although we currently have no commitments or agreements relating to any of these types of transactions.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

During the period covered by this report, prior to the closing of our initial public offering of common stock, we solicited written consents of our stockholders in lieu of an annual meeting to approve the following matters, and all of the matters described below were approved by the requisite voting power of our voting securities entitled to vote thereon:

- On January 14, 2004, our stockholders, acting by written consent, unanimously took the following actions:
  - approved an 8.5-for-1 split of our common stock;
  - approved a Certificate of Amendment to our Restated Certificate of Incorporation, as amended, increasing the number of shares of our common stock authorized for issuance in connection with the stock split;
  - approved and adopted a restated certificate of incorporation to be effective upon consummation of our IPO;
  - approved an amendment and restatement of our bylaws, to be effective upon consummation of our IPO;
  - approved a form of indemnification agreement between directors and executive officers and GTx;
  - approved the fees to be paid to non-employee directors and the audit committee chair;
  - adopted the 2004 Equity Incentive Plan;
  - adopted the 2004 Non-Employee Directors' Stock Option Plan; and

**GTx, Inc.**  
**(in thousands, except share and per share data)**

- approved a classified board of directors and elected the following persons in each class as follows:
  - Class I Directors (until the 2005 annual meeting of stockholders or until her successors are elected and qualified): Dr. Rosemary Mazanet;
  - Class II Directors (until the 2006 annual meeting of stockholders or until their successors are elected and qualified): Marc S. Hanover and John H. Pontius; and
  - Class III Directors (until the 2007 annual meeting of stockholders or until their successors are elected and qualified): Dr. Mitchell S. Steiner and J.R. Hyde, III.

**ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K**

## (a) Exhibits

Number	Description
3.1	Restated Certificate of Incorporation of GTx, Inc. filed February 6, 2004, as amended <sup>(1)</sup>
3.2	Amended and Restated Bylaws of GTx, Inc. <sup>(1)</sup>
4.1	Reference is made to Exhibits 3.1 and 3.2
4.2	Specimen of Common Stock Certificate <sup>(1)</sup>
4.3	Amended and Restated Registration Rights Agreement between Registrant and Oracle Partners, L.P. dated August 7, 2003 <sup>(1)</sup>
4.4	Amended and Restated Registration Rights Agreement between Registrant and J. R. Hyde, III dated August 7, 2003 <sup>(1)</sup>
4.5	Amended and Restated Registration Rights Agreement between Registrant and Memphis Biomed Ventures dated August 7, 2003 <sup>(1)</sup>
10.1	Genotherapeutics, Inc. 1999 Stock Option Plan <sup>(1)</sup>
10.2	GTx, Inc. 2000 Stock Option Plan <sup>(1)</sup>
10.3	GTx, Inc. 2001 Stock Option Plan <sup>(1)</sup>
10.4	GTx, Inc. 2002 Stock Option Plan <sup>(1)</sup>
10.5	2004 Equity Incentive Plan and Form of Stock Option Agreement <sup>(1)</sup>
10.6	2004 Non-Employee Directors' Stock Option Plan and Form of Stock Option Agreement <sup>(1)</sup>
10.7	Reserved
10.8	Employment Agreement dated October 1, 2003, between Registrant and Mitchell S. Steiner, M.D. <sup>(1)</sup>
10.9	Employment Agreement dated October 1, 2003, between Registrant and Marc S. Hanover <sup>(1)</sup>
10.10	Employment Agreement dated October 1, 2003, between Registrant and Mark E. Mosteller <sup>(1)</sup>
10.11	Employment Agreement dated October 1, 2003, between Registrant and Henry P. Doggrell <sup>(1)</sup>
10.12	Form of Indemnification Agreement <sup>(1)</sup>
10.13	Lease Agreement, dated March 7, 2001, between The University of Tennessee and TriStar Enterprises, Inc. <sup>(1)</sup>
10.14	Sublease Agreement dated October 1, 2000, as amended, between Registrant and TriStar Enterprises, Inc. <sup>(1)</sup>
10.15†	Amended and Restated License and Supply Agreement dated October 22, 2001, between Registrant and Orion Corporation <sup>(1)</sup>
10.16†	Amendment No. 1 to the License and Supply Agreement dated March 5, 2003, between Registrant and Orion Corporation <sup>(1)</sup>
10.17†	Production and Manufacturing Agreement dated September 9, 2002, between Registrant and ChemSyn Laboratories (Department of EaglePicher Technologies, LLC) <sup>(1)</sup>



## Table of Contents

### (a) Exhibits

<u>Number</u>	<u>Description</u>
10.18†	Amendment No. 1 to the Production and Manufacturing Agreement dated September 30, 2003, between Registrant and ChemSyn Laboratories (Department of EaglePicher Technologies, LLC) <sup>(1)</sup>
10.19†	Quotation Agreement dated August 8, 2003 between Registrant and EaglePicher Pharmaceutical Services <sup>(1)</sup>
10.20†	Amended and Restated Exclusive License Agreement dated June 3, 2002, between Registrant and University of Tennessee Research Foundation <sup>(1)</sup>
10.21†	Amended and Restated Exclusive License Agreement dated June 14, 2003, between Registrant and University of Tennessee Research Foundation <sup>(1)</sup>
10.22†	Amended and Restated Exclusive License Agreement dated August 30, 2003, between Registrant and University of Tennessee Research Foundation <sup>(1)</sup>
10.23	Amendment No. 2 to the License and Supply Agreement dated December 29, 2003, between Registrant and Orion Corporation <sup>(1)</sup>
10.24†	Joint Collaboration and License Agreement dated March 16, 2004, between Registrant and Ortho Biotech Products, L.P.
14.1	Code of Ethics <sup>(2)</sup>
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer Pursuant to 18. U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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† Confidential treatment requested. The redacted portions have been filed separately with the SEC as required by Rule 406 of Regulation C.

(1) Incorporated by reference to the same exhibit filed with GTx's Registration Statement on Form S-1 (File No. 333-109700).

(2) Incorporated by reference to the same exhibit filed with GTx's Annual Report on Form 10-K for the year ended December 31, 2003.

### (b) Reports on Form 8-K:

On March 18, 2004, GTx filed a Current Report on Form 8-K, to furnish under Item 9 its March 17, 2004 public announcement of GTx's entry into a joint collaboration with Ortho Biotech Products, L.P. for andarine and specified backup SARM compounds.

On March 3, 2004, GTx filed a Current Report on Form 8-K, to furnish under Item 12 its March 3, 2004 public announcement of financial results for the quarter and year ended December 31, 2003.

**SIGNATURES**

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

**GTx, Inc.**

Date: May 7, 2004

By: /s/ Mitchell S. Steiner  
Mitchell S. Steiner, Chief Executive Officer

Date: May 7, 2004

By: /s/ Mark E. Mosteller  
Mark E. Mosteller, Chief Financial Officer  
(Principal Financial and Accounting Officer)



**EXHIBIT INDEX**

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- 31.1 Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

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(2) Incorporated by reference to the same exhibit filed with GTx's Annual Report on Form 10-K for the year ended December 31, 2003.

[ \* ] = 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.

EXHIBIT 10.24

## JOINT COLLABORATION AND LICENSE AGREEMENT

THIS JOINT COLLABORATION AND LICENSE AGREEMENT (the "Agreement") is made effective as of the 16th day of March, 2004 (the "Effective Date") by and between GTX, Inc., a Delaware corporation having its principal place of business at 3 North Dunlap St., 3rd Floor, Memphis, Tennessee 38163 ("GTX") and Ortho Biotech Products L.P., a limited partnership having its principal place of business at Route 22 East, Bridgewater, NJ 08807 ("Ortho"), each on behalf of itself and its Affiliates. GTX and Ortho are sometimes referred to herein individually as a "Party" and collectively as the "Parties", and references to "GTX" and "Ortho" shall include their respective Affiliates.

### RECITALS

Ortho is a wholly owned subsidiary of Johnson & Johnson, a multinational healthcare company with research, development and marketing activities worldwide, which desires to obtain additional potential drug products for osteoporosis and wasting, and possible other indications.

GTX is a men's healthcare company, which is developing compounds, including Andarine, an orally active, non-steroidal, selective androgen receptor modulator (SARM). GTX has conducted several Phase I clinical trials of Andarine and is planning Phase II and III clinical trials of such compound.

The Parties desire to develop and commercialize Andarine and possibly other specified SARM compounds throughout the world.

### ARTICLE I

#### DEFINITIONS

The following terms shall have the following meanings as used in this Agreement:

1.1 "Active Ingredient" means the material(s) in the Collaboration Product which provide its pharmacological activity.

1.2 "Additional Collaboration Compound" means any Collaboration Compound selected for Development other than, and in addition to, Andarine or a Replacement Collaboration Compound for Andarine.

1.3 "Affiliate" means an entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with GTX or Ortho. For the purposes of this definition, the term "control" (including, with correlative

meanings, the terms "controlled by" and "under common control with") as used with respect to a Party, shall mean the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such person or entity, whether through the ownership of voting securities, by contract or otherwise.

1.4 "Andarine" means [ \* ], and [ \* ] that have the activity described in Section 1.36(2).

1.5 "Business Day" means a day on which banking institutions in New York, NY are open for business.

1.6 "Clinical Studies" means human studies designed to measure the Safety, efficacy, Tolerability and appropriate dosage of a Collaboration Compound and/or Collaboration Product. Clinical Studies includes Phase I Clinical Trial, Phase IIA Clinical Trial, Phase IIB Clinical Trial, Phase III Clinical Trial, Phase IIIB Clinical Trial, and Phase IV Clinical Trial, as defined herein.

1.7 "Collaboration Compound" means (i) initially, Andarine and (ii) any other GTX SARM Compound selected by Ortho for Development pursuant to this Agreement. Collaboration Compounds include without limitation Additional Collaboration Compounds and Replacement Collaboration Compounds.

1.8 "Collaboration Product" means a drug product for use in humans in a form suitable for sale to an end user and/or for use in conducting Clinical Studies, containing as an Active Ingredient at least one Collaboration Compound.

1.9 "Combination Product" means (i) any pharmaceutical product that consists of a Collaboration Product that also contains another Active Ingredient that is not a Collaboration Compound, or (ii) any combination of a Collaboration Product and another pharmaceutical product that is not a Collaboration Product where such products are not formulated together but are sold together for a single invoiced price.

1.10 "Commercialization Activities" means activities relating to the manufacture of a Collaboration Product for sale to end users, or to the marketing and sale of a Collaboration Product, including Pre-Marketing activities, which in the Co-Promotion Territory is undertaken pursuant to a Marketing and Sales Plan.

1.11 "Confidential Information" shall have the meaning set forth in Section 9.1.

1.12 "Control" or "Controlled" means the possession of the right to grant a license or sublicense to intangible property rights (including patent rights, know-how and/or trade secret information), and the right to provide access to or cross-reference to regulatory filings or other data or information, in each case to the extent not in violation of the terms of any pre-existing agreement or other arrangement with any Third Party. "Control" expressly includes the right of ownership, in whole or in part, unless the Party having such right is restricted by contract or under law from granting such a license, access or right to reference.

1.13 "Co-Promotion" shall have the meaning set forth in Article VI, and "Co-Promote" shall have a correlative meaning.

1.14 "Co-Promotion Territory" means the United States, but only after GTX exercises its option to Co-Promote a Collaboration Product to the GTX Audience, on a Collaboration Product by Collaboration Product basis.

1.15 "Detail" (or "Details" and "Detailing") means, with respect to the Collaboration Product, the activity undertaken by a sales representative [ \* ] to provide [ \* ] of the Collaboration Product, in a fair and balanced manner consistent with the requirements of the Food Drug and Cosmetics Act, including but not limited to, the regulations of 21 C.F.R. 202, and [ \* ] in an effort to increase the number of physicians prescribing the Collaboration Product and/or the number of prescriptions for Collaboration Product, but excluding [ \* ].

1.16 "Development" or "Develop" means activities relating to obtaining Regulatory Approval of Collaboration Products, and activities relating to developing and scaling up the ability to manufacture and to continue to manufacture Collaboration Compounds and Collaboration Products, including activities of Third Party manufacturers to develop such manufacturing capabilities for Collaboration Products. Development includes but is not limited to Pre-Clinical Studies, pharmacology studies, toxicology studies, formulation, manufacturing process development and scale-up (including bulk compound production), quality assurance and quality control, technical support, pharmacokinetic studies, Clinical Studies, regulatory affairs activities and outside counsel regulatory legal services. For clarity, Development shall not include medicinal chemistry efforts directed at the production of new chemical variants of any GTX SARM Compound that are not themselves GTX SARM Compounds, but may include (to the extent provided in the Development Plan) the production of modified GTX SARM Compounds that contain radioactive isotopes (whether or not such modified compounds are included in GTX SARM Compounds) or other labeling or tracing residues that are used in analyzing the activity, pharmacokinetics or pharmacodynamics of Collaboration Compounds as provided in the Development Plan, and activities directed toward developing a process for manufacturing Collaboration Compounds.

1.17 "Development Budget" shall have the meaning set forth in Article IV.

1.18 "Development Expenses" means the expenses incurred by a Party or for its account by a Third Party (including capital expenditures made by a Third Party and reimbursed by a Party) which are generally consistent with a Development Plan and Development Budget and are specifically attributable to the Development of a Collaboration Compound or Collaboration Product not otherwise recovered or reimbursed. Development Expenses shall include, but are not limited to, the cost of labor (calculated, as to GTX, as provided in Section 4.5) and materials incurred in connection with Pre-Clinical and Clinical Studies (whether conducted internally or by a Third Party, individual investigators or consultants), toxicological, pharmacological, pharmacokinetic, metabolic, analytical, formulation, and chemical studies, final product scale-up, and qualification and validation batches as required by the FDA for the purpose of obtaining

Regulatory Approval of a Collaboration Product, and costs (and related fees) for preparing, submitting, reviewing or developing data or information for the purpose of submission to a governmental authority to obtain and/or maintain Regulatory Approval of a Collaboration Product.

1.19 "Development Plan" shall have the meaning set forth in Article IV.

1.20 "Drug Approval Application" means an application for Regulatory Approval required before commercial sale or use of a Product as a drug in a regulatory jurisdiction.

1.21 "Education" means professional and customer education, through any means, including (i) articles appearing in journals, newspapers, magazines, or other media, including direct mail and electronic media; (ii) seminars, exhibits and conventions; (iii) educational literature, visual aids, three dimensional educational items, and other educational materials; (iv) market research; and (v) symposia, advisory boards and opinion leader development activities; provided, however, that such term shall exclude direct sales force activity. All such Education means must be within current healthcare compliance guidelines.

1.22 "Effective Date" shall have the meaning set forth on page one of this Agreement.

1.23 "EMEA" means the European Medicine Evaluation Agency or any successor thereto.

1.24 "Executive Officers" means the Chief Executive Officer of GTx (or a senior officer of GTx designated by GTx's Chief Executive Officer) and the President of Ortho (or a senior officer of Ortho or one of its Affiliates).

1.25 "FDA" means the United States Food and Drug Administration or any successor thereto.

1.26 "First Collaboration Compound" means Andarine or its Replacement Collaboration Compound.

1.27 "[ \* ]" means [ \* ].

1.28 "FTE" means the equivalent of the work of one (1) employee full time for one (1) calendar year (consisting of at least a total of [ \* ] per calendar year) of work pursuant to the Development Plan with respect to Collaboration Products. Any employee who devotes less than [ \* ] per calendar year shall be treated as an FTE on a pro-rata basis calculated by dividing the actual number of hours worked during such calendar year by [ \* ].

1.29 "FTE Cost" means the cost to GTx of its [ \* ] personnel directly dedicated to the execution of the Development Plan [ \* ], and shall be calculated by multiplying the

FTE Rate by the number of GTX employees, agents or independent contractors performing such Development pursuant to the Development Plan.

1.30 "FTE Rate" means, as of the Effective Date, [ \* ] per FTE. Such rate shall be adjusted annually to reflect the total percentage increase in the U.S. Consumer Price Index for the time period from the Effective Date until the time at which such index was recalculated at the time of adjustment (with the first adjustment to occur January 1, 2005, with subsequent adjustments on each anniversary thereof).

1.31 "Generic" means a product that contains the same chemical entity as a Collaboration Product and that has received regulatory approval to be marketed and sold for an Indication for which the Collaboration Product is marketed and sold. In the United States, Generics shall only include those products approved under an ANDA based on the NDA of the Collaboration Product.

1.32 "GTX Audience" means those urologists who are licensed to practice in the United States to whom GTX will promote Collaboration Product, as designated pursuant to Section 6.3.

1.33 "GTX Know-how" means Information which (i) GTX discloses to Ortho under this Agreement and (ii) is within the Control of GTX. Notwithstanding anything herein to the contrary, GTX Know-how shall exclude GTX Patents.

1.34 "GTX/Ortho Development" means Development of Collaboration Compounds for Indications that are primarily directed to the treatment of male health diseases and/or conditions.

1.35 "GTX Patent" means the rights granted by any governmental authority under a Patent which claims Andarine and/or GTX SARM Compounds, or methods of using and processes for making such compounds, which Patent is owned or Controlled by GTX. A list of the GTX Patents identified as of the Effective Date is attached hereto as Exhibit A. GTX Patents include without limitation GTX's interest in any Joint Patents.

1.36 "GTX SARM Compounds" means Andarine and/or non-steroidal selective androgen receptor modulators that (1) [ \* ], are [ \* ], any [ \* ] issued, any [ \* ] and [ \* ]; and (2) (a) [ \* ]; (b) [ \* ]; and (c)(i) [ \* ]; or (ii) [ \* ]; or (iii) [ \* ]. GTX SARM Compounds shall also include [ \* ] described in (1) that also [ \* ] in (2). For avoidance of doubt, if a compound is described in (1) but does not also meet the requirements of (2), such compound shall not be a GTX SARM Compound and GTX shall retain all rights to such compound. It is understood by the Parties that GTX has [ \* ] and that [ \* ] may include GTX SARM Compounds and/or Excluded SARM Compounds. "Excluded SARM Compounds" means compounds that are [ \* ] and/or compounds that are included in Exhibit D2. For example, the GTX Patents listed on Exhibit A includes continuation-in-part applications which include Excluded SARM Compounds. GTX shall retain all rights to Excluded SARM Compounds. For avoidance of doubt, the parties have set forth on Exhibit D1 certain compounds that, as of the Effective Date, are [ \* ] and are included within clause (1) of the first sentence of this Section 1.36 (and are therefore eligible to be



GTx SARM Compounds if they also fulfill the requirements of clause (2) of this Section 1.36), and on Exhibit D2 certain compounds that are, as of the Effective Date, Excluded SARM Compounds.

1.37 "IND" shall mean (i) an Investigational New Drug Application as defined in the United States Food, Drug and Cosmetic Act and applicable regulations promulgated thereunder by the FDA, or (ii) the equivalent application to the equivalent agency in any other country or group of countries, the filing of which is necessary to commence clinical testing of a pharmaceutical product in humans in a particular jurisdiction.

1.38 "Indication" means any disease or condition for which a Collaboration Compound may have therapeutic, ameliorative or preventive activity and for which a Collaboration Compound can be Developed.

1.39 "Information" means (i) techniques and data relating to Collaboration Compounds, Collaboration Products, Combination Products or GTx SARM Compounds to the extent provided to a Party for use in joint Development, or for Commercialization thereof, including (but not limited to) inventions, practices, methods, knowledge, know-how, skill, experience, test data including pharmacological, toxicological, Pre-Clinical Studies and clinical test data, analytical and quality control data, marketing, pricing, distribution, cost, sales and manufacturing data or descriptions, and compounds, compositions of matter, assays and biological materials related thereto.

1.40 "Joint Development Committee" or "JDC" means the committee established pursuant to Article II.

1.41 "Joint Patent" shall have the meaning set forth in Section 10.4.

1.42 "Koseisho" means the Japanese Ministry of Health and Welfare, or any successor agency thereto.

1.43 "Launch Date" means the date of the first offer for commercial sale, following Regulatory Approval, of a Collaboration Product.

1.44 "Major European Country" means any of the United Kingdom, France, Germany, Spain and Italy.

1.45 "Market Exclusivity" means, as to a given country, a given product and a given time period, that no Generic version of such product is then being sold in such country.

1.46 "Marketing" means the sale, promotion and advertising of a Collaboration Product in the Co-Promotion Territory as set forth in Article VI and in the Marketing and Sales Plan.

1.47 "Marketing Expenses" means the costs that are generally consistent with a Marketing and Sales Plan that are incurred after the Launch Date of a Collaboration

Product and are specifically attributable to the sale, promotion, advertising, and marketing of such Collaboration Product. Marketing Expenses shall include costs of Phase IV Clinical Trials.

1.48 "Marketing and Sales Committee" shall have the meaning set forth in Section 6.4.

1.49 "Marketing and Sales Plan" shall have the meaning set forth in Section 6.5.

1.50 "Material Breach" shall have the meaning set forth in Section 13.2(e).

1.51 "NDA" means a complete New Drug Application and all amendments and supplements thereto filed with the FDA, including all documents, data, and other information concerning a Collaboration Product, which are necessary for, or included in, an application for Regulatory Approval by the FDA to market such Collaboration Product, as more fully defined in 21 C.F.R. Section 314.5 et seq.

1.52 "NDA Approval" means the approval of an NDA by the FDA required before commercial sale or use of a Collaboration Product as a drug in the United States.

1.53 "Net Sales" means, consistent with, in the United States, generally accepted accounting principles and, in the rest of the Royalty Bearing Territory, Ortho worldwide practices and procedures, and in each such case as consistently applied across the Ortho pharmaceutical product line, the amount invoiced by Ortho, its Affiliates, and its distributors and sub-licensees to Customers for sales of licensed Product in the Royalty Bearing Territory, less accruals estimated, credits taken, and actual payments (to the extent not previously accrued) made for:

(a) discounts, credits, retroactive price reductions, rebates, refunds, charge backs, allowances and adjustments granted to non-sublicensee Third Parties, including Medicaid, and managed care and similar types of rebates, rejections, market withdrawals, recalls (provided such recalls are in accordance with Section 6.22 of this Agreement) and returns, and administrative fees charged by hospital buying groups and managed care organizations in the United States, each to the extent consistent with Ortho's usual course of dealing for its products other than the Products;

(b) trade, quantity and cash discounts and rebates actually allowed or given (other than to a distributor that is an Affiliate of Ortho), each to the extent consistent with Ortho's usual course of dealing for its products other than the Product;

(c) sales, excise, turnover, value-added, and similar taxes assessed on the sale of the Product (other than income taxes of Ortho, its Affiliates or sublicensees), and import and customs duties;

(d) shipping and insurance charges, postage, and freight out;

and

(e) government imposed rebates or discounts.

Sales of Product by and between Ortho and its Affiliates and sublicensees are not sales to Third Parties and shall be excluded from Net Sales calculations for all purposes. Sales of Product for use in conducting clinical trials of Product in a country in order to obtain the first Regulatory Approval of Product in such country shall be excluded from Net Sales calculations for all purposes. Net Sales shall be determined in a manner consistent for all products sold by or on behalf of Ortho and in accordance with applicable U.S. generally accepted accounting principles.

In the event the Product is sold as part of a Combination Product in a country, the Net Sales of the 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, during the applicable Net Sales reporting period, by the fraction,  $A/(A+B)$ , where:

A is the average sale price of the Product by Ortho, its Affiliates or sublicensees when sold separately in finished form in such country and B is the average sale price by Ortho, its Affiliates or sublicensees 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 the Product is sold as part of a Combination Product and is 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 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 Product 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 the Product is 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 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, provided that in no event shall  $(D-E)/D$  be [ \* ].

In the event that the Net Sales of the Product 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 Product 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.

1.54 "Ortho Development" means all Development other than the GTx/Ortho Development.

1.55 "Ortho Know-how" means Information which (i) Ortho discloses to GTx under this Agreement and (ii) is within the Control of Ortho. Notwithstanding anything herein to the contrary, Ortho Know-how shall exclude Ortho Patents.

1.56 "Ortho Patent" means the rights granted by any governmental authority under a Patent which covers an invention relating to the composition of matter, formulation, method of making or method of using Collaboration Compounds or Collaboration Products, which Patent is Controlled by Ortho. As of the Effective Date, Ortho has not identified any Ortho Patents. Ortho Patents include Ortho's interest in any Joint Patents.

1.57 "Osteoporosis Indication" means the treatment of [ \* ].

1.58 "[ \* ]" means [ \* ].

1.59 "Patent" means (i) valid and enforceable United States or foreign patents, reexaminations, reissues, renewals, extensions, term restorations, and foreign counterparts thereof, and (ii) pending applications for United States or foreign patents thereof.

1.60 "Patent Expenses" means the fees, expenses and disbursements of outside counsel, and payments to Third Party agents, incurred in connection with the preparation, filing, prosecution and maintenance of GTx Patents or Ortho Patents covering Collaboration Compounds or Collaboration Products, including the costs of patent interference and opposition proceedings but excluding the costs of any other Patent enforcement proceedings.

1.61 "Phase I Clinical Trial" means that portion of the clinical development program which provides for the first introduction into humans of a Product with the purpose of determining human toxicity, metabolism, absorption, elimination and other pharmacological action, as more fully defined in 21 C.F.R. Section 312.21(a).

1.62 "Phase IIA Clinical Trial" means that portion of the clinical development program which provides for the initial trials of a Collaboration Compound on a limited number of patients for the purpose of determining whether the Collaboration Compound affects a surrogate marker or indicator of pharmacological or clinical activity in the proposed therapeutic indication.

1.63 "Phase IIB Clinical Trial" means that portion of the clinical development program which provides for the definitive, well controlled clinical trials of a Collaboration Compound in patients for the purpose of determining the safe and effective

dose range in the proposed therapeutic indication, as more fully described in 21 C.F.R. Section 312.21(b).

1.64 "Phase III Clinical Trials" means that portion of the clinical development program which provides for continued trials of a Product on sufficient numbers of patients to establish the safety and efficacy of a Product and generate pharmaco-economic data to support Regulatory Approval in the proposed therapeutic indication, as more fully defined in 21 C.F.R. Section 312.21(c).

1.65 "Phase IIIB Clinical Trials" means product support clinical trials of a Collaboration Product, which is not required for receipt of initial Regulatory Approval but which may be useful in providing additional drug profile data or expansion of the Collaboration Product's label claim, and which is commenced after NDA filing but before NDA Approval.

1.66 "Phase IV Clinical Trials" means product support clinical trials, including but not limited to trials including new drug delivery systems, of a Collaboration Product with an approved label claim that is commenced after receipt of Regulatory Approval in the country where such trial is being conducted. These trials shall be considered a part of Commercialization.

1.67 "Pre-Clinical Studies" means studies of a Collaboration Product in animals other than humans, including those studies conducted in whole animals and other test systems, designed to determine the toxicity, bioavailability, and pharmacokinetics of a Collaboration Compound and whether the Collaboration Compound has a desired effect.

1.68 "Pre-Marketing" means Commercialization Activities undertaken prior to and in preparation for the launch of a Collaboration Product, consistent with a Marketing and Sales Plan and prior to the first commercial launch of such Collaboration Product. Pre-Marketing activities shall include, but are not limited to, advertising, Education, market research, Phase IIIB Clinical Trials, Phase IV Clinical Trials, sales force training, trademark activities (including selection, filing, prosecution and enforcement) and other activities included within the Marketing and Sales Plan prior to the first commercial launch of such Collaboration Product.

1.69 "Products" means Collaboration Products.

1.70 "Proof of Concept Trial" means any Phase IIA Clinical Trial or Phase IIB Clinical Trial that is designed to demonstrate that a Collaboration Product meets clinical criteria established by the JDC with respect to a given indication.

1.71 "Regulatory Agency" means any governmental authority, including without limitation the FDA or EMEA, with responsibility for granting any licenses or approvals or granting pricing and/or reimbursement approvals necessary for the marketing and sale of a Collaboration Product in any country or group of countries.

1.72 "Regulatory Approval" means any approvals by government pricing or health authorities in a country or supra-national organization (including, but not limited to, FDA and EMEA), product and/or establishment licenses, registrations or authorizations of any federal, state or local regulatory agency, department, bureau or other governmental entity, in each case that are necessary for the commercial manufacture, use, storage, importation, export, transport or sale of Collaboration Products in a regulatory jurisdiction.

1.73 "Replacement Collaboration Compound" means a GTX SARM Compound that is selected to replace a Collaboration Compound then under development as described in Section 4.6.

1.74 "Royalty Bearing Product" means a Collaboration Product marketed directly or indirectly by Ortho, its Affiliate or sublicensee alone or together with GTX or its Affiliates in the Royalty Bearing Territory.

1.75 "Royalty Bearing Sales" means the Net Sales in the Royalty Bearing Territory.

1.76 "Royalty Bearing Territory" means the world.

1.77 "Royalty Term" shall have the meaning set forth in Section 3.5.

1.78 "Safety" means the absence of adverse experiences associated with the administration of a drug to a patient that are significant, serious or life threatening to the patient or demonstrate significant toxicological effect(s) of such drug on one or more body tissues that are not balanced by a countervailing benefit to the patient. The Safety of a product will be determined in view of the risk to benefit relationship of such product in the relevant patient population.

1.79 "[ \* ]" means [ \* ].

1.80 "Third Party" means any entity other than GTX or Ortho and their respective Affiliates.

1.81 "Tolerability" means the absence of adverse experiences, other than those that are Safety-related experiences, associated with administration of a drug to patients that such patients, or their physicians, deem unpleasant to an extent that can materially and adversely affect market potential or market penetration of a Collaboration Product.

1.82 "Trademark Expenses" means the fees, expenses and disbursements of outside counsel, and payments to Third Party agents incurred in connection with the preparation, filing, prosecution, registration and maintenance of trademarks covering Collaboration Compounds or Collaboration Products, including the costs of trademark interference and opposition proceedings, but excluding other trademark enforcement proceedings.

1.83 "Unit Net Sales Price" means the average Net Sales amount received during either the applicable calendar quarter (as used in Section 7.1) or during the applicable period (as used in Section 13.6) by Ortho, its Affiliates or sublicensees for each tablet or other dosage form of a Collaboration Product written by a Urologist and filled and sold by a pharmacist in the United States.

1.84 "Urologist" means a urologist licensed to practice in the United States, or a nurse practitioner or physician assistant who works for such a urologist.

1.85 "UTRF" means the University of Tennessee Research Foundation.

1.86 "Valid Patent Claim" means a claim (a) of any issued, unexpired patent that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise, or (b) of any patent application that has not been cancelled, withdrawn or abandoned or been pending more than seven (7) years.

1.87 "Wasting Indication" means the treatment of the effects of diseases involving a reduction in lean body weight, whether due to [ \* ] or other chronic medical conditions.

## ARTICLE II

### MANAGEMENT

#### 2.1 Joint Development Committee.

(a) Formation of JDC. GTX and Ortho shall form a Joint Development Committee ("JDC"). The JDC shall be comprised of equal numbers (up to three (3) from each Party) of appropriately expert and experienced individuals, with one such person assigned by each Party as such Party's co-chair. Either Party may designate a substitute for a committee member to participate in the event one of that Party's regular committee members is unable to be present at a meeting.

(b) Meetings. Meetings of each of the JDC may be called by either Party on ten (10) calendar days written notice to the other unless such notice is waived by the Parties. Such committees may be convened, polled or consulted from time to time by means of telecommunication, video communication, or correspondence. The JDC will meet at least quarterly, at sites to be designated by the chairpersons of such committees or through teleconference or video conference, as agreed upon by the JDC.

(c) Agendas. Each Party will disclose to the other proposed agenda items along with appropriate Information at least five (5) calendar days in advance of each meeting of the JDC.

(d) Responsibilities of the JDC. The JDC will oversee the Parties' efforts for Ortho Development and will oversee and coordinate the Parties' efforts with respect to GTx/Ortho Development. The JDC will review and comment on the Development Plans and Development Budgets and make recommendations with respect to adjustment of GTx/Ortho Development, budget and timetables and the assessment of whether a Collaboration Compound shall proceed to the next stage of Development. Ortho will update the JDC periodically, but at least quarterly, of all Development activities. The JDC will review and approve, with respect to GTx/Ortho Development, the addition of new indications, the ceasing of Development of Andarine, and the addition of a Replacement Collaboration Compound or an Additional Compound. In, addition, the JDC shall review and approve any proposal by GTx to designate a compound not to be a GTx SARM Compound, as defined herein. In this regard, GTx agrees to provide the JDC with sufficient information and data in connection with [ \* ] so that the JDC can agree or disagree with GTx's position. Such information shall be provided at a JDC meeting and the JDC shall have thirty (30) calendar days after it receives the information and data to decide whether or not it agrees with GTx. If the JDC disagrees with GTx's position, GTx may proceed to develop and commercialize its compound independent of this collaboration, provided, however, Ortho shall retain its rights to arbitrate the classification of such compound under Article XV (and GTx may also initiate such an arbitration in order to clarify its rights to such compound). If the JDC agrees that the compound is not a GTx SARM Compound, Ortho shall promptly provide to GTx a written statement confirming that Ortho has no rights under this Agreement in or to such compound.

(e) Decisions by the JDC.

(i) Ortho shall present to the JDC the portion of the Development Plan and Development Budget that relates to the Ortho Development at the same level of detail as is contained in the portion of the Development Plan and Development Budget that relates to the GTx/Ortho Development. However, this presentation and any subsequent discussion of the contents of the portion of the Development Plan and Development Budget related to the Ortho Development shall be for advisory purposes only.

(ii) All decisions by the JDC that relate to GTx/Ortho Development shall be made unanimously, after an open and informed discussion of the matters as to which decisions are being made, including, but not limited to those matters relating to the portion of the Development Plan and Budget directed to GTx/Ortho Development. If the JDC is unable to make a unanimous decision on such matters, the matter will be referred to the Executive Officers of GTx and Ortho. If such officers do not reach agreement on such matter within twenty (20) calendar days after it is referred to them, then subject to Section 4.1, the decision of Ortho on such matter will be final and determinative, so long as such decision does not contradict or modify the terms of this Agreement.



(f) Subcommittees of the JDC. The JDC will have the power to form subcommittees with equal (unless otherwise agreed in writing) and appropriate representation from GTX and Ortho.

ARTICLE III

LICENSING FEES; MILESTONE PAYMENTS; ROYALTIES; REPORTING

3.1 Licensing Fee.

(a) As partial payment for the licenses granted by GTX pursuant to this Agreement, Ortho shall pay to GTX a non-refundable, non-creditable \$6.0 Million license fee within fifteen (15) Business Days after the Effective Date of this Agreement. Payment shall be made by wire transfer.

(b) As a partial payment for the licenses granted by GTX pursuant to this Agreement, Ortho shall pay to GTX a non-refundable, non-creditable [ \* ] at the time that [ \* ] of a Collaboration Product for [ \* ]. Ortho will pay such amount within fifteen (15) Business Days after receipt of an invoice from GTX. Payment shall be made by wire transfer.

3.2 Milestone Payments. In addition to the payments due to GTX under Section 3.1, Ortho shall make the following non-refundable, non-creditable milestone payments to GTX after the first occurrence of each milestone that follows, unless, at anytime prior to the date on which such milestone payment is due, Ortho has provided notice of termination, which termination thereafter becomes effective. The payments set forth herein shall each be due and payable by Ortho within [ \* ] Business Days following receipt from GTX of a notice and invoice regarding the achievement of the milestone event set forth herein. Payment shall be made by wire transfer.

(a) First Collaboration Compound:

MILESTONE EVENT -----	PAYMENT -----
[ * ] in a Proof of Concept Trial of a Collaboration Product for the [ * ].**	[\$ [ * ]
[ * ] in a Proof of Concept Trial of a Collaboration Product for the [ * ].**	[\$ [ * ]
[ * ] in a Phase III Clinical Trial of a Collaboration Product [ * ] for the [ * ].	[\$ [ * ]
[ * ] in a Phase III Clinical Trial of a Collaboration Product [ * ] for the [ * ].	[\$ [ * ]
Regulatory Approval by the FDA of a Collaboration Product [ * ] for the [ * ].	[\$ [ * ]

MILESTONE EVENT -----	PAYMENT -----
Regulatory Approval by the FDA of a Collaboration Product [ * ] for the [ * ].	\$[ * ]
Regulatory Approval by the EMEA of a Collaboration Product [ * ] for the [ * ].*	\$[ * ]
Regulatory Approval by the EMEA of a Collaboration Product [ * ] for the [ * ].*	\$[ * ]
Regulatory Approval by the Koseisho of a Collaboration Product [ * ] for the [ * ].	\$[ * ]
Regulatory Approval by the Koseisho of a Collaboration Product [ * ] for the [ * ].	\$[ * ]

\*If a centralized filing with the EMEA is not made for the relevant Collaboration Product for the [ \* ], but the JDC decides to pursue Regulatory Approval in Europe using the mutual recognition procedure or on an individual country basis, then the milestone shall be deemed to be achieved upon the Launch Date for such Collaboration Product in the first Major European Country.

\*\* This trial is [ \* ] as proposed in [ \* ], as applicable, is the [ \* ].

For clarity, if a Collaboration Product is developed initially for [ \* ], such [ \* ] shall be the [ \* ]. If such development is successful and such product is commercialized for such [ \* ], and Ortho develops such Collaboration Product for [ \* ], such [ \* ] shall be a [ \* ]. If development of such Collaboration Product for such [ \* ] is terminated, but such product is then developed and commercialized for a [ \* ], then for the purpose of calculating milestones hereunder, any milestones that are due with respect to a [ \* ] that were not previously paid by Ortho for the Collaboration Product for a [ \* ] shall be due when such milestone is achieved for the [ \* ] (i.e., the [ \* ] would function as a [ \* ] for the purposes of this Section 3.2).

(b) Additional Collaboration Compounds:

MILESTONE EVENT -----	PAYMENT -----
[ * ] in a Proof of Concept Trial of a Collaboration Product [ * ].	\$[ * ]
[ * ] in a Phase III Clinical Trial of a Collaboration Product [ * ].	\$[ * ]

MILESTONE EVENT -----	PAYMENT -----
Regulatory Approval by the FDA of a Collaboration Product [ * ].	\$[ * ]
Regulatory Approval by the EMEA of a Collaboration Product [ * ].*	\$[ * ]
Regulatory Approval by the Koseisho of a Collaboration Product [ * ].	\$[ * ]

\*If a centralized filing with the EMEA is not made for the relevant Collaboration Product for the [ \* ], but the JDC decides to pursue Regulatory Approval in Europe using the mutual recognition procedure or on an individual country basis, then the milestone shall be deemed to be achieved upon the Launch Date for such Collaboration Product in the first Major European Country.

(c) Replacement Collaboration Compound. If the JDC (or Ortho, with respect to Ortho Development) decides to cease Development of Andarine or another Collaboration Compound that the Parties Develop in addition to Andarine and decides to Develop, instead of the Collaboration Compound for which Development was so terminated, another Collaboration Compound (a "Replacement Collaboration Compound"), Ortho shall not be obligated to make the same milestone payments for the Replacement Collaboration Compound as it already made in connection with the Collaboration Compound which was replaced, and shall only be obligated to make any milestone payments for the Replacement Collaboration Compound that were not made for the Collaboration Compound that was replaced by such Replacement Collaboration Compound. It is understood that in no event shall Ortho be obligated to make the payment due pursuant to this Section 3.2 on any milestone more than once with respect to the same Collaboration Compound (or its "Replacement Collaboration Compound") regardless of the number of different forms or formulations of the Collaboration Compound that are developed[ \* ].

3.3 Limitation on Milestone Payments. Other than the milestone payments recited in Section 3.2, Ortho shall not be obligated to make any other milestone payments in connection with Andarine, a Replacement Collaboration Compound, or any Additional Collaboration Compound.

3.4 Royalty Rates. Ortho shall pay to GTx an incremental, tiered royalty equal to the applicable royalty rate set forth below multiplied by the relevant portion of annual Royalty Bearing Sales of each Collaboration Product sold in the Royalty Bearing Territory as follows:

Portion of Annual Net Sales of Each Collaboration Product -----	Rate -----
First \$[ * ]	[ * ]
> \$[ * ] and < or = \$[ * ]	[ * ]
> \$[ * ] and < or = \$[ * ]	[ * ]
> \$[ * ] and < or = \$[ * ]	[ * ]
> \$[ * ] and < or = \$[ * ]	[ * ]
> \$[ * ]	[ * ]

Said royalty shall be calculated as follows: Assume [ \* ] of Net Sales of a Collaboration Product in a calendar year, the royalty would be [ \* ] = a royalty of [ \* ].

3.5 Payment of Royalties. Within twenty (20) Business Days after the end of each calendar quarter for which royalty fees are payable by Ortho to GTX with respect to Net Sales in the Royalty Bearing Territory pursuant to Section 3.4, Ortho shall submit to GTX a report, on a country by country basis, providing in reasonable detail an accounting of all Net Sales (including an accounting of all unit sales of Product) made during such calendar quarter and the calculation of such applicable royalty fees under Section 3.4. Within twenty (20) Business Days after submission of such report, Ortho shall pay GTX all royalties payable by it under Section 3.4 as indicated in the report by wire transfer. Ortho will pay GTX royalties on Net Sales of each Collaboration Product invoiced by Ortho, its Affiliates and its sublicensees at the rates shown in Section 3.4 above.

(a) Royalties shall be payable on a product by product and country by country basis until the later of (i) the expiration of the last to expire Valid Claim of a GTX Patent or a Joint Patent claiming the composition of matter for such Collaboration Product in such country (either, a "Relevant Valid Claim"), or (ii) ten (10) years following the Launch Date of such Collaboration Product in such country (such period of time, the "Royalty Term") where there are no patents.

(b) Royalties shall be paid at the rate set forth in Section 3.4 during the Royalty Term, except in a given country where (A) no Relevant Valid Claim covering the composition of matter of such Collaboration Product exists during a calendar quarter for which royalties are being calculated under Section 3.4, and (B) Market Exclusivity does not exist for such Collaboration Product in such country [ \* ] immediately prior to the [ \* ]. If the conditions of (A) and (B) are satisfied, then the royalty rates set forth in Section 3.4 shall be reduced for sales occurring during such calendar quarter by:

[ \* ], if the number of units of Collaboration Products invoiced by Ortho, its Affiliates or sublicensees in such country are [ \* ] of the number of all units of products (including Collaboration Products) containing the Active Ingredient contained in such Collaboration Product (such number, "All Units") that are sold in such country;

[ \* ], if the number of units of Collaboration Products invoiced by Ortho, its Affiliates or sublicensees in such country are [ \* ] of All Units that are sold in such country;

[ \* ], if the number of units of Collaboration Products invoiced by Ortho, its Affiliates or sublicensees in such country are [ \* ] of All Units that are sold in such country; or

[ \* ], if the number of units of Collaboration Products invoiced by Ortho, its Affiliates or sublicensees in such country are [ \* ] of All Units that are sold in such country.

Market Exclusivity shall be deemed to exist during the [ \* ] following the Launch Date in each country.

### 3.6 Payment of Third Party Royalties.

(a) In addition to the royalties of Section 3.4, [ \* ] shall [ \* ] any royalties due by GTX to UTRF under the Amended and Restated License Agreement between GTX and UTRF dated June 3, 2002, and the Amended and Restated License Agreement between GTX and UTRF dated June 14, 2002 (collectively, the "UTRF Agreements"), with respect to the sale of Collaboration Products by Ortho, its Affiliates or sublicensees. [ \* ] shall make such payments [ \* ]. Specifically, [ \* ] shall deliver to UTRF true and accurate reports as required under Section 5.2 of the UTRF Agreements, and shall pay all royalties due to UTRF under Section 4.2 of the UTRF Agreements within the time periods required therein. [ \* ] shall provide copies of each such report to [ \* ] simultaneously with its delivery of such report to UTRF. In no event shall any amounts paid by [ \* ] hereunder be included as [ \* ].

(b) If a Royalty Bearing Product is being sold in any country with respect to which a Third Party owns or Controls a patent, from which GTX has not obtained a license, and such Third Party is entitled to receive royalties pursuant to a patent license required in order to make or sell the composition of matter of the Collaboration Compound included in such Royalty Bearing Product, then Ortho shall be entitled to [ \* ] of any royalty paid to such Third Party against amounts due to GTX pursuant to Sections 3.4 and 3.5, provided, however, that in no event shall the royalty due to GTX pursuant to Sections 3.4 and 3.5 be reduced by means of such offset to [ \* ] of the royalty otherwise payable thereunder.

3.7 Ortho's Rights Upon Expiration of Royalty Term. Upon expiration of the royalty term for a Royalty Bearing Product in a country as described above, Ortho shall thereafter have a paid-up, non-exclusive license under the GTX Know-How to make, have made, use, sell, offer for sale, have sold and import that Royalty Bearing Product in that country.

3.8 Compulsory License. If at any time and from time to time a Third Party in any country shall, under the right of a compulsory license granted or ordered to be granted by a competent governmental authority, manufacture, use or sell any Collaboration Product, with respect to which royalties would be payable to GTX pursuant to this Article, then Ortho may reduce the royalty on sales in such country of such Collaboration Product, to [ \* ].

3.9 Sales by Sublicensees. In the event Ortho, subject to the provisions of this Agreement, grants licenses or sublicenses to others to make or sell Royalty Bearing Products, such licenses or sublicenses shall include an obligation for the licensee or the sublicensee to account for and report its Royalty Bearing Sales of such Royalty Bearing Products on the same basis as if such sales were Royalty Bearing Sales by Ortho, and Ortho shall pay royalties to GTX as if the Royalty Bearing Sales of Ortho.

### 3.10 Tax Matters.

(a) Ortho Payments to GTX Without Withholding. Ortho will make all payments to GTX under this Agreement without deduction or withholding for Taxes except to the extent that any such deduction or withholding is required by law in effect at the time of payment; provided that Ortho shall use commercially reasonable efforts to minimize any such required deductions or withholdings to the extent permitted by applicable laws, rules and regulations.

(b) Ortho Payment of Tax. Any Tax required to be withheld on amounts payable under this Agreement will promptly be paid by Ortho on behalf of GTX to the appropriate governmental authority, and Ortho will furnish GTX with proof of payment of such Tax. Any such Tax required to be withheld will be an expense of and borne by GTX. Ortho will give notice of its intention to begin withholding any such Tax in advance and cooperate to use reasonable and legal efforts to reduce such Tax on payments made to GTX hereunder.

(c) Cooperation Between Ortho and GTX. Ortho and GTX will cooperate with respect to all documentation required by any government taxing authority or reasonably requested by Ortho to secure a reduction in the rate of applicable withholding Taxes.

(d) GTX Indemnification for Ortho's Failure to Withhold. If Ortho had a duty to withhold Taxes in connection with any payment it made to GTX under this Agreement but Ortho failed to withhold, and such Taxes were assessed against and paid by Ortho, then GTX will indemnify and hold harmless Ortho from and against such Taxes. Notwithstanding anything to the contrary in this Section, GTX shall not be responsible for indemnifying Ortho for interest and penalties attributable to any period [ \* ] written notice of such assessment or proposed assessment to Ortho and ending on the date Ortho provides GTX written notice of such assessment or proposed assessment, and provided further that GTX shall be entitled to protest the assessment of such Tax. If Ortho makes a claim under this Section 3.10(d), it will comply with the obligations imposed by Section 3.10(b) as if Ortho had withheld Taxes from a payment to GTX.

(e) Tax. Solely for purposes of this Section, "Tax" or "Taxes" means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including interest, penalties and additions thereto) that are imposed by a government taxing authority on GTX's receipt of payments hereunder. Notwithstanding the foregoing, "Tax" or "Taxes" shall not include charges, value-added taxes, taxes

imposed on Ortho's income, or assessments or fees of any nature (or any interest, penalties or additions thereto) imposed by the FDA or any related or successor agency.

(f) Protest. Ortho shall promptly notify GTX in writing of any assessment, proposed assessment or other claim for any additional amount of Tax assessed by the United States. Notwithstanding any other provision of this Section, GTX may, at its own expense, protest any assessment, proposed assessment, or other claim by any governmental authority for any additional amount of Tax or seek a refund of such amounts paid if permitted to do so by law or if the payment of such amounts are its ultimate contractual responsibility under the terms of this Agreement. Ortho shall cooperate with GTX in any protest by providing records, giving testimony and providing such additional information or assistance as may reasonably be necessary to pursue such protest.

3.11 United States Dollars. All dollar (\$) amounts specified in this Agreement are United States dollar amounts.

3.12 Payments to or Reports by Affiliates. Any payment required under any provision of this Agreement to be made to either Party, or any report required to be made by any Party, shall be made to or by an Affiliate of that Party if such Affiliate is designated by that Party as the appropriate recipient or reporting entity.

3.13 Payment of Additional Royalties. GTX shall receive an additional royalty on sales of Collaboration Products that it Co-Promotes, as set forth in Sections 7.1 and, if applicable, 13.6.

3.14 Payments by Wire Transfer. Any payments due to GTX hereunder shall be made by wire transfer to the following (or as provided in any alternative instructions that GTX may provide by written notice to Ortho from time to time):  
[ \* ].

#### ARTICLE IV

#### DEVELOPMENT

4.1 Development Responsibility. Ortho will be solely responsible for Development of all Collaboration Products and, as a result, shall be responsible for carrying out Development pursuant to the Development Plan including both Ortho Development and GTX/Ortho Development. While Ortho is solely responsible for Development, GTX agrees to carry out tasks under the Development Plan, if any, reasonably assigned to it with respect to GTX/Ortho Development, pursuant to the mutual agreement of the Parties.

#### 4.2 Development Plan.

(a) Development Carried Out Pursuant to Development Plan and Development Budget. The Development of each Collaboration Compound shall be

carried out pursuant to a development plan ("Development Plan") and development budget ("Development Budget"). An outline of the Development activities the Parties intend to carry out during 2004 and 2005 is attached as Exhibit C (the "Initial Plan"). The Parties will agree upon a preliminary Development Plan and Development Budget [ \* ] after the Effective Date that sets forth the Development activities to be performed by the Parties during 2004 and 2005, together with a budget therefor. [ \* ] after the Effective Date, such Development Plan and Development Budget shall be expanded to include other Development activities and related budgets to be conducted for Collaboration Products. The Development Plan and Development Budget will be updated by Ortho on an annual basis.

(b) GTX to Provide Ortho With Information Necessary for Development. GTX shall provide Ortho with access to (and copies of, which may be in partially or wholly electronic form, to the extent requested) all of the raw data and reports related to the Development of any of the Collaboration Compounds and/or Collaboration Products, including those Developed by the GTX/Ortho Development and those Developed by the Ortho Development, provided that in no event will GTX be obligated to provide to Ortho any such information that relates also to compounds described in Section 1.36(1) but not Section 1.36(2), unless such information is reasonably necessary for the Development of Collaboration Compounds.

(c) Content of Development Plan. The Development Plan shall describe the proposed overall program of all the Development, including, but not limited to, Pre-Clinical Studies, toxicology, formulation, chemical process development, Clinical Studies, regulatory plans and other elements of obtaining Regulatory Approval, and projected timelines for the Development events. The Development Plan will specify Party-specific execution responsibilities of the program expected during the Development (consistent with this Agreement) through obtaining Regulatory Approval for each Collaboration Compound and/or Collaboration Product, and shall further include a Development Budget for all Development proposed. The Development Plan for the Development will identify endpoints needed for initiation of the next phase of the Development.

#### 4.3 Development Efforts.

(a) In carrying out the Development and the Development Plan, Ortho agrees to use the level of time, effort and funding as is consistent with that expended on other Ortho projects at a similar stage of Development with a target market of similar size and importance. Ortho's failure to comply with such diligence obligations shall constitute a breach of this Agreement.

(b) Specifically, and without limiting Section 4.3(a), Ortho shall use commercially reasonable efforts to conduct the activities set forth in the Initial Plan.

4.4 Drug Approval Applications. Consistent with the Development Plan, Ortho shall be responsible for the filing of all Drug Approval Applications and seeking Regulatory Approvals for Collaboration Compounds and/or Collaboration Products. The



Parties shall consult and cooperate in the preparation of each such Drug Approval Application and in obtaining Regulatory Approvals. Ortho shall solely own all Drug Approval Applications and Regulatory Approvals. [ \* ] after GTX provides Ortho with a top line summary of completion of the clinical trial that GTX is currently conducting that it has deemed to be a Phase ID clinical trial as described in the Initial Plan [ \* ] (the "Phase ID Clinical Trial"), GTX shall transfer or assign its ownership of IND No. [ \* ] to Ortho or its Affiliate as designated by Ortho, and shall take such other actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights hereunder to Ortho or its Affiliate as designated by Ortho.

#### 4.5 Development Expenses.

(a) GTX Development Expenses. GTX's Development Expenses incurred after the Effective Date in connection with its personnel's Development efforts shall be calculated [ \* ], and Development Expenses incurred by GTX shall also include any amounts paid by GTX to Third Parties that otherwise qualify as Development Expenses, which shall be reimbursed as provided in subsection (b) below.

(b) Ortho to Reimburse GTX for Development Expenses. Ortho shall reimburse GTX for its costs of conducting the Phase ID Clinical Trial that GTX incurs prior to the Effective Date by paying to GTX an amount not to exceed \$ 687,000 within thirty (30) Business Days after receipt of an invoice. In the event that GTX incurs any Development Expenses after the Effective Date, such expenses shall initially be borne by GTX, subject to reimbursement as provided herein. Each Party shall calculate and maintain records of Development Expenses incurred by it. GTX shall report quarterly to Ortho its Development Expenses, with such reports to be submitted within twenty (20) Business Days after the end of each calendar quarter of each calendar year. The Parties shall seek to resolve any questions related to such accounting statements within ten (10) Business Days following receipt. Ortho shall reimburse GTX for any undisputed Development Expenses GTX incurred within thirty (30) Business Days of receiving the GTX report. If Ortho disputes its obligation to reimburse any Development Expenses for which GTX seeks reimbursement hereunder, such dispute shall be submitted for resolution pursuant to Article XV.

4.6 Replacement Collaboration Compounds; Additional Collaboration Compounds. At any time, Ortho may select a Collaboration Compound other than Andarine for Development pursuant to this Agreement in addition to Andarine, which shall be an Additional Collaboration Compound. Furthermore, if the Ortho determines that further Development of Andarine or an Additional Collaboration Compound, if any, is not desirable, then it may select another Collaboration Compound to replace Andarine or such Additional Collaboration Compound (and such replacement compound shall be a "Replacement Collaboration Compound"). In either of the foregoing events, within forty-five (45) calendar days after the selection of such Additional Collaboration Compound or Replacement Collaboration Compound, then Ortho shall update the then-current Development Plan and Development Budget to provide for Development of such compound.

## ARTICLE V

### LICENSES

#### 5.1 Patent Licenses to Conduct Development.

(a) Subject to the terms and conditions of this Agreement, GTX grants to Ortho an exclusive (except as to GTX), royalty-bearing, worldwide license under the GTX Patents to conduct Development of Collaboration Products pursuant to the Development Plan.

(b) Subject to the terms and conditions of this Agreement, Ortho grants to GTX a non-exclusive, paid-up, worldwide license under the Ortho Patents to conduct GTX's responsibilities under the Development Plan with respect to Collaboration Products.

#### 5.2 Patent Licenses to Conduct Commercialization Activities.

(a) Subject to the terms and conditions of this Agreement, GTX hereby grants to Ortho an exclusive (even as to GTX), royalty-bearing, worldwide license, with the right to grant sublicenses, under GTX Patents for GTX SARM Compounds to make, have made, use, sell, have sold, offer for sale, import, export, and distribute Collaboration Products. Notwithstanding the foregoing, GTX shall retain the right under the GTX Patents to Co-Promote Collaboration Products in the Co-Promotion Territory to the GTX Audience if it exercises its right to Co-Promote such Collaboration Products under Section 6.2.

(b) Subject to the terms and conditions of this Agreement, Ortho hereby grants to GTX a non-exclusive, fully-paid, worldwide license, without the right to grant sublicenses, under the Ortho Patents to use, sell, and offer for sale Collaboration Products in the Co-Promotion Territory to the GTX Audience if it exercises its right to Co-Promote such Collaboration Products under Section 6.2.

#### 5.3 Know-how Licenses.

(a) Subject to the terms and conditions of this Agreement, GTX grants Ortho, an exclusive (except as to GTX), royalty-bearing, worldwide license to use GTX Know-how to Develop and/or Commercialize Collaboration Products pursuant to the terms of this Agreement.

(b) Subject to the terms and conditions of this Agreement, Ortho hereby grants to GTX a non-exclusive, fully-paid, worldwide license, without the right to grant sublicenses, under the Ortho Know-How to perform its obligations under the Development Plan to Develop Collaboration Products, and to use, sell, and offer for sale Collaboration Products in the Co-Promotion Territory to the GTX Audience if it exercises its right to Co-Promote such Collaboration Products under Section 6.2.

5.4 Distribution Through Third Party Distributors. GTx grants Ortho the right to sell or distribute Collaboration Products through its Affiliates or Third Parties in any country, except as otherwise provided in Section 5.5.

5.5 Sublicensing. Ortho may grant sublicenses under Sections 5.1, 5.2, 5.3 and 5.6 provided, however, that Ortho may not grant sublicenses or rights to any Third Party (but may grant sublicenses or rights to its Affiliates) for the purpose of selling, offering for sale, or distributing Collaboration Products in the Co-Promotion Territory.

5.6 Third Party Technology. The licenses granted under this Article include sublicenses of Third Party technology to the extent that such sublicenses can be so granted. To the extent the licenses include sublicenses of Third Party technology, the licenses and rights granted to either Party under such Third Party technology in any event, shall be subject to the terms and conditions of the license agreement pursuant to which the underlying license, and the sublicensing rights thereunder, were granted.

5.7 No Implied Licenses; Retained Rights. Each Party retains all rights under its Patents and know-how that are not expressly granted to the other Party pursuant to this Agreement. Additionally, notwithstanding anything to the contrary in this Article V, GTx retains the right under the GTx Patents and GTx Know-how to use Collaboration Compounds and Collaboration Products in its internal research and development efforts other than for the purpose of Developing or Commercializing Collaboration Compounds or Collaboration Products, which it shall perform only pursuant to this Agreement. Furthermore, Ortho acknowledges that the licenses provided to it in Sections 5.1 through 5.3 do not grant to Ortho any rights to practice the technology claimed in the GTx Patents in connection with the development or commercialization of compounds that are not Collaboration Compounds, including without limitation Excluded SARM Compounds.

5.8 Independent Research. Except with respect to the GTx SARM Compounds defined in Section 1.36, each Party is free to develop other pharmaceutical products independent of this Agreement, including without limitation, any other SARM products that are not Collaboration Products. Neither Party has an obligation to disclose information relating to medicinal chemistry or other topics relating to SARMS, except to the extent such information may relate to Collaboration Compounds or Collaboration Products.

## ARTICLE VI

### COMMERCIALIZATION

6.1 Ortho as Marketing Party. Ortho will be the marketing Party with respect to all Collaboration Products. As marketing Party Ortho shall have full and exclusive decision making authority with respect to all Commercialization Activities for all Collaboration Products, provided that such decisions are consistent with this Agreement and except as otherwise set forth in this Agreement.

6.2 GTX's Option to Co-Promote in the United States. GTX shall have an option to provide Details in the United States for each Collaboration Product Developed pursuant to the GTX/Ortho Development to urologists who are licensed to practice in the United States, provided that GTX meets the requirements set forth in this Article VI, and subject to the provisions of Section 6.3 and 6.7. Any such activities conducted by GTX pursuant to this Article VI, if GTX exercises such option, shall be deemed "Co-Promotion." GTX may exercise its option to Co-Promote on a Product by Product basis, and a decision not to Co-Promote a specific Product shall not affect GTX's rights to Co-Promote any other Product under this Agreement. However, if GTX fails to exercise its option to Co-Promote any specific Product, or later terminates its Co-Promotion of such Product, such non-exercise or termination shall be irrevocable as for such Product. Additional Collaboration Products will be Co-Promoted under the same terms as recited herein with respect to the first Collaboration Product.

6.3 GTX to Notify Ortho of its Election to Co-Promote; Changes in the GTX Audience.

(a) GTX may exercise its option by informing Ortho in writing of its decision to exercise the Co-Promotion option for a Collaboration Product [ \* ] after [ \* ]. Upon GTX's exercise of such option, the United States shall become the Co-Promotion Territory with respect to such Collaboration Product, GTX shall have the right to perform Details targeting the GTX Audience (determined in accordance with Section 6.3(b)) with respect to such Collaboration Product, and the provisions of Article VII shall be used in determining additional compensation to be paid to GTX.

(b) GTX shall have the right to Co-Promote Collaboration Products to all of the practicing urologists in the United States, and to elect to include a portion of, or all of, such physicians in the GTX Audience, subject to Section 6.7 and this Section 6.3. Within [ \* ] after GTX first exercises its right to Co-Promote, GTX shall provide to Ortho a list of urologists licensed to practice in the United States that will constitute the GTX Audience, for Ortho's approval thereof, which shall not be unreasonably withheld or delayed, and which approval or disapproval shall be consistent with this Agreement. GTX shall periodically [ \* ] update the list of urologists that constitute the GTX Audience, provided that any such change shall not become effective until [ \* ] after Ortho receives any updated list from GTX, and further provided that such changes shall be in accordance with Section 6.3(c). Ortho shall have [ \* ], and [ \* ] consistent with this Agreement. Except as provided in Section 6.7, GTX shall have the exclusive right to provide Details for the GTX Audience.

(c) During the time GTX is Co-Promoting a Product, GTX shall not have the right to alter the number of physicians included in the GTX Audience for a given Product by [ \* ] in any given [ \* ] commencing after GTX begins to Co-Promote such Product without Ortho's approval, which shall not be unreasonably withheld or delayed and which shall be consistent with this Agreement. GTX shall notify Ortho in writing of any such change in the number of physicians included in the GTX Audience [ \* ] before the end of any relevant [ \* ] for which it desires such increase to apply. Additionally, if GTX has elected to Co-Promote Products pursuant to this Article VI but has not

performed its obligations under Section 6.6(a)(iv), and therefore has [ \* ], then GTX shall have the right to increase the proportion of the GTX Audience to which it has the right to provide Details by [ \* ] in each [ \* ] following the [ \* ] of GTX's commencement of Co-Promotion of such Products, provided that GTX gives written notice to Ortho [ \* ] before the end of any relevant [ \* ] during which it is then Co-Promoting such Product to less than all of the GTX Audience stating the proportion of the GTX Audience by which GTX desires to increase its Detailing efforts during the [ \* ]. For clarity, GTX may only increase the proportion of the GTX Audience to which it will Co-Promote if GTX has [ \* ].

6.4 Marketing and Sales Committee. Ortho and GTX will form a Marketing and Sales Committee [ \* ] to the first anticipated Launch Date. The Marketing and Sales Committee shall meet from time to time [ \* ], at mutual agreeable times and locations, to discuss and coordinate the Marketing and Co-Promotion of the Collaboration Product, including but not limited to, the assignment of Details and to discuss the Marketing and Sales Plan. Ortho will have the final responsibility (subject to GTX's rights to Co-Promote), with the cooperation and assistance of GTX for defining the resources required for the marketing and sale of the Collaboration Product, and for establishing Detailing, Marketing, pricing and promotion strategies with respect to the Collaboration Product and budgets therefor. Any disagreements or disputes arising from the Marketing and Sales Committee shall be resolved in a matter consistent with [ \* ] this Agreement.

6.5 Marketing and Sales Plan. [ \* ] to the first anticipated Launch Date, Ortho shall prepare and present to the Marketing and Sales Committee for its review and comment on a Marketing and Sales Plan. The Marketing and Sales Plan shall set forth, among other items, Detailing and Marketing strategies for each Collaboration Product, and shall specify the level of marketing efforts anticipated for licensed urologists in the United States. The Marketing and Sales Plan shall be updated at least annually by Ortho and presented to the Marketing and Sales Committee for review and comment. The Marketing and Sales Plan shall set the required number of Details to be provided by each of the Parties (as applicable). Additionally, the Marketing and Sales Plan may not be modified to provide for material increases in the number of Details to be provided by GTX for Collaboration Products to be Co-Promoted by GTX in the [ \* ] following the effective date of such update without GTX's prior written consent.

6.6 Requirements for GTX Co-Promotion. In order for GTX to be eligible for Co-Promotion of a given Collaboration Product, GTX must meet the following requirements:

(a) GTX shall have the following infrastructure in place for each Collaboration Product at the following times:

(i) [ \* ] after providing Ortho with written notice of its intent to Co-Promote under Section 6.3, GTX shall [ \* ];

(ii) [ \* ] to the estimated Marketing Date (as defined below in this Section 6.6) for the Collaboration Product, GTX must have [ \* ];

(iii) [ \* ] to the estimated Marketing Date for the Collaboration Product, GTX must have [ \* ]; and

(iv) [ \* ] to the estimated Marketing Date for the Collaboration Product, GTX must [ \* ], and shall have [ \* ].

(b) To enable GTX to plan its compliance with the requirements of this Section 6.6, Ortho shall keep GTX informed of its good faith estimates of the Marketing Date of each Collaboration Product in the United States. If any such estimate provided by Ortho is subsequently modified so that the Marketing Date is projected to occur earlier than previously estimated, then GTX shall not be in breach of this Section 6.6 so long as it is using commercially reasonable efforts to perform its obligations under this Section 6.6.

(c) "Marketing Date" shall mean, for a Collaboration Product, either the Launch Date of such Collaboration Product, if such date has not occurred prior to the time that GTX exercised its option to Co-Promote such Product, or the first anticipated date upon which Ortho plans to commence its marketing campaign for such Collaboration Product [ \* ] for which the GTX Audience may prescribe such products, if the Launch Date for such Collaboration Product has previously occurred.

#### 6.7 Co-Promotion Sales Forces.

(a) If GTX exercises its option to Co-Promote a given Collaboration Product, Ortho and GTX shall deploy their respective sales forces to Detail the Collaboration Product as required by the Marketing and Sales Plan. In conducting such Detailing, Ortho and GTX shall comply with all applicable laws and shall use commercially reasonable efforts consistent with accepted pharmaceutical industry business practices (including, but not limited to, the relevant American Medical Association Guidelines). No Party shall be required to undertake any activity under this Agreement which it believes, in good faith, may violate any law. The GTX sales force shall abide by the same ethical conduct guidelines as the Ortho sales force, including, but not limited to any healthcare compliance guidelines issued by any U.S. government organization.

(b) The GTX sales force promoting Collaboration Products shall include [ \* ].

(c) GTX shall keep Ortho informed of the status of its efforts to meet its Co-Promotion requirements. If GTX believes it will not meet the requirements set forth in Section 6.6(a), GTX shall notify Ortho. If Ortho believes that GTX has failed, or is likely to fail, to meet the foregoing requirements, it shall so notify GTX in writing and the Parties shall thereafter discuss whether any such failure has occurred, and appropriate steps and time periods for GTX to thereafter cure any such failure, for a period of [ \* ]. Resolution of any outstanding issues will be conducted through the Marketing and Sales Committee pursuant to Section 6.4.

(i) Any failure by GTX to comply with the requirements of Section 6.6 (other than subsection 6.6(a)(iv)) shall give rise to Ortho's ability to terminate

GTx's ability to Co-Promote the relevant Collaboration Product upon written notice to GTx (which shall not become effective until expiration of the foregoing discussion or cure period), but shall not be deemed to be a breach of this Agreement giving Ortho the right to terminate this Agreement. In the event of any failure by GTx to comply with subsection (iv), GTx shall continue to have the right to Co-Promote Collaboration Products to the GTx Audience, but [ \* ], and Ortho may [ \* ]. For example, if GTx [ \* ], then it may [ \* ] and Ortho may [ \* ]. In such event, after such [ \* ], GTx shall have the right to [ \* ], provided that it has then [ \* ], and further provided that [ \* ].

6.8 Sales Force Training. GTx sales representatives who will be Co-Promoting Collaboration Product hereunder will be trained by Ortho together with Ortho's sales representatives at a location to be determined by Ortho. Ortho shall [ \* ], provided that GTx shall [ \* ].

6.9 GTx Sales Force. All Detailing carried out hereunder by GTx shall be [ \* ]. Except as provided in Section 6.8, [ \* ], including, but not limited to, [ \* ]. In addition, GTx shall, consistent with customary pharmaceutical business practice and all applicable laws, rules and regulations, [ \* ] in accordance with the Marketing and Sales Plan. GTx may not [ \* ], unless approved in writing by Ortho in advance.

6.10 Detail Reports. GTx, [ \* ] after the end of each month, will provide to Ortho on an electronic medium a record of its Detailing activity by [ \* ]. This file will provide information on all Details [ \* ], along with information regarding samples, if any, that [ \* ]. Once submitted to Ortho, such Detail report described herein may not be revised by GTx and payments described in Section 7.1 shall be based on the information contained in such Detail report, subject, however, to revisions, if any, to the detail report from an audit under Section 6.11.

6.11 Co-Promotion Audit of Performance. Ortho shall have the right to review and audit, not more than once per year, GTx's Detail records during regular business hours, upon reasonable notice, to confirm satisfaction of the obligations set forth in this Article VI. GTx may redact such records if necessary to protect confidentiality of portions of such records unrelated to Collaboration Products. Ortho shall provide to GTx a copy of the results of any such audit. If, after such review, the Parties are unable to agree as to the results of Ortho's audit, Ortho may demand a verification of such audit of GTx's Detail reports to be conducted by a mutually agreed upon auditor, such verification to be at Ortho's sole expense. In addition, Ortho representatives may accompany GTx sales representative on Details to monitor their performance. Furthermore, Ortho may audit GTx's Detailing performance using [ \* ] or other commercially developed service or product.

6.12 Failure to Perform. If, based on the Detail reports GTx submits (as revised based on any audit described in Section 6.11), GTx fails to conduct [ \* ] of the Details it is required to provide (taking into consideration the adjustments to such level that GTx is permitted to make pursuant to Section 6.7(c)), as set forth in the Marketing and Sales Plan, for [ \* ], it shall be considered in breach of this Article VI and Ortho may terminate GTx's right to Co-Promote hereunder by giving GTx thirty (30) calendar days'

advance written notice of the termination of its Co-Promotion right hereunder. However, such breach shall not be considered a material breach giving Ortho the right to terminate this Agreement under Section 13.2.

6.13 Medical Inquiries. Ortho shall respond to all medical questions or inquiries relating to the Collaboration Product being Co-Promoted hereunder, which are directed to each Parties' respective sales representatives, unless such question or inquiry can be answered by reference to the FDA approved labeling and package insert. Ortho shall designate a medical liaison to whom GTX shall instruct the GTX sales force to direct medical questions or inquiries relating to the Co-Promoted Collaboration Product.

6.14 Governmental Contact. GTX shall notify Ortho's Regulatory Affairs Department upon being contacted by the FDA or any state drug regulatory agency or any comparable governmental agency in the Co-Promotion Territory with respect to the Co-Promoted Collaboration Product. Ortho shall retain responsibility for communicating with all such governmental agencies and responding to any contacts or inquiries of such agencies.

6.15 Regulatory Disputes/Lawsuits. Ortho shall retain exclusive authority and responsibility for handling, in any manner it deems appropriate, any disputes or law suits with any agencies regarding the regulatory status of the Co-Promoted Collaboration Product.

6.16 Sales. All sales of Collaboration Products in the Co-Promotion Territory shall be booked by Ortho. Ortho shall have the right to reject any order received by it for a Collaboration Product; provided, however, that Ortho shall not reject orders on an arbitrary basis, but only with reasonable justification and consistent with the general policies applied by it with respect to orders for other similar pharmaceutical products sold by it.

6.17 Orders. A sales representative's only in-state activity is solicitation of orders by company representatives for sales of tangible personal property, which orders are sent outside the state (except NJ) for approval or rejection and if approved, are filled by shipment or delivery from a point outside the state (except NJ). "Solicitation of Orders" is defined as encompassing "requests for purchases" as well as "those activities that are ancillary to requests for purchases, those that serve no independent business function apart from their connection to the soliciting of orders. GTX is not authorized to solicit or accept any sales orders for the Co-Promoted Collaboration Products. If, for any reason, GTX receives a sales order for the Co-Promoted Collaboration Product, GTX shall promptly forward such orders to Ortho.

6.18 Co-Promotion Limitation of Scope. The scope of the Co-Promotion for GTX will be limited specifically to [ \* ]. The Marketing and Sales Plan shall set the required number of Details for each of the Parties.

6.19 Commercialization Efforts. Ortho shall use reasonable efforts consistent with its normal business practices to Commercialize the Collaboration Product in those



countries in which it has obtained Regulatory Approval. Without limiting the foregoing, Ortho shall effect a Marketing Date in the United States [ \* ] of obtaining Regulatory Approval of a Collaboration Product by the FDA.

6.20 Commercialization in Royalty Bearing Territory. Commercialization of Collaboration Products in the Royalty Bearing Territory, except to the extent of GTX's right to Co-Promote Collaboration Products to the GTX Audience, shall be conducted independently by Ortho and decisions regarding, for example, pricing, advertising, and product recalls shall be the sole responsibility of Ortho.

6.21 Pricing, Pricing Approvals and Product Distribution. Ortho shall set all prices for all Collaboration Products in all territories, shall obtain pricing and reimbursement approvals for Collaboration Products as may be required, shall be responsible for distribution of each Collaboration Product worldwide Territory and shall book all sales for Collaboration Products.

6.22 Product Recalls. If Ortho believes that a recall of a Collaboration Product is necessary, Ortho shall promptly undertake, at its sole expense, such recall following notification to GTX. The decision of Ortho concerning such recall shall be final.

6.23 Advertising and Promotion. With respect to printed promotional (including all advertisements and DTC-programs appearing in journals) materials or printed educational materials for Collaboration Products, Ortho shall be solely responsible for the content of such materials and the preparation thereof, at Ortho's sole expense.

6.24 GTX Right to Opt Out of Co-Promotion. At any time after it exercises its option to Co-Promote a given Collaboration Product, GTX may elect by [ \* ] advance written notice to Ortho to cease Co-Promotion of such Collaboration Product. After any such election by GTX, GTX shall cooperate with Ortho to transition responsibility for providing Details to the GTX Audience for such Collaboration Product to Ortho. GTX's rights under this Section 6.24 shall apply on a product by product basis.

6.25 Additional Support by GTX. If Ortho desires GTX to participate in Marketing Activities other than providing Details for Collaboration Products, such as by [ \* ], the Parties shall discuss the proposed activities. If GTX agrees in writing to conduct such activities, the Marketing and Sales Plan shall be revised to reflect such activities [ \* ].

ARTICLE VII

CO-PROMOTION PAYMENT

7.1 Additional Royalty. For any Collaboration Product that is Co-Promoted by GTX to the GTX Audience, GTX shall at a minimum first earn a royalty as set forth in Section 3.4 in the Co-Promotion Territory. GTX shall also earn an Additional Royalty with respect to sales of Collaboration Products that GTX Co-Promotes, which will be calculated as follows:

(a) Twenty (20) Business Days after the end of each calendar quarter, Ortho will determine, using data obtained from Third Party sources reasonably acceptable to GTX, the total number of prescriptions written for the Collaboration Product(s) by the GTX Audience and filled by the pharmacy during the preceding quarter, and shall provide to GTX a detailed calculation of the royalty due to GTX pursuant to this Section 7.1 along with a copy of the Third Party information upon which such calculation is based. Ortho shall pay all royalties due to GTX pursuant to this Section 7.1 within twenty (20) Business Days after submission of such report to GTX.

(b) The following formula will be used to calculate the Additional Royalty owed to GTX for the preceding quarter:

[ \* ]

wherein

[ \* ]

The Additional Royalty shall not be subject to any offsets or reductions that may be applicable to royalties due to GTX pursuant to Section 3.4. GTX shall have the right to audit Ortho's records to confirm the accuracy of payments made hereunder as provided in Section 12.4.

7.2 Term. Ortho shall pay the Additional Royalty as provided under this Article 7 with respect to each Collaboration Product Co-Promoted in the Co-Promotion Territory to the GTX Audience until such Collaboration Product is permanently withdrawn from, or is no longer being Co-Promoted in, the Co-Promotion Territory.

ARTICLE VIII

MANUFACTURE AND SUPPLY

8.1 Manufacture and Supply During Development. Ortho will be solely responsible for the manufacture of Collaboration Products for use during the Development of Collaboration Products as provided in this Agreement, except that following the Effective Date, GTX shall remain responsible for the manufacture of Collaboration Products until the Parties transition to Ortho responsibility for the manufacture of Collaboration Products, or components thereof, for which GTX has been

responsible prior to the Effective Date. Promptly following the Effective Date, the Parties shall agree upon and implement a plan for effecting such transition, which may include without limitation GTX continuing to be a party to Third Party manufacturing agreements existing as of the Effective Date for the remainder of the term of such agreements, or GTX assigning to Ortho (if it is permitted to do so under the relevant agreement) its interest in such agreements; provided that if any such agreement also relates to the supply of products other than Collaboration Products, then GTX shall have no obligation to effect any such assignment. In this regard, Ortho and not GTX shall be a party to all future manufacturing agreements with Third Parties for the supply of Collaboration Products during Development. Payments to manufacturers of Collaboration Products for Development purposes and related costs will be [ \* ]. For clarity, if GTX [ \* ] after the Effective Date for such purpose, then Ortho shall [ \* ]. As used in this Article, "manufacture" means manufacture of Collaboration Products in bulk form and finished dosage form.

8.2 Manufacture and Supply During Commercialization. Ortho shall be solely responsible for the commercial manufacture of Collaboration Products in such a manner as to assure quality assurance as stringent as such quality assurance standards used by Ortho and its Affiliates in the manufacture of its other pharmaceutical products, continuity and security of supply, compliance with cGMP, and compliance with all applicable regulatory requirements. In this regard, Ortho shall be a party to all agreements covering the commercial supply of Collaboration Products. Such manufacturer(s) may include Third Parties.

8.3 Clinical Supplies. In cases where GTX supplies Ortho with Collaboration Compound or Collaboration Product for clinical studies, such supplies will be provided [ \* ].

8.4 Quality Assurance. Ortho shall also have day to day responsibility for commercial manufacturing and formulation issues related to product safety and regulatory compliance. GTX shall provide technical support reasonably required by Ortho or Third Parties for the manufacture of Collaboration Products. Ortho shall [ \* ].

8.5 Technology Transfer in Event of Termination by Ortho. In the event that this Agreement terminates (other than for a Material Breach by GTX), then Ortho shall continue to manufacture and supply (either itself or through its Affiliates or Third Parties) Collaboration Products in the manner and to the extent provided prior to notice of such termination, from the time notice of such termination is provided until such time as GTX is able to secure an equivalent alternative commercial manufacturing source; said time [ \* ], provided that GTX using its commercially reasonable efforts is unable to secure such an alternative source during such time period. To this end, as of the effective date of such termination, Ortho shall use commercially reasonable efforts to [ \* ]. For any Collaboration Products supplied by Ortho or its Affiliates, [ \* ] pursuant to this Section for the [ \* ] shall [ \* ]. Such [ \* ]. For example, [ \* ]. If termination is the result of a serious Safety issue, Ortho shall not be obligated to continue manufacturing the Collaboration Product associated with the serious Safety issue.

ARTICLE IX

CONFIDENTIALITY

9.1 Confidentiality Exceptions. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, for the term of this Agreement and for [ \* ] thereafter, the receiving Party shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as permitted in this Agreement any Information and other information and materials furnished to it by the other Party pursuant to this Agreement; any provisions of this Agreement that are the subject of an effective order of the Securities Exchange Commission granting confidential treatment pursuant to the Securities Act of 1934, as amended; and any Information developed during the term of, and pursuant to, this Agreement (collectively, "Confidential Information"), except to the extent that it can be established by the receiving Party that such Confidential Information:

(a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was disclosed to the receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the disclosing Party not to disclose such information to others; and

(e) was independently developed by the receiving Party without reliance on Confidential Information of the other Party as shown by documentary evidence.

9.2 Authorized Disclosure.

(a) Each Party may disclose Confidential Information hereunder to the extent such disclosure is reasonably necessary in filing or prosecuting patent applications, prosecuting or defending litigation, complying with applicable governmental regulations, or conducting Pre-Clinical Studies or Clinical Trials; provided, however, that if a Party is required by law or regulation to make any such disclosures of the other Party's Confidential Information it will, except where impracticable for necessary disclosures, for example in the event of medical emergency, give reasonable advance notice to the other Party of such disclosure requirement (e.g., filings with the SEC and stock markets) and, except to the extent inappropriate in the case of patent applications, will use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed, unless in the opinion of such disclosing Party's legal counsel such Confidential Information is legally required to be fully disclosed. In addition, and

with prior notice to the other Party of each Third Party with whom a confidential disclosure agreement is being entered into, each Party shall be entitled to disclose, under a binder of confidentiality containing provisions as protective as those of this Article, Confidential Information to any Third Party for the purpose of carrying out the purposes of this Agreement. Nothing in this Article shall restrict any Party from using for any purpose any Confidential Information independently developed by it without access to or use of the other Party's Confidential Information during the term of this Agreement, or from using Confidential Information that is specifically derived from Pre-Clinical Studies or Clinical Studies to perform marketing, sales or professional services support functions as is customary in the pharmaceutical industry.

(b) Notwithstanding anything herein to the contrary, either Party (and any employee, representative, or other agent of either Party) may disclose to any and all persons, without limitation of any kind, the tax treatment and tax structure of the transactions contemplated by this Agreement and all materials of any kind (including opinions or other tax analyses) that are provided to it relating to such tax treatment and tax structure; provided however, that such disclosure shall not be made to the extent reasonably necessary to comply with any applicable federal or state securities laws. For the purposes of the foregoing sentence, (i) the "tax treatment" of a transaction means the purported or claimed federal income tax treatment of the transaction, and (ii) the "tax structure" of a transaction means any fact that may be relevant to understanding the purported or claimed federal income tax treatment of the transaction.

9.3 Survival. Sections 9.1 through 9.4 of this Article shall survive the termination or expiration of this Agreement for a period of [ \* ].

9.4 Termination of Prior Agreement. This Agreement supersedes the Confidentiality Agreement between GTX and Ortho dated October 8, 2002 and amended on June 2, 2003. All Information exchanged between the Parties under that Agreement shall be deemed Confidential Information and shall be subject to the terms of this Article, and shall be included, respectively, within the definitions of GTX Know-how if GTX is the disclosing Party and Ortho Know-how if Ortho is the disclosing Party.

9.5 Publications. Except to the extent set forth in Sections 9.2 and 9.6, each Party shall provide to the other the opportunity to review any proposed scientific/technical publications or scientific presentations which relate to Collaboration Compounds or Collaboration Products as early as reasonably practical, but [ \* ] to the intended submission for publication (except with the written consent of the other Party). The reviewing Party will provide the publishing Party with its response to the publishing Party's request to publish [ \* ] of receipt of such request. No publication shall be made by any Party without the written agreement of or approval by the other Party. However, the failure of the receiving Party to respond to such request [ \* ] period shall be deemed to be approval of such request and the publishing Party shall then be free to proceed with said publication or presentation. Notwithstanding the foregoing, publications regarding Commercialization Activities or that are reasonably needed to effectively Commercialize the Collaboration Product may be made by Ortho even if GTX does not approve, provided

that GTX may request a reasonable delay on such publication to seek patent protection on any patentable inventions disclosed therein.

9.6 Public Disclosures. Subject to the further provisions of this Section, neither Party shall originate any written publicity, news release or public announcement, whether to the public or press, concerning this Agreement, including the subject matter to which it relates, performance under it or any of its terms, or any amendment hereto save only such announcements that are required by law (or the applicable rules of any securities exchange or market on which a Party's securities are listed or traded) to be made or that are otherwise agreed by the Parties or expressly permitted in this Agreement. Such announcements shall be factual and as brief as reasonable under the circumstances. In addition, each Party agrees to submit to the other Party, for review and written approval, any question and answer sheet or similar materials ("Q & A") prior to using such materials as the basis for written or oral disclosures, which written or oral disclosures must, in any event, be consistent in content with the information contained in the approved Q & A. Routine references to this Agreement and the arrangements hereunder shall be allowed in the usual course of business, and shall be consistent with any approved Q & A relating thereto. Once information has been approved for disclosure as part of an approved Q & A or publication under this Section, either Party may use such approved information in written publicity, news releases, public announcements and other future communications with Third Parties. If a Party decides to make an announcement or any filing with a governmental agency or securities exchange or market as required by law or the applicable rules of any securities exchange or market on which a Party's securities are listed or traded, it will give the other Party [ \* ] advance notice, where possible, of the text of the announcement or content of the filing so that the other Party will have an opportunity to comment upon the announcement or filing. To the extent that the receiving Party reasonably requests that any information in the materials proposed to be disclosed be maintained as confidential, the disclosing Party shall use commercially reasonable efforts to request confidential treatment of such information pursuant to Rule 406 of the Securities Act of 1933 or Rule 25b-2 of the Securities Exchange Act of 1934, as applicable (or any other applicable regulation relating to the confidential treatment of information), except to the extent that the disclosing Party receives advice from its legal counsel that such Confidential Information is required to be disclosed under applicable laws or regulations. Notwithstanding the foregoing, publications regarding [ \* ] may be made by Ortho even if GTX does not approve.

#### ARTICLE X

##### OWNERSHIP OF INTELLECTUAL PROPERTY AND PATENT RIGHTS

10.1 Ownership. Each Party shall solely own, and that Party alone shall have the right to apply for, Patents within and outside of the United States for any inventions made solely by that Party's employees or independent contractors in the course of performing work under this Agreement. Inventions made jointly by employees or independent contractors of GTX and Ortho shall be owned jointly by GTX and Ortho, without a duty of accounting. For clarity, either Party shall be free to grant licenses or other rights under Inventions jointly owned by the Parties, to the extent consistent with

the licenses granted to the other Party pursuant to this Agreement. The law of joint ownership of inventions of the United States shall apply to any joint ownership of Patents claiming joint inventions of the Parties.

10.2 Invention Disclosures. Each Party shall promptly provide to the other any invention disclosure submitted in the normal course of its operations and disclosing an invention arising during the course of and pursuant to this Agreement (such inventions, "Inventions").

10.3 Disclosure of Provisional and Non-Provisional Patent Applications. In addition to the disclosures required under Article XII, each Party shall provide to the other, within a reasonable time prior to filing, a copy of each non-provisional patent application proposed to be filed by such Party disclosing an Invention arising during the course of and pursuant to this Agreement and each Party shall provide to the other, immediately after filing, a copy of each provisional patent application actually filed by such Party disclosing an Invention. The contents of any patent application submitted to either Party pursuant to this Section 10.3 covering an invention solely owned by such Party shall be deemed the Confidential Information of the Party providing such application.

#### 10.4 Patent Filings.

(a) Ortho Patent, GTx Patent and Joint Patent Filings. Each Party, at its sole discretion, responsibility, and cost shall prepare, file, prosecute and maintain Patents to cover Inventions made solely by its own employees or independent contractors and use reasonable efforts to file initially all such applications in the United States or the appropriate forum under the circumstances. Ortho shall file, prosecute and maintain Patents to cover Inventions relating to the discovery, evaluation, manufacture, use or sale of Collaboration Compounds or Collaboration Products that are made jointly by employees or independent contractors of GTx and Ortho and the JDC shall select the Party that shall be responsible for filing, prosecuting and maintaining patent applications and other Patents claiming other jointly owned Inventions (all Patents or jointly owned Inventions, herein referred to as "Joint Patents"). [ \* ]. The determination of the countries in which to file Joint Patents shall be made [ \* ]. The Party responsible for filing a Joint Patent shall have the right to direct and control all material actions relating to the prosecution or maintenance of Joint Patents, subject to the other Party's ability to comment on such filings and the filing Party's reasonable consideration of such comments. The Party responsible for filing a Joint Patent shall provide prior written notice to the other Party of the countries in which it intends to file, including conflict proceedings, reexaminations, reissuance, oppositions and revocation proceedings, provided, however, that such other Party shall have the right to file or continue prosecution in countries in which the filing Party determines it wishes to abandon or not file such Joint Patent.

(b) Ortho and GTx Patent Strategy. Each Party shall keep the other Party apprised of the status of each Joint Patent for which it is responsible and shall seek the advice of such other Party with respect to patent strategy and drafting applications

and shall give reasonable consideration to any suggestions or recommendations concerning the preparation, filing, prosecution, maintenance and defense thereof. The Parties shall cooperate reasonably in the prosecution of all Joint Patents and other GTX Patents or Ortho Patents covering Collaboration Products and shall share all material information relating thereto, including all material communications from patent offices, promptly after receipt of such information. If the Parties are unable to agree as to who is the filing Party or as to any aspect of patent prosecution of a Joint Patent or a Patent covering a Collaboration Product, each Party at its expense shall be free to take whatever action it deems appropriate to protect the joint Invention or Collaboration Product, including the filing of patent applications subject to prior notification of the other Party. If, during the term of this Agreement, the filing Party intends to allow any Patent covering a Product to which the Party has license rights under this Agreement to lapse or become abandoned without having first filed a substitute, the filing Party shall, whenever practicable, notify the other Party of such intention [ \* ] to the date upon which such Patent shall lapse or become abandoned, and the other Party shall thereupon have the right, but not the obligation, to assume responsibility for the prosecution, maintenance and defense thereof and all expenses related thereto.

(c) Diligence in Patent Filings. The Parties agree to use reasonable efforts to ensure that any Patent filed outside of the United States prior to a filing in the United States will be in a form sufficient to establish the date of original filing as a priority date for the purposes of a subsequent filing in the United States.

(d) Cooperation by Ortho and GTX in Patent and Regulatory Filings. The Parties shall cooperate in order to avoid loss of any rights that may otherwise be available to the Parties under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, the Supplementary Certificate of Protection of the Member States of the European Union and other similar measures in any other country. Without limiting the foregoing, Ortho shall notify GTX upon receipt of Regulatory Approval to market a Collaboration Compound or Collaboration Product in the United States, and timely supply GTX with all information necessary to file an application for patent term extension for a relevant GTX Patent, [ \* ] following Regulatory Approval. GTX agrees to timely file any such application, unless it reasonably objects to seeking such extension for such Patent (in which case the dispute shall be resolved pursuant to Article XV). The obligations set forth in this Section shall apply with respect to patent term extensions, or the equivalent, in any other country. Any application for patent term extension in the United States shall be made by the Party who Controls the relevant patent.

10.5 Third Party Patent Rights. Except as expressly provided in Section 11.1, neither Party makes any warranty with respect to the validity, perfection or dominance of any Patent or other proprietary right or with respect to the absence of rights in Third Parties which may be infringed by the manufacture or sale of any Product. Each Party agrees to bring to the attention of the other Party any Patent or Patent application it discovers, or has discovered, and which relates to GTX SARM Compounds.



## 10.6 Enforcement Rights.

(a) Notification of Infringement. If either Party learns of any infringement or threatened infringement by a Third Party of the GTX Patents or Ortho Patents, such Party shall promptly notify the other Party and shall provide such other Party with all available evidence of such infringement.

(b) Enforcement. GTX shall have the right, but not the obligation, to institute, prosecute and control at its own expense any action or proceeding with respect to infringement by any Third Party of any GTX Patents (other than Joint Patents) covering the manufacture, use, importation, exportation, sale or offer for sale of Collaboration Products by reason of the manufacture, use or sale of products competitive with Collaboration Products, using counsel of its own choice. Ortho shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. If GTX fails to bring such an action or proceeding or otherwise take appropriate action to abate such infringement [ \* ] of notice by Ortho to GTX requesting action, Ortho will have the right but not the obligation to bring and control, at its expense, any such action or proceeding relating to GTX Patents by counsel of its own choice and GTX will have the right to be represented in any such action by counsel of its own choice and at its own expense. With respect to Ortho Patents (including Joint Patents), Ortho shall have the right, but not the obligation, to institute, prosecute and control at its own expense any action or proceeding with respect to infringement by any Third Party of any Joint Patents or Ortho Patents covering the manufacture, use, importation, exportation, sale or offer for sale of Collaboration Products by reason of the manufacture, use or sale of products competitive with Collaboration Products, using counsel of its own choice. GTX shall have the right, at its own expense, to be represented in any such action by counsel of its own choice in connection with any such litigation. If one Party brings any such action or proceeding, the other Party agrees to be joined as a party plaintiff if necessary to prosecute the action or proceeding and to give the first Party reasonable assistance and authority to file and prosecute the suit. If any GTX Patent or Ortho Patent (other than a Joint Patent) is infringed other than by the manufacture, use or sale of products competitive with Collaboration Products, then the Party Controlling such Patent shall be free to seek to terminate such infringement without obligation to the other Party. If a Joint Patent is infringed other than by the manufacture, use or sale of a product competitive with a Collaboration Product, the Parties shall discuss whether to proceed in terminating such infringement jointly, but in the absence of their agreement to do so, either Party may seek to terminate such infringement.

(c) Settlement with a Third Party. The Party that controls the prosecution of a given action shall also have the right to control settlement of such action; provided, however, that if one Party controls such action, no settlement shall be entered into without the written consent of the other Party if such settlement would materially and adversely affect the interests of such other Party. If the other Party shall refuse to grant such consent, then the dispute will be resolved pursuant to Article XV.

(d) Damage Award or Settlement Payments. Any damage award or settlement payments made to either or both of GTX or Ortho in connection with any such

action relating to infringement of a GTX Patent or an Ortho Patent, whether obtained by judgment, settlement or otherwise shall be allocated, (i) first, [ \* ], (ii) second, to [ \* ], and (iii) third, [ \* ].

10.7 Defense and Settlement of Third Party Claims. If a Third Party asserts that a patent, trademark or other intangible right owned by it is infringed by the manufacture, use, or sale of any Collaboration Product, Ortho will be solely responsible for defending against any such assertions at its cost and expense, but no settlement may be entered into without the written consent of GTX if such settlement would materially and adversely affect GTX's interests or the GTX Patents.

10.8 Allocation of Patent Expenses. On a country-by-country basis, Patent Expenses arising from GTX Patents shall be borne [ \* ], Patent Expenses arising from Ortho Patents shall be borne [ \* ], and Patent Expenses arising from Joint Patents shall be borne [ \* ], unless otherwise agreed.

10.9 Assignment of Joint Patents. Neither Party may assign its rights under any Joint Patent except with the prior written consent of the other Party; provided, however, that either Party may assign such rights without consent to an Affiliate or other permitted assignee under this Agreement in connection with a merger or similar reorganization or the sale of all or substantially all of its assets.

10.10 Trademarks and Trademark Expenses. Ortho shall be solely responsible for the selection, registration, and maintenance of all trademarks which it employs in connection with the marketing, promotion and sale of Collaboration Product(s) and shall solely own and control such trademarks in the Royalty Bearing Territory. Each Party recognizes the exclusive ownership by the other Party of any proprietary names, logotypes or trademarks furnished by it (including its Affiliates) that are not specific to Collaboration Products for use exclusively in connection with Collaboration Products. Either Party shall not, either while this Agreement is in effect, or at any time thereafter, register, use or attempt to obtain any right in or to any such name, logotype or trademark of the other Party or in and to any name, logotype or trademark confusingly similar to the other Party's.

## ARTICLE XI

### REPRESENTATIONS AND WARRANTIES

#### 11.1 Representations and Warranties.

(a) Parties' Representations and Warranties. Each of the Parties hereby represents and warrants to the other Party as follows:

(i) Parties' Authority to Enter Into Agreement. This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms. The execution, delivery and performance of the Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a Party or by which it is bound, nor violate any law or regulation of

any court, governmental body or administrative or other agency having jurisdiction over it. Each Party expressly represents and warrants that it has the full power and authority to enter into this Agreement and to carry out the obligations contemplated hereby.

(ii) Parties Will Not Provide Third Parties With Conflicting Rights. Such Party has not, and during the term of the Agreement will not, grant any right to any Third Party under its Patents and know-how that are licensed to the other Party pursuant to this Agreement which would conflict with the licenses granted to the other Party hereunder.

(iii) GTX Prior Obligations. To the best of its knowledge, GTX is obligated under only the UTRF Agreements to pay to any Third Party royalties with respect to Collaboration Products [ \* ].

(b) GTX Representations and Warranties to Ortho. GTX hereby represents and warrants to Ortho as follows:

(i) Validity of GTX Patents. As of the Effective Date, GTX has supplied Ortho with all information known to GTX and in GTX's possession that relates to the validity of the issued GTX Patents.

(ii) Infringement. As of the Effective Date, it has not received any notices of infringement or any written communications relating in any way to a possible infringement with respect to Andarine, and it is not aware that the manufacture, use or sale of Andarine as set forth herein infringes any Third Party patent rights which have not been licensed to GTX.

(iii) GTX's Power and Authority. GTX expressly represents and warrants that it has the full power and authority to enter into this Agreement and to carry out the obligations contemplated hereby. GTX expressly represents and warrants that it owns (in whole or in part) or otherwise Controls all Patents and know-how that are the subject of the licenses granted to Ortho herein.

11.2 Performance by Affiliates. The Parties recognize that each Party may perform some or all of its obligations under this Agreement through Affiliates, provided, however, that each Party shall remain responsible for and be a guarantor of the performance by its Affiliates and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance.

## ARTICLE XII

### INFORMATION AND REPORTS

12.1 Information and Reports During Development and Commercialization. Ortho and GTX will disclose and make available to each other upon written request and without charge (other than reimbursement to the providing Party for reasonable duplicating, postage and related expenses) all pre-clinical, clinical, regulatory, commercial, marketing, promotion, pricing, sales and other Information, including copies

of all preclinical and clinical reports, known by Ortho or GTX that directly concern Collaboration Compounds or Collaboration Products, as provided for in this Agreement. Each Party will use commercially reasonable and diligent efforts to disclose to the other Party all significant Information relating to Collaboration Compounds or Collaboration Products promptly after it is learned or its significance is appreciated. Ortho shall [ \* ]. Without limitation of the foregoing, each Party shall supply to the other the Information required by the other Party and reasonably requested by it (either as a routine practice or as a specific request) for purposes of compliance with regulatory requirements relating to Collaboration Compounds or Collaboration Products.

12.2 Complaints. Each Party shall maintain a record of all complaints it receives with respect to any Collaboration Product. Each Party shall notify the other Party of any complaint with regulatory implications received by it in sufficient detail and [ \* ] after the event, and in any event in sufficient time to allow the responsible Party to comply with any and all regulatory requirements imposed upon it in any country.

12.3 Adverse Event Reporting. The Parties recognize that Ortho as the holder of Drug Approval Applications for Collaboration Products may be required to submit information and file reports to various governmental agencies on Collaboration Products under clinical investigation, Collaboration Products proposed for marketing, or marketed Collaboration Products. Such information must be submitted at the time of initial filing for investigational use in humans and at the time of a request for Regulatory Approval of a new Collaboration Product. In addition, Ortho may be required to provide supplemental information on Collaboration Products at periodic intervals and to report adverse drug experiences at more frequent intervals depending on the severity of the experience and whether or not the event is unexpected. GTX will (a) provide Ortho with all adverse event information and Safety-related data from pre-clinical laboratory, animal toxicology, and pharmacology studies, and Clinical Studies, in its Control that are necessary for Ortho to comply with all applicable laws with respect to the Products, and (b) report and provide such information to Ortho in such a manner and time so as to enable Ortho to comply with all applicable laws. Each Party shall adhere to the adverse event reporting procedures set forth in Exhibit B.

#### 12.4 Records of Revenues and Expenses.

(a) Maintenance; Audits. Each Party shall keep complete and accurate records which are relevant to revenues, costs, reimbursements and other payments to be made under this Agreement, including, without limitation, information used to calculate Net Sales, Royalty Bearing Sales and royalty calculations, existing Third Party royalty payments due for licenses granted by such Third Parties, other license fees and other payments and royalties due under this Agreement. Such records shall be open at the location(s) where such records are maintained, upon reasonable notice, during regular business hours and under obligations of confidence, [ \* ]. The inspecting Party may examine such records at its expense (not more often than once each year) by an independent, certified public accountant, reasonably acceptable to the other Party, for the sole purpose of verifying for the inspecting Party the accuracy of calculations, amounts and classifications of such revenues, costs or payments made under this Agreement. In

the absence of material discrepancies (i.e., in those instances where discrepancy [ \* ] the amounts payable under this Agreement) identified in any such audit, the accounting expenses shall be paid by the Party requesting the audit. If material discrepancies are identified, the audited Party shall bear all accounting expenses. If the review of such records reveals that the audited Party has failed to accurately report information, then the relevant Party shall promptly pay any amounts due to the inspecting Party together with interest on such amount, calculated at a rate equal to [ \* ] Any records or accounting information received by a Party from the other Party shall be Confidential Information for purposes of Article IX. Results of any such audit shall be provided to both Parties, subject to Article IX. Audits of Detail reports shall be governed by Section 6.11 and not by this Section 12.4.

(b) Audit Disagreement. If there is a dispute between the Parties following any audit performed pursuant to Section 12.4(a), either Party may refer the issue (an "Audit Disagreement") to an independent certified public accountant for resolution. In the event an Audit Disagreement is submitted for resolution by either Party, the Parties shall comply with the following procedures:

(i) The Party submitting the Audit Disagreement for resolution shall provide written notice to the other Party that it is invoking the procedures of this Section.

(ii) Within thirty (30) calendar days of the giving of such notice, the Parties shall jointly select a recognized international accounting firm to act as an independent expert to resolve such Audit Disagreement.

(iii) The Audit Disagreement submitted for resolution shall be described by the Parties to the independent expert, which description may be in written or oral form, within ten (10) calendar days of the selection of such independent expert.

(iv) The independent expert shall render a decision on the matter as soon as practicable.

(v) The decision of the independent expert shall be final and binding and shall not be subject to Article XV hereof, unless such Audit Disagreement involves alleged fraud, breach of this Agreement or construction or interpretation of any of the terms and conditions hereof.

(vi) All fees and expenses of the independent expert, including any Third Party support staff or other costs incurred with respect to carrying out the procedures specified at the direction of the independent expert in connection with such Audit Disagreement, shall be borne by the Party against whom such expert rules.

## ARTICLE XIII

### TERM AND TERMINATION

13.1 Term. This Agreement shall commence as of the Effective Date and, unless sooner terminated as provided in this Article XIII, (a) the provisions relating to Development and Commercialization shall continue in effect until the Parties are not Developing or Commercializing any Collaboration Compounds or Collaboration Products within the Royalty-Bearing Territory; and (b) the provisions relating to Commercialization shall continue in effect until the date on which Ortho is no longer obligated to pay a royalty to GTx on Royalty Bearing Sales of Products or any Additional Royalty.

#### 13.2 Termination for Material Breach.

(a) Right to Terminate. Subject to the provisions of this Section, if either Party (the "Breaching Party") shall have committed a Material Breach and such Material Breach shall remain uncured and shall be continuing for a period of one hundred twenty (120) calendar days following receipt of notice thereof by the other Party (the "Non-Breaching Party"), then, in addition to any and all other rights and remedies that may be available, the Non-Breaching Party shall have the right to terminate this Agreement effective upon the expiration of such one hundred twenty (120) calendar day period. Any such notice of alleged Material Breach by one party (the "Accusing Party") shall include a reasonably detailed description of all relevant facts and circumstances demonstrating, supporting and/or relating to each such alleged Material Breach by the other party ("Accused Breaching Party").

(b) Excuse. If the Accused Breaching Party, upon written notice delivered to the Accusing Party prior to the expiration of such one hundred twenty (120) calendar day period, shall assert in good faith that any such alleged Material Breach described in the Accusing Party's notice, whether in payment of moneys or otherwise, was not a Material Breach, or was excused by reason of material failure of performance by the other Party or Third Parties or by reason of Force Majeure, or shall otherwise in good faith dispute such alleged Material Breach, then the Parties shall continue to perform under this Agreement, subject to all of its terms and conditions, and the matter shall be resolved pursuant to the provisions of Article XV. In such event, the Accusing Party shall not be entitled to terminate this Agreement pursuant to this Section unless and until (i) it shall be determined pursuant to Article XV that the Accused Breaching Party has committed a Material Breach and (ii) such Material Breach has not been cured prior to such determination pursuant to Article XV. To the extent that it is determined pursuant to a final and non-appealable decision under Article XV that the Accused Breaching Party did commit a Material Breach and failed to cure the same within the period provided for in clause (ii) above, then the Accusing Party may immediately terminate this Agreement and, in addition to all damages determined pursuant to the provisions of Article XV to be due and owing from the Breaching Party to the Non-Breaching Party under this Agreement, the Breaching Party shall be liable for the Non-Breaching Party's reasonable attorneys' fees incurred in connection with resolving such matter pursuant to

Article XV. If a final and non-appealable decision is made under Article XV that no Material Breach was committed by the Accused Breaching Party, then the decision maker under Article XV may elect to require the Accusing Party to pay the Accused Breaching Party's attorneys' fees incurred in connection with resolving such matter if he or she determines that the Accusing Party's basis for providing a notice of Material Breach to the other Party was not reasonable.

(c) Termination. If the Non-Breaching Party terminates this Agreement pursuant to the provisions of Sections 13.2(a) and (b), then the following provisions shall apply:

(i) the Non-Breaching Party shall receive an exclusive (even as to the Breaching Party), worldwide right and license, with the right to grant sublicenses, to all Patents and Product-specific trademarks Controlled by the Breaching Party as of the date of termination to the extent that a license under such Patents and Trademarks is necessary to enable the other Party to make, have made, import, export, use, sell, offer for sale and have sold Collaboration Products without infringing such Patents or Trademarks. The Non-Breaching Party shall also have the exclusive right (but not the obligation), subject to the rights of Third Parties existing prior to the Effective Date to enforce such Patents against competitive product infringement relating to Collaboration Products, and the exclusive right (but not the obligation) to enforce such Product-specific trademark rights against infringers;

(ii) if Ortho is the Non-Breaching Party, pursuant to Section 13.2(c)(i), the Co-Promotion shall cease and the royalty percentages recited in Section 3.4 shall be offset by any damages incurred by the Non-Breaching Party in connection with such Material Breach, provided that in no event shall the royalty due pursuant to Section 3.4 be reduced by more than [ \* ] .

(iii) all licenses and rights to the Breaching Party under the Non-Breaching Party's patents, trademarks, and know-how shall terminate; and

(iv) all Confidential Information supplied by the Non-Breaching Party to the Breaching Party shall be returned to the Non-Breaching Party, except that the Breaching Party may retain one copy of such information solely for legal archive purposes.

(d) Remaining Obligations. Except where expressly provided for otherwise in this Agreement, termination of this Agreement shall not relieve the Parties hereto of any liability, including any obligation to make payments hereunder, which accrued hereunder prior to the effective date of such termination, nor preclude any Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement nor prejudice any Party's right to obtain performance of any obligation.

(e) "Material Breach". For purposes of this Agreement and except as expressly provided otherwise in this Agreement, "Material Breach" means the breach of

or failure to perform, in a material respect, a Party's material obligations under this Agreement. Without limiting the foregoing and by way of example only, the term "Material Breach" shall be deemed to include [ \* ]. In no event shall a failure to [ \* ], in and of itself, be deemed to constitute a Material Breach, unless such failure is a result of acts, events or conduct that is otherwise a Material Breach. The Parties acknowledge and agree that a failure to exercise any right or option with respect to any Product shall not be deemed to constitute a Material Breach hereunder.

(f) Survival. The provisions of this Section 13.2 shall survive termination of this Agreement.

13.3 Termination by Ortho. Ortho may terminate Development and/or Commercialization of a Collaboration Compound and/or a Collaboration Product upon [ \* ] prior written notice to GTX; provided, however, that in the event that termination is the result of a concern over Safety, termination shall be effective [ \* ] after written notice. Notwithstanding the foregoing, if Ortho terminates the Agreement under this Section 13.3, and such termination is effective prior to the completion of a clinical trial that has already begun, Ortho shall be obligated to complete the clinical trial at its expense unless the termination was for Safety-related reasons.

13.4 Effect of Termination by GTX Under Section 13.2 or by Ortho Pursuant to Section 13.3. If GTX terminates this Agreement for material breach by Ortho pursuant to Section 13.2, or Ortho terminates this Agreement pursuant to Section 13.3, Ortho shall continue to be obligated during the termination notice period to perform all of its obligations under this Agreement, including its obligation to pay Development Expenses; provided, however, that if such termination occurred pursuant to Section 13.3, Ortho shall have no obligation to make any milestone payments with respect to any milestone achieved during the termination notice period. In addition, as a result of any such termination:

(a) all licenses and rights to GTX Patents and GTX Know-how granted to Ortho hereunder shall terminate;

(b) all Confidential Information supplied by GTX to Ortho shall be returned to GTX, except that Ortho may retain one copy of such information solely for legal archive purposes;

(c) Ortho shall be obligated to GTX under Section 8.5 to the extent provided therein, except wherein termination is under Section 13.3 as the result of a Safety issue;

(d) Ortho shall promptly transfer and assign ownership of all INDs, Drug Approval Applications and Regulatory Approvals related to Collaboration Compounds, Collaboration Products to GTX, and shall take such other actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights hereunder to GTX; and



(e) Ortho shall grant GTX (i) an exclusive, royalty-free, worldwide license to all Joint Patents to make, use, sell, offer for sale and import Collaboration Products, (ii) an exclusive, worldwide royalty-bearing license under Ortho Patents covering Inventions to make use, sell, offer for sale and import Collaboration Products, and (iii) an exclusive, royalty-free, worldwide license under all trademarks Controlled by Ortho that are used, or intended for use, specifically with Collaboration Products. GTX shall have the right to grant sublicenses under the foregoing licenses. If such termination occurs after completion of a Phase IIB Clinical Trial for a Collaboration Product (determined by the completion of the final report for the study), GTX shall pay to Ortho a royalty on Collaboration Products covered by a Valid Claim of an Ortho Patent equal to [ \* ] of Net Sales of such Collaboration Products (calculated as if such sales were by Ortho) provided that the offsets and reductions set forth in Sections 3.5 and 3.6 shall apply mutatis mutandis to the calculation of the royalty due to Ortho pursuant to this Section 13.4. Additionally, in any termination by GTX pursuant to Section 13.2 or by Ortho pursuant to Section 13.3, GTX shall have the exclusive right (but not the obligation) to enforce such Patents against competitive product infringement relating to Collaboration Products, and such trademarks against infringers.

13.5 Surviving Rights. The rights and obligations set forth in this Agreement shall extend beyond the term or termination of the Agreement only to the extent expressly provided for herein, or the extent that the survival of such rights or obligations are necessary to permit their complete fulfillment or discharge. Without limiting the foregoing, Sections 3.7, 8.5, 10.1, 12.2 and 12.3 (as to activities occurring during the term of the Agreement), 12.4, 13.4 (if applicable to such termination), and 13.5, and Articles 14 (as applicable to activities conducted during the term of the Agreement or pursuant to licenses retained by a party thereafter, and as to Section 14.4, as provided therein), 15 and 16 shall survive expiration or termination of this Agreement.

13.6 Change of Control. In the event of a GTX Change of Control (defined below), Ortho shall have the following rights and options with respect to this Agreement:

(a) Notice by Ortho. In the event that a GTX Change of Control occurs during the term of this Agreement, Ortho shall have the right and option, exercisable upon written notice to GTX delivered at any time within sixty (60) calendar days after the effective date of such Change of Control, to terminate GTX's right of Co-Promotion.

(b) Royalty Payment Upon Termination by Ortho of Co-Promotion. Upon a Change of Control, if Ortho elects to terminate GTX's rights of Co-Promotion pursuant to Section 13.6(a), then Ortho shall pay to GTX (or its successor, if not GTX) a Royalty Payment under this Section 13.6(b) on Net Sales of Collaboration Products by Ortho, its Affiliates or sublicensees in the United States to Urologists, to compensate GTX for the Additional Royalty that GTX would have had the opportunity to earn had Co-Promotion not terminated, as follows:

(i) Termination If GTX has Co-Promoted [ \* ]. If at the time Ortho terminates Co-Promotion, GTX has been Co-Promoting at least one (1)

Collaboration Product for [ \* ], then Ortho would pay to GTX for each Collaboration Product that has then been Co-Promoted by GTX for [ \* ] a Royalty Payment B, calculated as follows:

[ \* ]

[ \* ]

Ortho would pay to GTX all Royalty Payments due to it pursuant to this Section 13.6(b)(i) from the date that GTX's Co-Promotion right terminates [ \* ].

(ii) Termination If GTX Has [ \* ]. If at the time Ortho terminates GTX's right of Co-Promotion, [ \* ], or GTX has been Co-Promoting a Collaboration Product to the GTX Audience for [ \* ], then Ortho would pay to GTX a Royalty Payment B2 calculated as follows:

[ \* ]

[ \* ]

Ortho would pay to GTX such Royalty Payment for each such Collaboration Product from either (i) the Marketing Date for such Product, if such date had not occurred when GTX's right of Co-Promotion terminated, or (ii) the date of termination of GTX's right of Co-Promotion, if the Marketing Date had occurred prior thereto (either (i) or (ii), as applicable, the "Start Date"), [ \* ].

EXAMPLE 1 (Section 13.6(b)(i) Scenario):

[ \* ]

EXAMPLE 2 (Section 13.6(b)(i) Scenario):

[ \* ]

EXAMPLE 3 (Section 13.6(b)(ii) Scenario):

[ \* ]

(iii) Payments. The foregoing Royalty Payment for the relevant calendar quarter would be paid at the times and in the manner set forth in Article III for royalties due to GTX. Additional Royalties due pursuant to this Section 13.6 shall not be subject to any offsets or reductions that may be applicable to royalties due to GTX pursuant to Section 3.4. GTX shall have the right to audit Ortho's records to confirm the accuracy of payments made hereunder as provided in Section 12.4.

(iv) Limitation; Clarification. For clarity, if at the time GTX's right of Co-Promotion terminates, GTX is [ \* ] that is later [ \* ], then a Royalty Payment would be due to GTX with respect to [ \* ].

(c) Definitions. For the purposes of this Section 13.6, the following terms shall have the following definitions:

(i) "GTx Change of Control" means any transaction or series of related transactions in which a Major Health Care Company acquires or becomes the beneficial owner of (i) more than [ \* ] of the outstanding voting securities of GTx or the surviving entity, whether by merger, consolidation, reorganization, tender offer or similar means, or (ii) all or substantially all of the assets of GTx.

(ii) "Major Health Care Company" shall mean a Third Party pharmaceutical or biotechnology company (including a "group" within the meaning of Section 13(d)(3) of the Securities Exchange Act of 1934 but excluding Ortho and any affiliates of Ortho) whose worldwide net sales of human pharmaceutical products, including consumer over-the-counter pharmaceutical products, in the most recently completed fiscal year for which audited financial statements are publicly available at the time such Change of Control occurs, causes such company (or group) [ \* ], or if such information is not publicly available, as appropriately provided by GTx.

#### ARTICLE XIV

#### INDEMNIFICATION

14.1 Ortho and GTx. Ortho and GTx shall each indemnify, defend and hold harmless the other Party and their officers, directors, agents, employees and Affiliates against and from any and all Third Party actions, proceedings, claims, suits, judgments, expenses (including reasonable attorney fees), losses, liabilities and damages (collectively, "Indemnification Claims" or "Claims") which the other Party may incur or suffer to the extent such arise out of or are based upon (i) the material default by such Party in the performance of any obligation of a Party in this Agreement or the material breach of any warranty, representation, or agreement made by such Party in this Agreement, (ii) the intentional misconduct or negligent acts or omissions to act, (iii) any noncompliance by such Party of applicable laws, rules or regulations in the course of its conduct under this Agreement.

14.2 Ortho. Ortho further agrees to defend, indemnify and hold harmless GTx, its officers, directors, agents, employees and Affiliates, from and against (i) all Claims incurred by or assessed against GTx for activities prior to any termination of this Agreement on account of any claim that the manufacture, use or sale of Collaboration Product in the Territory infringes the patent, trademark or other intellectual property right of any third party, or (ii) any Claims relating to personal injuries (including death) or product liability or other loss or damage by Third Parties resulting from or relating to the manufacture, labeling, sale, use, storage, transportation, distribution or handling of Collaboration Product, unless and to the extent such loss or damage was primarily due to the negligence, recklessness or willful misconduct of GTx (whether committed by affirmative act or by omission).

14.3 Procedure. The Party seeking indemnification (the "Indemnified Party") shall inform the other Party promptly of any such Indemnifiable Claim which is brought against it and shall, to the extent such Indemnifiable Claim is brought by a Third Party, at the other Party's request, cooperate fully with the other Party in defending such Indemnifiable Claim. The Indemnified Party, at its expense, shall have the right to advise and consult on and participate in any related suit or proceeding, subject to the ultimate control of the Indemnifying Party. The other Party ("Indemnifying Party") shall have full control over the suit or proceedings, including the right to settle, through counsel of its choice who is reasonably acceptable to the Indemnified Party; provided, however, the Indemnifying Party will not, absent the consent of the Indemnified Party (which consent will not be unreasonably withheld), consent to the entry of any judgment or enter into any settlement that (1) provides for any relief other than the payment of monetary damages for which the Indemnifying Party shall be solely liable and (2) where the claimant or plaintiff does not release the Indemnified Party from all liability in respect thereof. If the Indemnifying Party declines to accept control of the defense of such claim or action, the Indemnified Party may retain counsel at the expense of the Indemnifying Party and control the defense of the claim or action, provided that the claim or action may not be settled by the Indemnified Party without the approval of the Indemnifying Party, which approval shall not be unreasonably withheld or delayed. Any payment made by the Indemnifying Party to settle any claim or action hereunder shall be at its own cost and expense.

14.4 Insurance. GTx agrees during the term of the Agreement and for a period of at least three (3) years thereafter to maintain (a) workers' compensation insurance for all of its employees, the limits of which shall be as required under statute; and (b) commercial general liability insurance (including but not limited to product liability insurance, including for clinical trials and contractual liability coverage) on a claims made form having limits of not less than [ \* ] and [ \* ]. When GTx hires sales representatives (if it exercises its right to Co-Promote), it shall expand its coverage to include automobile insurance, and it shall increase its commercial general liability insurance and product liability insurance to have limits of not less than [ \* ] and [ \* ]. For all insurance coverage written on a claims made basis, the retroactive date, if any, shall precede the Effective Date. In addition, GTx shall [ \* ] if the policy or policies are cancelled or not renewed and not replaced by another claims made policy with the same (or an earlier) retroactive date either [ \* ]. All insurance companies must be rated A or better in the most recent AM Best Rating Guide. GTx, upon request, agrees to provide Ortho with a certificate of insurance evidencing its retention of such insurance coverage and any updates thereto.

## ARTICLE XV

### DISPUTE RESOLUTION

15.1 Disputes. The Parties recognize that disputes as to certain matters may from time to time arise during the term of this Agreement that relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an

expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this if and when a dispute arises under this Agreement.

15.2 Disputes Referred First to Executive Officers. Unless otherwise specifically recited in this Agreement, disputes between the Parties shall be referred to the Parties' respective Executive Officers or their successors, for attempted resolution by negotiations [ \* ] after such issue is submitted for resolution to such officers.

15.3 Resolution of Dispute by Alternate Means. In the event the designated Executive Officers are not able to resolve such dispute, either Party may at any time after the [ \* ] period seek to resolve the dispute through other means as provided herein; provided, however, disputes regarding strategies for Development or the content of the Development Plan or Development Budget and those that arise with respect to marketing strategies or the content of the Marketing and Sales Plan shall be resolved in favor of Ortho (to the extent consistent with this Agreement) and not subject to the Alternative Dispute Resolution provided in this Article XV.

15.4 Alternative Dispute Resolution. Any dispute controversy or claim arising out of or relating to the validity, construction, enforceability or performance of this Agreement, including disputes relating to an alleged breach or to termination of this Agreement, but excluding (i) any dispute, controversy or claim arising out of or relating to the validity, enforceability, or infringement of any GTX Patent or any Ortho Patent and (ii) other than disputes which are expressly prohibited herein from being resolved by this mechanism, shall be settled by binding Alternative Dispute Resolution ("DR") in the manner described below:

(a) If a Party intends to begin a DR to resolve a dispute, such Party shall provide written notice (the "DR Request") to counsel for the other Party informing such other Party of such intention and the issues to be resolved.

(b) [ \* ] after receipt of the DR Request, the other Party may, by written notice to counsel for the Party initiating DR, add additional issues to be resolved.

15.5 Arbitration Procedures. A DR initiated under this Agreement will proceed in accordance with the Commercial Arbitration Rules of the American Arbitration Association for Large, Complex Cases then in effect, insofar as such rules are not inconsistent with the provisions expressly set forth in this Agreement, unless the Parties mutually agree otherwise. However, the Parties do not intend to submit the issue for resolution by such association unless they mutually agree to do so, in writing.

15.6 Arbitrators. The arbitration shall be carried out by a single arbitrator who shall be a retired United States judge or justice and shall be selected by the Parties [ \* ] of receipt of the DR Request in accordance with the procedure described below:

(a) The Parties shall select the arbitrator as described below, which may but need not be selected from a list of arbitrators such as the CPR Panel of Distinguished Neutrals of the Center for Public Resources, subject to: (1) his/her

availability and willingness to serve, (2) his/her availability to commence the arbitration within a reasonable period of time, (3) his/her agreement to charge fees and expenses that are reasonable under the circumstances, and (4) his/her commitment to render his/her award within the time periods provided in this Section.

(b) Each Party will exchange a list of [ \* ] qualified arbitrators and in the event that both Parties agree on a single person then such person shall be the arbitrator. In submitting the ten names, each Party shall prioritize from one to ten the persons on their respective lists. In the event that there is more than one common name on the Parties' lists, the person having the lowest combined priority number shall be selected as the arbitrator. The combined priority number shall be the sum of the order numbers assigned to that person by the Parties. Thus, if one person was GTX's number two priority and Ortho's number three priority, and another person was GTX's number two priority and Ortho's number four priority, the former would be appointed. If more than one person has the lowest combined priority number, the person for whom there is less difference between the order numbers assigned by the Parties shall be appointed. Thus, if one person was GTX's number one priority and Ortho's number four priority, and another person was GTX's number two priority and Ortho's number three priority, the latter person would be appointed. If this method does not produce an arbitrator, or if there are no common names, the Parties shall alternatively strike from the combined list until only one name remains, which shall be selected as the arbitrator. The Party to strike first shall be determined by the toss of a coin.

(c) In the event the arbitrator is unable to meet the requirements set forth in (a) above, then, in the event the first selected arbitrator was common to both lists and there was more than one common name on the Parties' lists, the arbitrator having the next lowest combined priority number who is able and willing to serve pursuant to these requirements shall be selected. If there is no such individual, then the Parties shall use the alternate strike method set forth above. In the event an arbitrator selected by the alternate strike methodology is unable or unwilling to serve consistent with the requirements set forth above, then the alternate striking procedure shall be retraced in reverse order until the arbitrator is selected.

(d) The arbitrator shall be neutral, disinterested, impartial, and independent of the Parties and others having any known interest in the outcome, and shall abide by the AAA/ABA Code of Ethics for Arbitrators in Commercial Disputes. There shall be no ex parte communications with the arbitrator either before or during the arbitration, relating to the dispute or issues involved in the dispute or the arbitrator's views on any such issue.

15.7 Interim Review. Either Party may apply to any court having jurisdiction hereof and seek preliminary injunctive relief until such time as the arbitration award is rendered or the controversy is otherwise resolved.

15.8 Location. Any arbitration under this Section shall be conducted in New York, NY.

15.9 Discovery Proceedings. The Parties shall have the right to undertake complete discovery, as contemplated by and pursuant to Federal Rules 26-37 of the Federal Rules of Civil Procedure (with references to "court" in those Rules being considered references to the "arbitrator") except as they may be modified by the following:

(a) [ \* ] after selection of the arbitrator, each Party may serve on any other Party (i) interrogatories for the purpose of identification of documents and witnesses, (ii) requests for admissions, and (iii) requests for the production of documents and things. These discovery requests will be answered [ \* ] of receipt.

(b) At any time but not more than [ \* ] after the selection of the arbitrator, each Party may take depositions of employees or other witnesses of an opposing Party as a matter of right, subject to applicable limitations set forth in Rules 26-37.

(c) Any Party may conduct depositions of its own witnesses which may be introduced as evidence at the arbitration hearing if the other Party was given fair opportunity to attend the deposition and cross-examine.

(d) As they become aware of new documents or information, including experts who may be called upon to testify, all Parties remain under a continuing obligation to provide documents upon which they rely, to supplement their responses, and to honor any informal agreements or understandings between the Parties regarding documents or information to be exchanged. The arbitrator at the hearing will not consider documents that have not been previously exchanged, unless agreed by the Parties or used for purposes of impeachment.

(e) The Parties will promptly notify the arbitrator when an unresolved dispute exists regarding discovery issues. The arbitrator will discuss the matter with the Parties to determine the nature of the dispute and will attempt to resolve that dispute. If the arbitrator does not resolve the dispute, the arbitrators will arrange a conference concerning the dispute before the arbitrator by telephone, or in person, and the arbitrator will decide the dispute.

(f) All discovery shall be completed [ \* ] from selection of the arbitrator, unless extended by agreement of the Parties or by the arbitrator for good cause shown.

15.10 Hearings and Proceedings. The arbitrator will determine the specific location within New York, NY and the date and time of the arbitration hearing(s) and other proceedings after consultation with the arbitrator and the Parties and will provide reasonable notice of the hearing(s) date and time. The arbitrator will make every effort to schedule the arbitration hearing [ \* ] of the completion of all discovery, absent unusual circumstances.

(a) The Parties may mutually agree on or the arbitrator for good cause may order a rescheduling of the hearing date.

(b) The arbitrator will ordinarily conduct the arbitration hearing in the manner set forth in this Section except that (i) the Federal Rules of Evidence shall apply and (ii) the arbitrator shall render its decision in writing in the manner provided by Rule 52 of the Federal Rules of Civil Procedure, including a full and precise statement of the factual and legal bases for such decision. If the AAA rules and the rules of this Section conflict in any manner, the rules of this Section shall prevail. The arbitrator must hold an oral hearing, but may impose reasonable time limits on each phase of the proceeding and may limit testimony to exclude evidence that would be immaterial or unduly repetitive, provided that all Parties are afforded the opportunity to present material and relevant evidence and that each Party is given at least an approximately equal amount of time for presentation of its case.

(c) Written briefs may be filed up to [ \* ] before the hearing.

(d) The arbitrator will require witnesses to testify under oath if requested by any Party.

(e) Any Party desiring a stenographic record may secure a court reporter to attend the proceedings.

(f) The arbitrator will determine the order of proof, which will generally be similar to that of a court trial, including opening and closing statements.

(g) When the arbitrator determines that all relevant and material evidence and arguments have been presented, the arbitrator will declare the hearing closed. The arbitrator may defer the closing of the hearing for up to [ \* ] to permit the Parties to submit post-hearing briefs and or to make closing arguments, as the arbitrator deems appropriate, before rendering an award.

(h) The arbitrator will render the award and its decisions pursuant to Fed. R. Civ. P. 52 [ \* ] after the date of the closing of the hearing or, if an arbitration hearing has been waived, [ \* ] after the date of the arbitrator's receiving all materials specified by the Parties. The decision and award of the arbitrator will constitute the Arbitration Award and will be binding on the Parties.

(i) The arbitrator shall, in rendering his or her decision and award, apply the substantive law of the State of New York, without regard to its conflict of laws provisions, except that the interpretation of and enforcement of this Article shall be governed by the Federal Arbitration Act. The costs of the winning Party and the fees of the arbitrator shall be paid by the losing Party as determined by the arbitrator. If the arbitrator is unable to designate a losing party, it shall so state and each Party shall bear its own costs and the fees of the arbitrator shall be split equally between the Parties.

15.11 Award. The arbitrator is empowered to award any remedy allowed by law, including money damages, prejudgment interest and attorneys' fees, and to grant final, complete, interim, or interlocutory relief, including injunctive relief. Notwithstanding the foregoing, punitive or multiple damages may not be awarded.



15.12 Legal Fees. Except as set forth in Section 15.10(i) above, each Party shall bear its own legal fees.

15.13 Confidentiality. The DR proceeding shall be confidential and the arbitrator shall issue appropriate protective orders to safeguard each Party's Confidential Information. Except as required by law, no Party shall make (or instruct the arbitrator to make) any public announcement with respect to the proceedings or decision of the arbitrator without prior written consent of each other Party. The existence of any dispute submitted to DR, and the award, shall be kept in confidence by the Parties and the arbitrator, except as required in connection with the enforcement of such award or as otherwise required by applicable law.

15.14 Survivability. Any duty to arbitrate under this Agreement shall remain in effect and enforceable after termination of this Agreement for any reason.

15.15 Jurisdiction. For the purposes of this Article each Party agrees to abide by the award rendered in any arbitration, and the Parties agree to accept the jurisdiction of any court having jurisdiction over the Parties for the purposes of enforcing awards entered pursuant to this Article and for enforcing the agreements reflected in this Article, provided that the foregoing shall not be deemed to waive any rights of either Party under the Federal Arbitration Act.

## ARTICLE XVI

### MISCELLANEOUS

#### 16.1 Assignment.

(a) Affiliates. Either Party may assign any of its rights or obligations under this Agreement in any country to its Affiliates and may delegate its obligations under this Agreement in any country to its Affiliates; provided, however, that such assignment or delegation shall not relieve the assigning Party of its responsibilities for performance of its obligations under this Agreement.

(b) (i) Non-Affiliates. Except as provided in subsection (b)(ii) below, neither Party may assign its rights or obligations under this Agreement to a non-Affiliate without the prior written consent of the other Party, except in connection with a merger or similar reorganization or the sale of all or substantially all of its assets. This Agreement shall survive any such merger or reorganization of either Party with or into, or such sale of assets to, another party and no consent for such merger, reorganization or sale shall be needed; provided, that in the event of such merger, reorganization or sale, no intellectual property rights of the acquiring corporation shall be included in the technology licensed hereunder.

(ii) GTx's Right to Assign Rights to Receive Payment. GTx may assign its rights to receive payments hereunder to a Third Party or grant a security interest in its rights to receive payments hereunder.

(c) Benefit to Successors. This Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties. Any assignment not in accordance with this Agreement shall be void.

16.2 Retained Rights. Nothing in this Agreement shall limit in any respect the right of either Party to conduct research and development and to market products using such Party's technology other than as herein expressly provided.

16.3 Consents Not Unreasonably Withheld or Delayed. Whenever provision is made in this Agreement for either Party to secure the consent or approval of the other, that consent or approval shall not unreasonably be withheld or delayed, and whenever in this Agreement provision is made for one Party to object to or disapprove a matter, such objection or disapproval shall not unreasonably be exercised, even when not so expressly stated.

16.4 Force Majeure. Neither Party shall lose any rights hereunder or be liable to the other Party for damages or losses on account of failure of performance by the defaulting Party if the failure is occasioned by government action, war, fire, explosion, flood, strike, lockout, embargo, act of God, or any other similar cause beyond the control of the defaulting Party, provided that the Party claiming force majeure has exerted all reasonable efforts to avoid or remedy such force majeure and has given the other Party prompt notice describing such event, the effect thereof and the actions being taken to avoid or remedy such force majeure; provided, however, that in no event shall a Party be required to settle any labor dispute or disturbance.

16.5 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

16.6 No Trademark Rights. Except as otherwise provided herein, no right, express or implied, is granted by the Agreement to use in any manner any name or any trade name or trademark of the other Party or its Affiliates in connection with the performance of this Agreement.

16.7 Notices. All notices hereunder shall be in writing and shall be deemed given if delivered personally or by facsimile transmission (receipt verified), telexed, mailed by registered or certified mail (return receipt requested), postage prepaid, or sent by express courier service, to the Parties at the following addresses (or at such other address for a Party as shall be specified by like notice; provided that notices of a change of address shall be effective only upon receipt thereof).

If to GTX: GTX, Inc.  
3 North Dunlap St.  
3rd Floor  
Memphis, Tennessee 38163  
U.S.A.  
Attention: President  
Facsimile No.: [ \* ]

With a copy to: GTX, Inc.  
3 North Dunlap St.  
3rd Floor  
Memphis, Tennessee 38163  
U.S.A.  
Attention: General Counsel  
Facsimile No.: [ \* ]

If to Ortho: Ortho Biotech Products, L.P.  
Route 22 East  
Bridgewater, NJ 08807  
U.S.A.  
Attention: President  
Facsimile No.: [ \* ]

16.8 Waiver. Except as specifically provided for herein, the waiver from time to time by either of the Parties of any of their rights or their failure to exercise any remedy shall not operate or be construed as a continuing waiver of same or any other of such Party's rights or remedies provided in this Agreement.

16.9 Severability. If any term, covenant or condition of this Agreement or the application thereof to any Party or circumstances shall, to any extent or in any country, be held to be invalid or unenforceable, then (i) the remainder of this Agreement, or the application of such term, covenant or condition to Parties or circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby and each term, covenant or condition of this Agreement shall be valid and be enforced to the fullest extent permitted by law; and (ii) the Parties hereto covenant and agree to renegotiate any such term, covenant or application thereof in good faith in order to provide a reasonably acceptable alternative to the term, covenant or condition of this Agreement or the application thereof that is invalid or unenforceable, it being the intent of the Parties that the basic purposes of this Agreement are to be effectuated.

16.10 Ambiguities. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

16.11 Governing Law. This Agreement shall be governed by and interpreted under the laws of the State of New Jersey as applied to contracts entered into and performed entirely in New Jersey by New Jersey residents.

16.12 Headings. The Sections and paragraph headings contained herein are for the purposes of convenience only and are not intended to define or limit the contents of said Sections or paragraphs.

16.13 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

16.14 Entire Agreement; Amendments. This Agreement, including all Exhibits attached hereto, and all documents delivered concurrently herewith, set forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto and supersede and terminate all prior agreements and understandings between the Parties. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as set forth herein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties. This Agreement, including without limitation the exhibits, schedules and attachments hereto, are intended to define the full extent of the legally enforceable undertakings of the Parties hereto, and no promise or representation, written or oral, which is not set forth explicitly is intended by either party to be legally binding.

Both Parties acknowledge that in deciding to enter into the Agreement and to consummate the transaction contemplated thereby neither Party has relied upon any statement or representations, written or oral, other than those explicitly set forth herein.

16.15 Independent Contractors. The status of the Parties under this Agreement shall be that of independent contractors. Neither Party shall have the right to enter into any agreements on behalf of the other Party, nor shall it represent to any person that it has any such right or authority. Nothing in this Agreement shall be construed as establishing a partnership or joint venture relationship between the Parties.

16.16 Currency Exchange. All payments to be made by Ortho to GTX shall be made in U.S. Dollars, to a GTX bank account able to receive U.S. Dollars. Payments by Ortho to GTX shall be converted to U.S. Dollars in accordance with the following: the rate of currency conversion shall be calculated using a simple average of the mid-month and month-end rates as provided by Brown Brothers Harriman, 59 Wall Street, NY, NY 10005, for each relevant period, or if such rate is not available, the spot rate as published by The Wall Street Journal, Eastern Edition for such accounting period. This method of conversion is and shall be consistent with Ortho's then current methods, provided that such method shall utilize Third Party indices that are publicly available. Ortho shall give GTX prompt written notice of any changes to Ortho's customary and usual procedures for currency conversion, which shall only apply after such notice has been delivered and provided that such changes continue to maintain a set methodology for currency conversion.

IN WITNESS WHEREOF, GTX and Ortho have caused this Agreement to be executed as of the Effective Date first written above by their respective officers thereunto duly authorized.

GTX, INC.

Signed By: /s/ Mitchell S. Steiner, M.D.

-----  
Title: CEO / Vice Chairman

ORTHO BIOTECH PRODUCTS L.P.

Signed By: /s/ J. H. Johnson

-----  
Title: President

[ \* ] = 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.

## Exhibits

Exhibit A - List of GTX Patents

Exhibit B - Adverse Event Reporting Procedures

Exhibit C - Initial Plan

Exhibit D1 - Compounds that Fall Within Section 1.36(1)

Exhibit D2 - Excluded SARM Compounds

EXHIBIT A

U.S. PATENT APPLICATION OR PATENT NO.	FILING DATE	STATUS	ISSUE DATE	ASSIGNEES
[ * ]	[ * ]	[ * ]	[ * ]	
[ * ]	[ * ]	[ * ]	[ * ]	
[ * ]	[ * ]	[ * ]	[ * ]	
[ * ]	[ * ]	[ * ]	[ * ]	
[ * ]	[ * ]	[ * ]	[ * ]	
[ * ]	[ * ]	[ * ]	[ * ]	
[ * ]	[ * ]	[ * ]	[ * ]	

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ADVERSE EVENT REPORTING PROCEDURES

There will be one common database for both clinical and post-marketing adverse event data, which shall be the responsibility of Ortho. Ortho shall be responsible for furnishing timely notice of adverse events, including drug interactions, as required by applicable regulations, to all competent governmental agencies with respect to the Collaboration Products. GTX shall provide Ortho with all necessary assistance in complying with all adverse event reporting requirements established by, or required under, any applicable IND, NDA or Regulatory Approval and/or applicable law.

GTX shall furnish Ortho with timely notice of adverse events relating to Andarine or Collaboration Product(s), that it becomes aware of within the U.S. Ortho shall perform active follow-up to obtain adequate details of reports received to allow evaluation of reports of adverse events and drug interactions. Each party shall retain all documents, reports, studies and other materials relating to any and all adverse events.

[ \* ] = 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.



INITIAL PLAN

[ \* ]

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COMPOUNDS THAT FALL WITHIN SECTION 1.36(1)

[ \* ]

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EXHIBIT D2 - EXCLUDED SARM COMPOUNDS

TYPE OF SARM COMPOUNDS	EXCLUDED SARM COMPOUNDS
[ * ]	[ * ] [ * ] [ * ] [ * ]
[ * ]	[ * ] [ * ] [ * ] [ * ] [ * ]
[ * ]	[ * ] [ * ] [ * ] [ * ] [ * ]
[ * ]	[ * ] [ * ] [ * ] [ * ] [ * ]

[ \* ] = 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.

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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 reliability of financial reporting and the preparation of financial statement 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;

(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 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, summarize and report financial information; and

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

Dated: May 7, 2004

/s/ Mitchell S. Steiner

-----  
Mitchell S. Steiner  
Chief Executive Officer

Chief Financial Officer Certification

I, Mark E. Mosteller, certify that:

1. I have reviewed this quarterly report on Form 10-K 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 reliability of financial reporting and the preparation of financial statement 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;

(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 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, summarize and report financial information; and

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

Dated: May 7, 2004

/s/ Mark E. Mosteller

-----  
Mark E. Mosteller  
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 ending March 31, 2004, 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 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Mitchell S. Steiner

-----  
Mitchell S. Steiner  
Chief Executive Officer

May 7, 2004

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 ending March 31, 2004, 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 18 U.S.C. ss. 1350, as adopted pursuant to ss.906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Mark E. Mosteller

-----  
Mark E. Mosteller  
Chief Financial Officer

May 7, 2004