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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2006

OR

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

For the transition period from _____ to _____

Commission file number: 000-50549

GTx, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No o

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

Large accelerated filer o Accelerated filer ☑ Non-accelerated filer o

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

As of November 1, 2006, 31,011,385 shares of the registrant's Common Stock were outstanding.

GTx, INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2006
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PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2006 (unaudited)	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 44,551	$ 74,014
Accounts receivable	121	153
Inventory	236	135
Receivable from collaboration partner	27,898	—
Prepaid expenses and other current assets	1,330	1,702
Total current assets	74,136	76,004
Property and equipment, net	1,556	1,746
Purchased intangible assets, net	4,810	4,978
Receivable from collaboration partner, less current portion	1,189	—
Other assets	37	83
Total assets	$ 81,728	$ 82,811
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,344	$ 1,407
Accrued expenses	3,987	3,230
Deferred revenue — current portion	7,189	1,337
Total current liabilities	12,520	5,974
Deferred revenue, less current portion	24,972	2,958
Other long term liability	319	280
Capital lease obligation	16	20
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value: 60,000,000 shares authorized; 31,005,717 shares issued and outstanding at September 30, 2006 and 30,993,967 shares issued and outstanding at December 31, 2005	31	31
Deferred stock compensation	—	(1,725)
Additional paid-in capital	268,936	269,542
Accumulated deficit	(225,066)	(194,269)
Total stockholders' equity	43,901	73,579
Total liabilities and stockholders' equity	$ 81,728	$ 82,811

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Revenues:				
Product sales, net	$ 348	$ 288	$ 1,512	$ 2,133
Collaboration revenue	724	334	1,393	1,003
Total revenues	1,072	622	2,905	3,136
Costs and expenses:				
Cost of product sales	118	185	755	1,350
Research and development expenses	9,614	8,454	26,499	24,419
General and administrative expenses	2,867	2,271	8,509	7,433
Total costs and expenses	12,599	10,910	35,763	33,202
Loss from operations	(11,527)	(10,288)	(32,858)	(30,066)
Interest income	638	345	2,061	1,023
Net loss	$ (10,889)	$ (9,943)	$ (30,797)	$ (29,043)
Net loss per share:				
Basic	$ (0.35)	$ (0.40)	$ (0.99)	$ (1.18)
Diluted	$ (0.35)	$ (0.40)	$ (0.99)	$ (1.18)
Weighted average shares used in computing net loss per share:				
Basic	31,005,717	24,664,950	31,001,292	24,664,794
Diluted	31,005,717	24,664,950	31,001,292	24,664,794

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

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

	Nine Months Ended September 30,	
	2006	2005
Cash flows from operating activities:		
Net loss	$ (30,797)	$ (29,043)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	874	749
Share-based compensation	948	480
Directors' deferred compensation	105	95
Deferred revenue amortization	(1,393)	(1,003)
Foreign currency transaction loss	175	—
Changes in assets and liabilities:		
Accounts receivable	32	—
Inventory	(101)	273
Receivable from collaboration partner	(29,262)	—
Prepaid expenses and other current assets	372	(1,321)
Other assets	46	138
Accounts payable	(63)	1,055
Accrued expenses and other long term liability	796	3,023
Deferred revenue	29,259	—
Net cash used in operating activities	(29,009)	(25,554)
Cash flows from investing activities:		
Purchase of property and equipment	(308)	(799)
Purchase of intangible assets	(208)	(372)
Net cash used in investing activities	(516)	(1,171)
Cash flows from financing activities:		
Proceeds from exercise of employee stock options	66	9
Payments on capital lease obligation	(4)	(4)
Net cash provided by financing activities	62	5
Net decrease in cash and cash equivalents	(29,463)	(26,720)
Cash and cash equivalents, beginning of period	74,014	64,528
Cash and cash equivalents, end of period	$ 44,551	$ 37,808

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

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

1. BUSINESS AND BASIS OF PRESENTATION

Business

GTx, Inc. ("GTx," the "Company," or "we"), headquartered in Memphis, Tennessee, is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for cancer and serious conditions related to men's health. GTx's lead drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens, two essential classes of hormones. GTx operates in one business segment.

GTx is developing ACAPODENE ® (toremifene citrate), a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: first, a pivotal Phase III clinical trial for the treatment of serious side effects of androgen deprivation therapy, or ADT, for advanced prostate cancer and second, a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia, or high grade PIN. GTx has licensed to the Ipsen Group exclusive rights in Europe to develop and commercialize ACAPODENE® for the prevention of prostate cancer in high risk men and for the treatment of multiple side effects of androgen deprivation therapy. GTx also is developing ostarine, a selective androgen receptor modulator, or SARM. Ostarine is currently being evaluated in a Phase II clinical trial in 120 elderly men and postmenopausal women. We believe that ostarine has the potential to treat a variety of indications, including muscle wasting and bone loss in frail elderly patients, osteoporosis, muscle wasting in end stage renal disease patients, and severe burn wounds and associated muscle wasting. GTx has licensed to Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson (Ortho Biotech), andarine, another of GTx's SARMs, under a joint collaboration and license agreement.

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, 2005. Operating results for the three months and nine months ended September 30, 2006 are not necessarily indicative of the results that may be expected for the entire fiscal year ending December 31, 2006.

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

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.

Revenue Recognition

The Company recognizes net product sales revenue from the sale of FARESTON® less deductions for estimated sales discounts and sales returns. Revenue from product sales is recognized when the goods are shipped and title and risk of loss pass to the customer and the other criteria outlined in Staff Accounting Bulletin ("SAB") No. 101, "Revenue Recognition in Financial Statements" as amended by SAB No. 104 (together, "SAB No. 104") and Statement of Financial Accounting Standards No. 48 *"Revenue Recognition When Right of Return Exists"* are satisfied. The Company accounts for rebates to certain governmental agencies as a reduction of revenue. The Company allows customers to return product within a specified time period prior to and subsequent to the product's labeled expiration date. The Company estimates its accrual for product returns based on factors which include historical product returns and estimated product in the distribution channel which is expected to exceed its expiration date. At September 30, 2006 and December 31, 2005, the Company's accrual for product returns was $162 and $274, respectively. If actual future results are different than the Company's estimates, the Company may need to adjust its estimated accrual for product returns, which could have a material effect on earnings in the period of the adjustment.

Collaboration revenue consists of non-refundable up-front payments and license fees associated with the Company's collaboration and license agreements discussed in Note 4. The Company recognized revenue in accordance with SAB No. 104. Accordingly, revenues from licensing agreements are recognized based on the performance requirements of the agreement. Non-refundable up-front fees, where the Company has an ongoing involvement or performance obligation, are recorded as deferred revenue in the balance sheet and amortized as collaboration revenue in the condensed statements of operations over the term of the performance obligation.

Recent Accounting Pronouncements

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes-an interpretation of FASB Statement No. 109 "(FIN 48)"*, which clarifies the accounting for uncertainty in tax positions.

FIN 48 requires the recognition in the financial statements, the impact of a tax position, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 are effective as of January 1, 2007, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. The Company is currently evaluating the impact of adopting FIN 48 on the Company's financial statements.

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

2. SHARE-BASED COMPENSATION

Effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards ("SFAS") No. 123(R) "Share-Based Payment" and began recognizing compensation expense for its share-based payments based on the fair value of the awards. Share-based payments include stock option grants under the Company's stock option plans. SFAS No. 123(R) requires share-based compensation expense recognized since January 1, 2006 to be based on the following: a) grant date fair value estimated using the minimum value method in accordance with the original provisions of SFAS No. 123 "Accounting for Share-based Compensation" for unvested options granted prior to the Company's initial public offering ("IPO") in February 2004; b) grant date fair value estimated using the intrinsic value method for unvested options granted prior to the Company's IPO and previously accounted for using Accounting Principles Board Opinion ("APB") No. 25, *"Accounting for Stock Issued to Employees"*; c) grant date fair value estimated in accordance with the original provisions of SFAS No.123 for unvested options granted after the Company's IPO and prior to the adoption date and d) grant date fair value estimated in accordance with the provisions of SFAS No. 123(R) for unvested options granted on or after the adoption date. Prior to January 1, 2006, the Company accounted for share-based compensation expense using the intrinsic value recognition method prescribed by APB No. 25 and SFAS No.123. Since the Company adopted SFAS No. 123(R) under the modified prospective and the prospective transition methods, results from prior periods have not been restated. On the date of adoption of SFAS No. 123(R), the unamortized balance of deferred stock compensation of $1,725 was reduced to zero with an offsetting adjustment to additional paid-in capital.

The following table illustrates the effect on net loss and net loss per share if the Company had not adopted SFAS No. 123(R) and applied the fair value recognition provisions of SFAS No.123 and the intrinsic value recognition provisions of APB No. 25 to options granted under the Company's stock option plans in all periods presented. For purposes of this pro forma disclosure, the fair value of the options granted is estimated using the Black-Scholes-Merton option pricing model, the minimum value method and the intrinsic value method.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Net loss, as reported	$ (10,889)	$ (9,943)	$ (30,797)	$ (29,043)
Add: Share-based compensation expense included in reported net loss	362	165	1,053	573
Deduct: Share-based compensation expense determined under the fair value based method	(362)	(609)	(1,053)	(1,498)
Pro forma net loss	$ (10,889)	$ (10,387)	$ (30,797)	$ (29,968)
Net loss per share:				
Basic — as reported	$ (0.35)	$ (0.40)	$ (0.99)	$ (1.18)
Basic — pro forma	$ (0.35)	$ (0.42)	$ (0.99)	$ (1.22)
Diluted — as reported	$ (0.35)	$ (0.40)	$ (0.99)	$ (1.18)
Diluted — pro forma	$ (0.35)	$ (0.42)	$ (0.99)	$ (1.22)

Under SFAS No. 123(R) forfeitures are estimated at the time of valuation and reduce expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate. Under SFAS No.123 and APB No. 25, the Company elected to account for forfeitures when awards were actually forfeited, at which time all previous pro forma expense was reversed to reduce pro forma expense for that period.

Total share-based compensation expense for the three months ended September 30, 2006 was $362, of which $131 and $231 were recorded in the condensed statements of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the nine months ended September 30, 2006 was $1,053, of which $408 and $645 were recorded in the condensed statements of operations as research and development expenses and general and administrative expenses, respectively. Prior to the adoption of SFAS No. 123(R), the Company accounted for share-based compensation expense under APB No. 25. Total share-based compensation expense for the three months ended September 30, 2005 was $165, of which $113 and $52 were recorded in the condensed statements of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the nine months ended September 30, 2005, was $573, of which $353 and $220 were recorded in the condensed statements of operations as research and development expenses and general and administrative expenses, respectively. Included in share-based compensation expense for all periods presented is share-based compensation expense related to deferred compensation arrangements for the Company's directors which was $35 and $31 for the three months ended September 30, 2006 and 2005, respectively, and $105 and $95 for the nine months ended September 30, 2006 and 2005, respectively. The adoption of SFAS No. 123(R) has resulted in increased share-based compensation expense and net loss of $168 and $471 and increased net loss per share of $0.01 and $0.02 for the three months and nine months ended September 30, 2006, respectively. The current year increase in stock-based compensation expense is the result of recognizing stock-based compensation expense in accordance with the provisions of SFAS No. 123(R) as compared to recognizing stock-based compensation expense in accordance with the provision of APB No. 25.

GTx, Inc.
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SFAS No. 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required prior to the adoption of SFAS No. 123(R). The impact of adopting SFAS No. 123(R) on future results will depend on, among other things, levels of share-based options granted in the future, actual forfeiture rates and the timing of option exercises.

The Company grants options to purchase common stock to certain employees and directors under various plans at prices equal to the market value of the stock on the dates the options are granted. The options have a term of 10 years from the grant date and vest three years from the grant date for director options and in periods up to five years from the grant date for employee options. Employees have 90 days after the employment relationship ends to exercise all vested options except in the case of retirement, permanent disability or death, where exercise periods are generally longer. The fair value of each option grant is separately estimated for each vesting date. The fair value of each option is amortized into compensation expense on a straight-line basis between the grant date for the award and each vesting date. The Company estimates the fair value of certain stock option awards as of the date of the grant by applying the Black-Scholes-Merton option pricing valuation model. The application of this valuation model involves assumptions that are judgmental and highly sensitive in the determination of compensation expense. The weighted average for key assumptions used in determining the fair value of options granted in the three months and nine months ended September 30, 2006 and a summary of the methodology applied to develop each assumption are as follows:

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

Expected Price Volatility — This is a measure of the amount by which a price has fluctuated or is expected to fluctuate. We use an average expected price volatility of other publicly traded biopharmaceutical companies as it is management's belief that this is the best indicator of future volatility due to the limited period of time the Company's stock has been publicly traded. An increase in the expected price volatility will increase compensation expense.

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

Expected Life — This is the period of time over which the options granted are expected to remain outstanding and is based on management's estimate, taking into consideration vesting term, contractual term and historical actual life. Options granted have a maximum term of ten years. An increase in the expected life will increase compensation expense.

GTx, Inc.
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Dividend Yield — The Company has not made any dividend payments nor does it have plans to pay dividends in the foreseeable future. An increase in the dividend yield will decrease compensation expense.

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

A summary of stock option activity since our most recent fiscal year end is as follows:

	Options	Weighted Average Exercise Price
Outstanding at December 31, 2005	1,301,750	$8.27
Granted	219,834	$8.43
Exercised	(11,750)	$5.69
Forfeited	(38,500)	$9.39
Outstanding at September 30, 2006	1,471,334	$8.28

At September 30, 2006, the average remaining contractual term of all outstanding options was 7.31 years, with an aggregate intrinsic value of $2,531, with 473,108 of the outstanding options being exercisable with an average exercise price of $7.18, an average remaining contractual term of 6.08 years and an aggregate intrinsic value of $1,257. Shares reserved for future option grants were 1,554,672 at September 30, 2006. For the three months ended September 30, 2006 and 2005, the weighted average grant date fair values of options granted was $6.30 and $6.89, respectively. For the nine months ended September 30, 2006 and 2005, the weighted average grant date fair values of options granted was $5.60 and $6.42, respectively. There were 11,750 options exercised during the nine months ended September 30, 2006 and no options were exercised during the three months ended September 30, 2006. The total intrinsic value of options exercised during the nine months ended September 30, 2006 was $46. There were no options exercised during the nine months ended September 30, 2005. The Company issues new shares of common stock upon the exercise of options. At September 30, 2006, the total compensation cost related to non-vested awards not yet recognized was $2,962 with a weighted average expense recognition period of 1.97 years.

Under the Company's Amended and Restated 2004 Non-Employee Directors' Stock Option Plan, on the day immediately following each annual meeting of the Company's stockholders, each non-employee director receives an option to purchase shares of common stock. The number of shares of common stock subject to these annual grants is currently set at 8,000, and such number of shares may be increased or decreased by the Board of Directors. If an individual has not been serving as a non-employee director for the entire period since the preceding annual meeting of the Company's stockholders, the number of shares subject to such individual's annual grant will be reduced pro rata for each full month prior to the date of grant during which such individual did not serve as a non-employee director. In addition, each new director receives an option to purchase shares of common stock upon his or her election to the Board of Directors. The number of shares of common stock subject to these new director grants is currently set at

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

10,000, and such number of shares may be increased or decreased by the Board of Directors. These stock option grants are made at the fair market value as of the grant date. At September 30, 2006, there were options outstanding to purchase 125,334 shares of common stock under this plan with 142,666 shares of common stock remaining available for future issuance under this plan.

3. BASIC AND DILUTED NET LOSS PER SHARE

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

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

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Basic net loss per share				
Numerator:				
Net loss	$ (10,889)	$ (9,943)	$ (30,797)	$ (29,043)
Denominator (weighted average shares):				
Common stock outstanding at beginning of period	31,005,717	24,664,716	30,993,967	24,664,716
Exercise of employee stock options	—	234	7,325	78
Weighted average shares used in computing basic net loss per share	31,005,717	24,664,950	31,001,292	24,664,794
Basic net loss per share	$ (0.35)	$ (0.40)	$ (0.99)	$ (1.18)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Diluted net loss per share				
Numerator:				
Net loss	$ (10,889)	$ (9,943)	$ (30,797)	$ (29,043)
Denominator (weighted average shares):				
Common stock outstanding at beginning of period	31,005,717	24,664,716	30,993,967	24,664,716
Exercise of employee stock options	—	234	7,325	78
Weighted average shares used in computing diluted net loss per share	31,005,717	24,664,950	31,001,292	24,664,794
Diluted net loss per share	$ (0.35)	$ (0.40)	$ (0.99)	$ (1.18)

Weighted average options outstanding to purchase shares of common stock of 1,468,589 and 1,264,470 for the three months ended September 30, 2006 and 2005, respectively, and 1,461,301 and 1,224,911 for the nine months ended September 30, 2006 and 2005, respectively, were excluded from the calculations of diluted net loss per share as inclusion of the options would have had an anti-dilutive effect on the net loss per share for the periods.

4. COLLABORATION AND LICENSE AGREEMENTS

In September 2006, the Company entered into a collaboration and license agreement with Ipsen pursuant to which the Company granted Ipsen exclusive rights to develop and commercialize ACAPODENE® and other products containing toremifene in all indications which the Company has licensed from Orion Corporation, ("Orion"), which include indications for all diseases or indications in humans except the treatment and prevention of breast cancer in the European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States (collectively, the "European Territory"). In accordance with the terms of the agreement, Ipsen has agreed to pay the Company

GTx, Inc.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(in thousands, except share and per share data)
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€23,000 as a license fee and expense reimbursement, of which €1,500 will be paid in equal installments over a three year period. In October 2006, the Company received €21,500 (approximately $27,100) from Ipsen as the initial payment for the license fee and expense reimbursement. Pursuant to the agreement, GTx is also entitled to receive from Ipsen up to an aggregate of €39,000 in milestone payments depending on the successful development and launch of ACAPODENE® in certain countries of the European Territory for the high grade PIN indication, subject to certain conditions, and the ADT indication. Ipsen has agreed to be responsible for and to pay all clinical development, regulatory and launch activities to commercialize ACAPODENE® in the European Territory for both the high grade PIN indication and ADT indication. Ipsen has agreed to pay the Company a royalty equal to a graduating percentage of aggregate net sales of products containing toremifene (including ACAPODENE®) which rates will be dependent on whether such sales are for the high grade PIN indication or the ADT indication. GTx will remain responsible for paying upstream royalties on ACAPODENE® to both Orion and the University of Tennessee Research Foundation for the PIN indication and to Orion only for the ADT indication. Ipsen will purchase the bulk drug product supply directly from Orion and is responsible for the packaging and labeling of the final product.

The Company recorded deferred revenue of $29,259 related to the Ipsen upfront license fee and expense reimbursement which is expected to be amortized into revenue on a straight-line basis over the estimated development period for ACAPODENE® in the European Territory (see Note 1). The Company recognized as collaboration revenue $390 for the three months ended September 30, 2006 from the amortization of the Ipsen deferred revenue. Collaboration revenue for the three months ended September 30, 2006 also included $334 from the amortization of the upfront license fee received from Ortho Biotech under a joint collaboration and license agreement for andarine.

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

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

Forward-Looking Information

This Quarterly Report on Form 10-Q contains forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements include statements about:

- the anticipated progress of our research, development and clinical programs;
- potential future licensing fees, milestone payments and royalty payments including any milestone payments or royalty payments that we may receive under our collaboration and license agreements with Ortho Biotech and Ipsen;
- our and our collaborator's ability to market, commercialize and achieve market acceptance for our product candidates or products that we may develop;
- our ability to generate additional product candidates for clinical testing;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; and
- our estimates regarding the sufficiency of our cash resources.

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

Overview

We are a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for cancer and serious conditions related to men's health. Our lead drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens, two essential classes of hormones. We are developing ACAPODENE® (toremifene citrate), a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: first, a pivotal Phase III clinical trial for the treatment of serious side effects of androgen deprivation therapy, or ADT, for advanced prostate cancer, and second, a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia, or high grade PIN. We have licensed to the Ipsen Group exclusive rights in Europe to develop and commercialize ACAPODENE® for the prevention of prostate cancer in high risk men and for the treatment of multiple side effects of androgen deprivation therapy. We are also developing ostarine, a selective androgen receptor modulator, or SARM. We believe that ostarine has the potential to treat a variety of indications, including muscle wasting and bone loss in frail elderly patients, osteoporosis, muscle wasting in end stage renal disease patients, and severe burn wounds and associated muscle wasting. We initiated a proof of concept Phase II clinical trial of ostarine in May 2006 and completed enrollment in July 2006. We expect to report the data from the Phase II clinical trial in the fourth quarter of 2006. We have licensed to Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson (Ortho Biotech), andarine, another one of our SARMs, under a joint collaboration and license agreement.

We plan to build specialized sales and marketing capabilities to promote our product candidates to urologists and medical oncologists in the United States and to seek partners to commercialize our product candidates to broader markets in the United States and in the rest of the world.

We currently market FARESTON® (toremifene citrate 60 mg) tablets, which have been approved by the U.S. Food and Drug Administration, or FDA, for the treatment of metastatic breast cancer in post-menopausal women in the United States. In January 2005, we acquired from Orion Corporation, ("Orion"), the right to market FARESTON® tablets in the United States for the metastatic breast cancer indication. We also acquired a license to toremifene for all indications in humans worldwide, except breast cancer outside of the United States. The active pharmaceutical ingredient in FARESTON® is the same as in ACAPODENE®, but at a different dose. Acquiring the FARESTON® license allows us to control all toremifene based products in the United States and enhances the strategic value of our ACAPODENE® assets. Sales of pharmaceuticals for breast cancer in the SERM class have declined in recent years as aromatase inhibitors have gained market share. We believe that aromatase inhibitors will continue to capture breast cancer market share from SERMs, including from FARESTON®, resulting in a continued decline in FARESTON® sales.

In addition, we have an extensive preclinical pipeline generated from our own discovery program that includes the specific product candidates prostarine, a SARM for benign prostatic hyperplasia, and andromustine, an anticancer product candidate, for hormone refractory prostate cancer.

Our most advanced product candidate, ACAPODENE®, is being developed to treat both the multiple side effects of ADT and to prevent prostate cancer in high risk men with high grade PIN. ADT is the standard medical treatment for patients who have advanced, recurrent or metastatic prostate cancer, and we believe that there will be approximately one million prostate cancer survivors treated with ADT in 2008. We commenced a pivotal Phase III clinical trial of ACAPODENE® under a Special Protocol Assessment, or SPA, with the FDA for this indication in November 2003. We reached our enrollment goal in the fall of 2005 with approximately 1,400 patients randomized for the trial. In December 2005,

GTx conducted a planned interim analysis of bone mineral density ("BMD") in the first 197 patients to complete a full year of treatment. In each of three measurements (lumbar spine, hip and femoral neck), statistically significant positive changes in BMD were observed in patients on ACAPODENE®, when compared to patients on placebo, who on average lost bone. In June 2006, GTx conducted a lipid interim analysis of the same 197 patients. Patients treated with ACAPODENE® had statistically significant lower levels of total cholesterol, LDL, and triglycerides, reduction in the ratio of total cholesterol to HDL, and higher levels of HDL, when compared to patients on placebo. However, data on all patients completing the study will need to be evaluated before any conclusions about clinical significance of the lipid findings can be drawn. We anticipate that we will complete this Phase III clinical trial in the fourth quarter of 2007. If the results are favorable, we expect to file a New Drug Application, or NDA, with the FDA in the first half of 2008. We are conducting a voluntary one-year blinded Phase IIIb extension trial for patients from the Phase III study to gather additional fracture and safety data. This Phase IIIb clinical study is a separate clinical trial and will not affect the current timeline for the completion of the ongoing Phase III clinical trial in the fourth quarter of 2007 and the potential submission of the NDA with the FDA.

In the first quarter of 2005, we initiated a pivotal Phase III clinical trial of ACAPODENE® for the prevention of prostate cancer in men with high grade PIN, which is being conducted under a SPA with the FDA. We reached our enrollment goal of 1,260 patients in May 2006 and expect to enroll approximately 300 additional patients by the end of 2006 into the study who will also participate in sub-studies requested by the FDA. The trial is designed as a 36 month study, but provides for an interim analysis after a sufficient number of events have occurred to determine if the efficacy of the study drug has been statistically attained. We believe that an interim analysis of the trial results will occur either in the fourth quarter of 2007 or the first quarter of 2008. If the efficacy endpoint is achieved, we plan to file an NDA with the FDA during 2008. If we are able to file an NDA based on the results of the interim analysis, we will need to continue to collect safety data during the review process to satisfy the FDA's safety requirements set forth in the SPA.

In September 2006, we entered into a collaboration and license agreement with Ipsen Limited ("Ipsen"), a wholly owned subsidiary of the Ipsen Group, pursuant to which we granted Ipsen exclusive rights to develop and commercialize ACAPODENE® and other products containing toremifene in all indications which the company has licensed from Orion, which include indications for all diseases or indications in humans except the treatment and prevention of breast cancer in the European Union, Switzerland, Norway, Iceland, Lichtenstein, and the Commonwealth of Independent States (collectively, the "European Territory"). In the agreement, both parties have agreed that neither party will seek to commercialize, promote, market or sell certain products within the European Territory for an agreed period of time subsequent to the time of the first commercial launch of ACAPODENE® within the European Territory. We and Ipsen have also granted to each other a right of first negotiation with respect to the development, marketing, sale and distribution of any new SERM-based products for the field of the prevention and treatment of prostate cancer or related side effects, or any other indication the parties may agree on. In accordance with the terms of the agreement, Ipsen agreed to pay us €23 million as a license fee and expense reimbursement, of which €1.5 million will be deferred and paid in equal installments over a three year period. In October 2006, we received €21.5 million (approximately $27.1 million) from Ipsen as initial payment for the license fee and expense reimbursement. Pursuant to the agreement, we are also entitled to receive from Ipsen up to an aggregate of €39 million in milestone payments depending on the successful development and launch of ACAPODENE® in certain countries of the European Territory for the high grade PIN indication, subject to certain conditions, and the ADT indication. Ipsen has agreed to be responsible for and to pay for all clinical development, regulatory and launch activities to commercialize ACAPODENE® in the European Territory for both the high grade PIN indication and ADT indication. We will remain similarly responsible for all development and regulatory activities outside of the European Territory. However, Ipsen has agreed to pay a portion of our ACAPODENE®

development costs in the United States if certain conditions are met. Under the agreement, Ipsen must elect to retain its rights to commercialize ACAPODENE® and other products containing toremifene for the high grade PIN indication. Until such time as Ipsen shall make its election, however, it is required to initiate and carry out the development of ACAPODENE® for the high grade PIN indication in the European Territory and to pay all costs associated therewith. Depending on when Ipsen exercises this election, Ipsen may be required to pay an additional license fee as well as a premium on its share of the development and clinical trial expenses incurred by us in the United States since January 1, 2006, on account of ACAPODENE® for high grade PIN. If Ipsen does not exercise its election within a certain period, Ipsen will not be obligated to pay us for a portion of the development and clinical trial expenses incurred by us in the United States since January 1, 2006, on account of ACAPODENE® for the high grade PIN indication, and we may elect to terminate Ipsen's rights to commercialize toremifene-based products for this indication, in which event all of Ipsen's rights to ACAPODENE® for the high grade PIN indication (including all associated clinical trial data and regulatory filings and approvals) will revert to us. Ipsen has agreed to pay us a royalty equal to a graduating percentage of aggregate net sales of products containing toremifene (including ACAPODENE®) in the mid-teens, which could reach the mid-twenties based on certain sales price thresholds being met, and which rates will be dependent on whether such sales are for the high grade PIN indication or the ADT indication. We will remain responsible for paying upstream royalties on ACAPODENE® to both Orion and the University of Tennessee Research Foundation for the PIN indication and to Orion only for the ADT indication. Ipsen will purchase the bulk drug product supply directly from Orion and is responsible for the packaging and labeling of the final product.

In our third clinical program, ostarine, a SARM, is being developed to treat a variety of medical conditions relating to muscle wasting and/or bone loss in acute and chronic diseases. Ostarine is a novel non-steroidal agent designed to have anabolic activity like testosterone without unwanted side effects on the prostate and skin and in a once daily oral dose. We initiated a proof of concept Phase II clinical trial of ostarine in May 2006 and completed enrollment in July 2006. The three month placebo controlled clinical trial is evaluating multiple doses of ostarine in 60 elderly men and 60 postmenopausal women. The trial is designed to evaluate the activity of ostarine on building muscle and promoting bone as well as to assess safety in both elderly men and postmenopausal women. Endpoints of the trial include measurements of bone, fat, and muscle. We expect to report the data from the Phase II clinical trial in the fourth quarter of 2006. Based on ostarine's Phase II clinical data profile, we will select specific acute and chronic muscle wasting and/or bone loss diseases for further development. We plan to initiate a Phase IIb or Phase III clinical trial of ostarine in 2007.

In March 2004, we entered into a joint collaboration and license agreement with Ortho Biotech for andarine and specific backup compounds. We retain the right to independently develop all SARM compounds which are excluded from the collaboration, including ostarine. Under the terms of the agreement, we received an up-front licensing fee and reimbursement of certain andarine development expenses totaling approximately $6.7 million, which are being amortized into revenue over five years. We are entitled to receive additional licensing fees, milestone payments and royalty payments on any sales of licensed products. Johnson & Johnson Pharmaceutical Research & Development, an affiliate of Ortho Biotech, is responsible for further clinical development and related expenses for andarine and other licensed SARM compounds. Ortho Biotech may terminate the development or commercialization of andarine or any other licensed SARM compound under the agreement upon 90 days' notice, or 30 days' notice if there are safety issues, or may terminate the agreement for our uncured material breach.

Our net loss for the nine month period ended September 30, 2006 was $30.8 million. Our net loss included FARESTON® net product sales of $1.5 million and the recognition of collaboration revenue of $1.4 million for the nine months ended September 30, 2006. We have financed our operations and internal growth almost exclusively through private placements of preferred stock and our public offerings

of common stock. We expect to continue to incur net losses over the next several years as we continue our clinical development and research and development activities, apply for regulatory approvals of our product candidates, establish sales and marketing capabilities and grow our operations. With the receipt in October 2006 of the initial payment of the upfront license fee and expense reimbursement from our collaboration with Ipsen, we believe that our current cash resources, interest on these funds and product revenue from the sale of FARESTON will be sufficient to meet our projected operating requirements through the first quarter of 2008**.**

Since our inception in 1997, we have been focused on drug discovery and development programs. Research and development expenses represented 75.7% of our total operating expenses for the nine months ended September 30, 2006. Research and development expenses include our expenses for personnel associated with our research activities, screening and identification of product candidates, formulation and synthesis activities, manufacturing, preclinical studies, toxicology studies, clinical trials, regulatory affairs, and quality assurance activities.

We expect that research and development expenditures will continue to increase during the remainder of the year and in subsequent years due to (1) the continuation of the pivotal Phase III clinical trial of ACAPODENE® for the treatment of serious side effects of ADT for advance prostate cancer and the one-year Phase IIIb extension trial, (2) the continuation of the pivotal Phase III clinical trial of ACAPODENE® for the prevention of prostate cancer in men with high grade PIN, (3) the continued clinical and preclinical development of ostarine, (4) the continued development of other product candidates in our SARM program that are not included in our collaboration with Ortho Biotech, including prostarine, (5) the continued preclinical development of other product candidates, including andromustine, and (6) the increase in research and development personnel.

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

Program	Product Candidate/ Indication	Development Phase	Status
SERM	**ACAPODENE**		
	80 mg		
	Side effects of ADT	Pivotal Phase III clinical trial; Phase IIIb extension study	Phase III clinical trial ongoing under a SPA; attained enrollment goal; obtained statistically significant results from a planned BMD interim analysis in fourth quarter of 2005 and from a lipid interim analysis in second quarter of 2006
	ACAPODENE		
	20 mg		
	Prevention of prostate cancer in men with high grade PIN	Pivotal Phase III clinical trial	Phase III clinical trial ongoing under a SPA; attained enrollment goal and enrolling sub-studies
SARM	**Ostarine**		
	Muscle wasting and/or bone loss in acute and chronic diseases	Phase II clinical trial	Phase II clinical trial ongoing; attained enrollment goal
	Andarine		
	Cancer cachexia	Phase I clinical trial	Four Phase I clinical trials completed

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

Critical Accounting Policies and Significant Judgments and Estimates

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

readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our financial statements appearing in our Annual Report on Form 10-K for the year ended December 31, 2005 filed with the SEC, we believe that the following accounting policies are most critical to aid you in fully understanding and evaluating our reported financial results.

Revenue Recognition

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

We use revenue recognition criteria outlined in Staff Accounting Bulletin ("SAB") No. 101, *"Revenue Recognition in Financial Statements"* as amended by SAB No. 104 (together, "SAB 104") and Statement of Financial Accounting Standards ("SFAS") No. 48 *"Revenue Recognition When Right of Return Exists"* ("FAS No. 48") and Emerging Issues Task Force ("EITF") Issue 00-21, "*Revenue Arrangements with Multiple Deliverables"* ("EITF 00-21"). Accordingly, revenues from licensing and collaboration agreements are recognized based on the performance requirements of the agreement. Non-refundable up-front fees, where we have an ongoing involvement or performance obligation, are generally recorded as deferred revenue in the balance sheet and amortized as collaboration revenue in the condensed statements of operations over the term of the performance obligation. We estimated the performance obligation period to be five years for the development of andarine with Ortho Biotech and also for the development of ACAPODENE® for both the high grade PIN and ADT indications in the European Territory with Ipsen. The factors that drive the actual development period of a pharmaceutical product are inherently uncertain and include determining the timing and expected costs to complete the project, projecting regulatory approvals and anticipating potential delays. We use all of these factors in initially estimating the economic useful lives of our performance obligations, and we also continuously monitor these factors for indications of appropriate revisions.

We recognize net product sales revenue from the sale of FARESTON® less deductions for estimated sales discounts and sales returns. We recognize revenue from product sales when the goods are shipped and title and risk of loss pass to the customer and the other criteria of SAB No. 104 and SFAS No. 48 are satisfied. We account for rebates to certain governmental agencies as a reduction of revenue. We allow customers to return product within a specified time period prior to and subsequent to the product's labeled expiration date. As a result, we estimate an accrual for product returns based on factors which include historical product returns and estimated product in the distribution channel which is expected to exceed its expiration date. We retained substantially the same wholesale customers of, and the distribution channel that was used by another pharmaceutical company that distributed FARESTON® for six years prior to our obtaining the rights to market FARESTON® in January 2005. We also obtained historical product return trend information that we continue to update with our own product return data. We estimate the amount of product in the distribution channel which is expected to exceed its expiration date and be returned by the customer by receiving information from our three largest wholesale customers about the levels of FARESTON® inventory held by these customers. These three largest wholesale customers accounted for 94% of the total sales of FARESTON® for the nine month period ended September 30, 2006. Based on this information, which we have not independently verified, we estimate the number of months of product on hand. During the three months ended September 30, 2006, we reduced our estimated accrual for product returns by $126,000 which resulted in an increase to net product sales of $126,000 for the three months ended September 30, 2006. At September 30, 2006 and December 31, 2005, our accrual for product returns was $162,000 and $274,000, respectively. If actual future results

are different than our estimates, we may need to adjust our estimated accrual for product returns, which could have a material effect on earnings in the period of the adjustment.

Research and Development Costs

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

Patent Costs

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

Share-based Compensation

Effective January 1, 2006, we adopted SFAS No. 123(R) "Share-Based Payment" and began recognizing compensation expense for our share-based payments based on the fair value of the awards. Share-based payments include stock option grants under our stock option plans. Prior to January 1, 2006, we accounted for share-based compensation expense using the intrinsic value recognition method prescribed by Accounting Principles Board Opinion ("APB") No. 25 and SFAS No. 123. Since we adopted SFAS No. 123(R) under the modified prospective and the prospective transition methods, results from prior periods have not been restated. Under SFAS No. 123(R), forfeitures are estimated at the time of valuation and reduce expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate.

Total share-based compensation expense for the three months ended September 30, 2006 was $362,000, of which $131,000 and $231,000 were recorded in the condensed statements of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the nine months ended September 30, 2006 was $1.1 million, of which $408,000 and $645,000 were recorded in the condensed statements of operations as research and development expenses and general and administrative expenses, respectively. Prior to the adoption of SFAS No. 123(R), we accounted for share-based compensation expense under APB No. 25. Total share-based compensation expense for the three months ended September 30, 2005 was $165,000 of which $113,000 and $52,000 were recorded in the condensed statements of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the nine months ended September 30, 2005, was $573,000 of which $353,000 and $220,000 were recorded in the condensed statements of operations as research and development expenses and general and administrative expenses, respectively. Included in share-based compensation expense for all periods presented is share-based compensation expense related to deferred compensation arrangements for our directors, which was $35,000 and $31,000 for the three months ended September 30, 2006 and 2005, respectively, and $105,000 and $95,000 for the nine months ended September 30, 2006 and 2005, respectively. On the date of adoption of SFAS No. 123(R), the unamortized balance of deferred stock compensation of $1.7 million was reduced to zero with an offsetting adjustment to additional paid-in capital.

Recent Accounting Pronouncements

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes-an interpretation of FASB Statement No. 109 "(FIN 48)"*, which clarifies the accounting for uncertainty in tax positions.

FIN 48 requires the recognition in the financial statements, the impact of a tax position, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 are effective as of January 1, 2007, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. The Company is currently evaluating the impact of adopting FIN 48 on the Company's financial statements.

Results of Operations

Three Months Ended September 30, 2006 and 2005

Revenues

Revenues for the three months ended September 30, 2006 were $1.1 million as compared to $622,000 for the same period of 2005. Revenues include net sales of FARESTON® marketed for the treatment of metastatic breast cancer and collaboration income from Ortho Biotech for andarine and Ipsen for ACAPODENE®. During the three months ended September 30, 2006 and 2005, FARESTON® net sales were $348,000 and $288,000, respectively, while costs of products sales were $118,000 and $185,000, respectively. During the three months ended September 30, 2006, we reduced our estimated accrual for product returns by $126,000 which resulted in an increase in net product sales of $126,000 for the three months ended September 30, 2006. During the three months ended September 30, 2006, the sales price of FARESTON® increased by 9.7% while sales revenue increased by 21%, after the reduction in the accrual for product returns, and sales volume decreased by 26% as compared to the same period in 2005. Collaboration income was $724,000 for the three months ended September 30, 2006, of which $390,000 and $334,000 was from Ipsen and Ortho Biotech, respectively. Ipsen collaboration income was recognized for the period from September 7, 2006 to September 30, 2006. Collaboration income from Ortho Biotech was $334,000 for the three months ended September 30, 2005.

Research and Development Expenses

Research and development expenses increased by $1.1 million to $9.6 million for the three months ended September 30, 2006 from $8.5 million for the same period of 2005. The following table identifies the research and development expenses for each of our product candidates, as well as research and development expenses pertaining to our other research and development efforts for each of the periods presented. Research and development spending for past periods is not indicative of spending in future periods.

Program	Product Candidate/ Indication	Three Months Ended September 30, 2006	2005
		(in thousands)	
SERM	**ACAPODENE**		
	80 mg		
	Side effects of ADT	$ 2,016	$ 3,679
	ACAPODENE		
	20 mg		
	Prevention of prostate cancer in men with high grade PIN	2,455	1,996
SARM	**Ostarine**		
	Muscle wasting and/or bone loss in acute and chronic diseases	3,014	676
	Andarine		
	Cancer cachexia	14	36
Other research and development		2,115	2,067
Total research and development expenses		$ 9,614	$ 8,454

General and Administrative Expenses

General and administrative expenses increased during the three months ended September 30, 2006 to $2.9 million from $2.3 million for the three months ended September 30, 2005. The increase was primarily the result of increased personnel related expenses resulting from additional personnel and increased share-based compensation expense as a result of the adoption of SFAS No.123(R) effective January 1, 2006.

Interest Income

Interest income increased to $638,000 for the three months ended September 30, 2006 from $345,000 for the three months ended September 30, 2005. The increase was attributable to higher average interest rates in addition to higher average cash and cash equivalents balances during the three months ended September 30, 2006, as compared to the same period in 2005.

Results of Operations

Nine Months Ended September 30, 2006 and 2005

Revenues

Revenues for the nine months ended September 30, 2006 were $2.9 million as compared to $3.1 million for the same period of 2005. Revenues include net sales of FARESTON® marketed for the treatment of metastatic breast cancer and collaboration income from Ortho Biotech for andarine and Ipsen for ACAPODENE®. During the nine months ended September 30, 2006 and 2005, FARESTON® net sales were $1.5 million and $2.1 million, respectively, while costs of products sales were $755,000 and $1.4 million, respectively. During the nine months ended September 30, 2006, the sales price of FARESTON® increased by 9.7% while sales revenue and sales volume decreased by 29% and by 38%, respectively, as compared to the same period in 2005. Collaboration income was $1.4 million for the nine months ended September 30, 2006, of which $1.0 million and $390,000 was from Ortho Biotech and Ipsen, respectively. Collaboration income from Ortho Biotech was $1.0 million for the nine months ended September 30, 2005.

Research and Development Expenses

Research and development expenses increased by $2.1 million to $26.5 million for the nine months ended September 30, 2006 from $24.4 million for the same period of 2005. The following table identifies the research and development expenses for each of our product candidates, as well as research and development expenses pertaining to our other research and development efforts, for each of the periods presented. Research and development spending for past periods is not indicative of spending in future periods.

Program	Product Candidate/ Indication	Nine Months Ended September 30, 2006	Nine Months Ended September 30, 2005
		(in thousands)	
SERM	**ACAPODENE®**		
	80 mg		
	Side effects of ADT	$ 6,337	$ 9,177
	ACAPODENE®		
	20 mg		
	Prevention of prostate cancer in men with high grade PIN	8,530	5,213
SARM	**Ostarine**		
	Muscle wasting and/or bone loss in acute and chronic diseases	5,543	4,225
	Andarine		
	Cancer cachexia	44	136
Other research and development		6,045	5,668
Total research and development expenses		$ 26,499	$ 24,419

General and Administrative Expenses

General and administrative expenses increased during the nine months ended September 30, 2006 to $8.5 million from $7.4 million for the nine months ended September 30, 2005. The increase of approximately $1.1 million was primarily the result of increased personnel related expenses resulting from additional personnel to support our planned growth which accounted for approximately $.6 million of the increase. The remainder of the increase was due primarily to an increase in share-based compensation expense as a result of the adoption of SFAS No.123(R) effective January 1, 2006.

Interest Income

Interest income increased to $2.1 million for the nine months ended September 30, 2006 from $1.0 million for the nine months ended September 30, 2005. The increase of approximately $1.1 million was attributable to higher average interest rates in addition to higher average cash and cash equivalents balances during the nine months ended September 30, 2006, as compared to the same period in 2005.

Liquidity and Capital Resources

At September 30, 2006, we had cash and cash equivalents of $44.6 million, compared to $74.0 million at December 31, 2005. Net cash used in operating activities was $29.0 million and $25.6 million for the nine months ended September 30, 2006 and 2005, respectively. The use of cash in both periods resulted primarily from funding our net losses. Net cash used in investing activities was $516,000 and $1.2 million for the nine months ended September 30, 2006 and 2005, respectively. Net cash used in investing activities for both periods was primarily for the purchase of research and development equipment, software, computer equipment, and furniture and fixtures. We currently expect to make capital expenditures of approximately $500,000 for the remainder of 2006.

Net cash provided by financing activities was $62,000 for the nine month period ended September 30, 2006 and included proceeds from the exercise of employee stock options of $66,000, offset by principal payments under a capital lease obligation of $4,000. Net cash provided by financing activities for the nine months ended September 30, 2005 was $5,000 and included proceeds from the exercise of employee stock options of $9,000, offset by principal payments under a capital lease obligation of $4,000.

With the receipt in October 2006 of the initial license fee and expense reimbursement payment from our collaboration with Ipsen of approximately $27.1 million, we estimate that our current cash resources, interest on these funds, and product revenue from the sale of FARESTON® will be sufficient to meet our projected operating requirements through the first quarter of 2008. This estimate does not include additional funding that we may receive under our existing collaborations with Ortho Biotech and Ipsen, potential future collaboration agreements with other companies, or the potential future issuance and sale of our securities.

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

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- future clinical trial results;
- the achievement of certain milestone events under, and other matters related to, our collaboration and license agreements with Ortho Biotech and Ipsen;
- the terms and timing of any future collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;

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

Until we can generate a sufficient amount of product revenue, we expect to finance future cash needs through additional funding that we may receive under our collaborations with Ortho Biotech and Ipsen, public or private equity offerings, debt financing or other collaboration and licensing arrangements, as well as through interest income earned on cash balances. With the exception of payments that we may receive under our collaborations with Ortho Biotech and Ipsen, we do not currently have any commitments for future external funding. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, 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. The effect of a hypothetical decrease of one percentage point in the average interest rate earned on our cash equivalents would have resulted in a decrease in our interest income of approximately $599,000 for the nine months ended September 30, 2006.

We operate primarily in the United States. However, some of our clinical trial sites are located in Argentina, Canada, Germany, Ireland, Mexico and the United Kingdom which requires us to make payments for certain clinical trial services in foreign currencies. In accordance with the terms of a collaboration and license agreement, Ipsen Limited is required to pay us €23.0 million as a license fee and expense reimbursement. We are also entitled to receive from Ipsen up to €39.0 million in milestone payments depending on the successful development and launch of ACAPODENE® in certain countries of the European Territory. Ipsen's obligation to make payments to us in Euros exposes us to potential foreign currency transaction losses. Our exposure to foreign currency rate fluctuations will increase because we are obligated to pay Orion Corporation, our supplier of ACAPODENE® and FARESTON®, in Euros. However, such exposure is not expected to be material. We do not currently use derivative financial instruments to mitigate this exposure.

ITEM 4. CONTROLS AND PROCEDURES

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

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

There were no changes in our internal control over financial reporting during the third quarter of 2006 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 1A. RISK FACTORS

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

Risks Related to Our Financial Results and Need for Additional Financing

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

We have a limited operating history. As of September 30, 2006, we had an accumulated deficit of $225.1 million, of which $96.3 million related to non-cash dividends and adjustments to the preferred stock redemption value. We have incurred losses in each year since our inception in 1997. Net losses were $30.8 million for the nine months ended September 30, 2006, $36.8 million in 2005, $22.3 million in 2004, and $14.2 million in 2003. We expect to continue to incur significant and increasing operating losses for the foreseeable future. These losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Because of the numerous risks and uncertainties associated with developing small molecule drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. We have financed our operations and internal growth almost exclusively through sales of common stock and preferred stock. In addition, we have received upfront license fees and payments pursuant to our collaboration agreements with Ortho Biotech for andarine and certain other SARMs, and Ipsen Limited for European rights to ACAPODENE® and other toremifene-based products. FARESTON® is currently our only commercial product and, we expect, will account for all of our product revenue for the foreseeable future. For the nine months ended September 30, 2006, we recognized $1.5 million in net revenues from the sale of FARESTON®.

We expect our research and development expenses to increase in connection with our ongoing clinical trials. In addition, subject to regulatory approval of any of our product candidates, we expect to incur additional sales and marketing expenses and increased manufacturing expenses.

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

We will need to raise additional capital to:

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

With the receipt in October 2006 of the initial payment of the upfront license fee and expense reimbursement from our collaboration with Ipsen, we estimate that our current cash resources, interest on these funds and product revenue from the sale of FARESTON® will be sufficient to meet our projected operating requirements through the first quarter of 2008. This estimate does not include additional funding that we may receive under our existing collaboration agreements with Ortho Biotech and Ipsen, potential future collaboration agreements with other companies, or the potential future issuance and sale of our securities.

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

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- future clinical trial results;
- the achievement of certain milestone events under, and other matters related to, our collaboration and license agreements with Ortho Biotech and Ipsen;
- the terms and timing of any future collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- potential future licensing fees, milestone payments and royalty payments, including any milestone payments or royalty payments that we may receive under our collaboration and license agreements with Ortho Biotech and Ipsen;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop;
- the effect of competing technological and market developments;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

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

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

Risks Related to Development of Product Candidates

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

We have agreed to purchase from Orion our worldwide requirements of toremifene, the active pharmaceutical ingredient in ACAPODENE®, in finished tablet form at specified transfer prices under a license and supply agreement. Similarly, Ipsen has agreed to purchase from Orion ACAPODENE® tablets for clinical testing and commercial sale within the European Territory (as defined in our collaboration and license agreement with Ipsen) under an amended supply agreement with Orion. As such, both we and Ipsen rely on Orion as the single source supplier of ACAPODENE®.

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

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

Under our joint collaboration and license agreement with Ortho Biotech, Ortho Biotech is responsible for the manufacture, packaging and supply of andarine for both clinical trials and commercialization. We have relied on EaglePicher Pharmaceutical Services as our single supplier for ostarine, and we are currently assessing our manufacturing needs for additional clinical trial materials and commercial supply of ostarine as we continue to review our clinical strategy for ostarine. We will evaluate whether to continue to rely on the manufacturing capabilities of EaglePicher or whether some or all of the manufacturing process should be transferred to another contract manufacturer as we plan for our clinical trials and potential commercial launch of ostarine. If our current supply of ostarine becomes unusable, if our ostarine supply is not sufficient to complete our clinical trials, or if we are unsuccessful in identifying a contract manufacturer or negotiating a manufacturing agreement on a timely basis for our clinical trials and potential commercial launch, we could experience a delay in receiving an adequate supply of ostarine.

We may not be able to maintain or renew our existing or any other third-party manufacturing arrangements on acceptable terms, if at all. If we are unable to continue relationships with Orion for ACAPODENE® and EaglePicher or Ortho Biotech for ostarine or andarine, respectively, or to do so at an acceptable cost, or if these or other suppliers fail to meet our requirements for these product candidates or for ostarine for any reason, we would be required to obtain alternate suppliers. However, we may not be permitted to obtain alternate suppliers for ACAPODENE® under our license agreement with Orion if Orion terminates its supply of ACAPODENE® due to our uncured material breach or bankruptcy. Any

inability to obtain alternate suppliers, including an inability to obtain approval from the FDA of an alternate supplier, would delay or prevent the clinical development and commercialization of these product candidates.

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

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

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

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

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

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

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

development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

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

The loss of Ortho Biotech or Ipsen as a collaborator in the development or commercialization of andarine or ACAPODENE®, respectively, any dispute over the terms of our collaborations with Ortho Biotech or Ipsen, or any other adverse development in our relationships with Ortho Biotech or Ipsen could materially harm our business and might accelerate our need for additional capital. For example, while we initially anticipated proceeding with Phase II clinical studies of andarine within a reasonable period subsequent to entering into our collaboration agreement with Ortho Biotech, to date Ortho Biotech has not initiated a Phase II clinical trial. We do not know when, or if, Ortho Biotech will initiate a Phase II clinical trial of andarine, and any failure to do so could have an adverse effect on our business, including with respect to our potential receipt of related milestone payments. Additionally, Ipsen is obligated to initiate and conduct appropriate clinical studies as required by the appropriate regulatory authorities in order to obtain marketing approvals of ACAPODENE® within the European Territory. Any failure on the part of Ipsen to initiate these studies could delay the commercialization of ACAPODENE® within the European Territory.

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

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

- we are not able to control the amount and timing of resources that Ortho Biotech or Ipsen devotes to andarine or ACAPODENE®, respectively;
- we may not be able to control the amount and timing of resources that our potential future partners may devote to our product candidates;
- our partners may experience financial difficulties or changes in business focus;
- we may be required to relinquish important rights such as marketing and distribution rights;
- under certain circumstances, Ipsen may not be required to commercialize ACAPODENE® in certain countries of the European Territory if it is determined that it is not commercially reasonable for it to do so;
- pricing reimbursement constraints within the European Territory may diminish the prospects of our receiving royalty payments from Ipsen on aggregate net sales of ACAPODENE® in some or all of the countries within the European Territory;

- should a collaborator fail to develop or commercialize one of our compounds or product candidates, we may not receive any future milestone payments and will not receive any royalties for this compound or product candidate;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- a collaborator could move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our product candidates.

Additionally, we and Ipsen have agreed that neither party will seek to commercialize, promote, market or sell certain products within the European Territory for an agreed period of time subsequent to the time of the first commercial launch of ACAPODENE® within the European Territory. We and Ipsen have also agreed to grant to the other a right of first negotiation with respect to the development, marketing, sale and distribution of any new SERM-based products for the field of the prevention and treatment of prostate cancer or related side effects, or any other indication the parties agree on.

Risks Related to Our Intellectual Property

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

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

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

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

If some or all of our, or our licensors', patents expire or are invalidated or are found to be unenforceable, or if some or all of our patent applications do not yield issued patents or yield patents with narrow claims, or if we are estopped from asserting that the claims of an issued patent cover a product of a third party, we may be subject to competition from third parties with products with the same active pharmaceutical ingredients as our product candidates.

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

Our rights to specified patent applications relating to SARM compounds that we have licensed from the University of Tennessee Research Foundation, or UTRF, are subject to the terms of UTRF's license with The Ohio State University Research Foundation, or OSURF, and our rights to future related improvements are subject to UTRF's exercise of an exclusive option under its agreement with OSURF for such improvements, which UTRF can exercise at no additional cost to it. In addition, under the terms of our agreements with the diagnostic companies to which we provide clinical samples from our Phase IIb and Phase III clinical trial of ACAPODENE®, we will not obtain any intellectual property rights in any of their developments, including any test developed to detect high grade PIN or prostate cancer.

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

Our and our licensors' ability to obtain patents can be highly uncertain and involve complex and in some cases unsettled legal issues and factual questions. Furthermore, different countries have different procedures for obtaining patents, and patents issued in different countries provide different degrees of protection against the use of a patented invention by others. Therefore, if the issuance to us or our

licensors, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

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

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

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

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

Even in the event that patents are issued from our pending method of use patent applications, after the expiration of the patent covering the composition of matter of toremifene in a particular country, competitors could market and sell toremifene products for uses for which FARESTON® has already been approved. Thus, physicians in such countries would be permitted to prescribe these other toremifene products for indications that are protected by our method of use patents or patents issuing from pending patent applications, even though these toremifene products would not have been approved for those uses, and in most cases the competitor would not be liable for infringing our patents. Moreover, because Orion

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

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

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

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

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

In addition, under our collaboration and license agreement with Ipsen, Ipsen may be entitled to offset a portion of any royalties due to us in any calendar year on account of ACAPODENE® sales to pay for costs incurred by Ipsen to obtain a license to any dominant intellectual property rights that are infringed by such ACAPODENE® sales.

Risk Related to Regulatory Approval of Our Product Candidates

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

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

Changes in the regulatory approval policy during the development period, changes in or the enactment of additional regulations or statutes, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Even if the FDA approves a product candidate, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product, and may impose ongoing requirements for post-approval studies, including additional research and development and clinical trials. The FDA also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

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

The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. For example, we believe that if the results of our ongoing Phase III clinical trial of ACAPODENE® for the reduction in the incidence of prostate cancer in men with high grade PIN are sufficiently positive, that trial will be sufficient to serve as a single pivotal Phase III clinical trial for this indication. In September 2005, we received a Special Protocol Assessment from the FDA. A SPA is designed to facilitate the FDA's review and approval of drug products by allowing the agency to evaluate the proposed design and size of clinical trials that are intended to form the primary basis for determining a drug product's efficacy. If agreement is reached with the FDA, a SPA documents the terms and conditions under which the design of the subject trial will be adequate for submission of the efficacy and human safety portion of a NDA. However, there are circumstances under which we may not receive the benefits of the SPA, notably including if the FDA subsequently identifies a substantial scientific issue essential to determining the product's safety or efficacy. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Furthermore, even if we file an application with the FDA for marketing approval of a product candidate, it may not result in marketing approval from the FDA.

We do not expect to receive regulatory approval for the commercial sale of any of our product candidates that are in development for the next few years. Similarly, it is not anticipated that Ipsen will receive the appropriate regulatory approvals to market ACAPODENE® within the European Territory until at least the same time period, if not later, than we expect to receive regulatory approval within the United States. The inability to obtain FDA approval or approval from comparable authorities in other countries for our product candidates would prevent us or our collaborators from commercializing these product candidates in the United States or other countries. See the section entitled "Business — Government Regulation" under Part I, Item 1 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2005 filed with the Securities and Exchange Commission, for additional information regarding risks associated with approval, as well as risks related to post-approval requirements.

Risks Related to Commercialization

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

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

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

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

FARESTON® is currently our only marketed product. Sales of FARESTON® in the United States have been declining and we anticipate that they will continue to do so. Continued sales of FARESTON® could be impacted by many factors. The occurrence of one or more of the following risks may cause sales of FARESTON® to decline more than we currently anticipate:

- the loss of the availability of Orion's website to market FARESTON®, which is an important source of advertising;
- the loss of one or more of our three largest wholesale drug distributors, which accounted for approximately 94% of our revenue generated from the sale of FARESTON® for the nine months ended September 30, 2006;
- the continued success of competing products, including aromatase inhibitors;
- the loss of coverage or reimbursement for FARESTON® from Medicare and Medicaid, private health insurers or other third-party payors;

- exposure to product liability claims related to the commercial sale of FARESTON®, which may exceed our product liability insurance;
- the failure of Orion to maintain regulatory filings or comply with applicable FDA requirements with respect to FARESTON®;
- the ability of third parties to market and sell generic toremifene products that will compete with FARESTON® for the treatment of breast cancer after the composition of matter patents that we license from Orion expire in the United States in September 2009;
- the loss of Orion, upon which we rely as a single source, as our supplier of FARESTON®; and
- our inability to manufacture FARESTON® until Orion's patents with respect to the composition of matter of toremifene expire if Orion terminates our license and supply agreement due to our uncured material breach or bankruptcy.

Sales of pharmaceuticals for breast cancer in the SERM class have declined in recent years as aromatase inhibitors have gained market share. We believe that aromatase inhibitors will continue to capture breast cancer market share from SERMs, including from FARESTON®, resulting in a continued decline in FARESTON® sales.

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

We have limited experience as a company in the sales, marketing and distribution of pharmaceutical products. There are risks involved with building our own sales and marketing capabilities, as well as entering into arrangements with third parties to perform these services. For example, building a sales force is expensive and time-consuming and could delay any launch of a product candidate. Similarly, we are relying on Ipsen to market and distribute our ACAPODENE® product candidates through Ipsen's established sales and marketing network within the European Territory. If our collaboration and license agreement with Ipsen is terminated for any reason, our ability to sell our ACAPODENE® product candidates in the European Territory would be adversely affected, and we may be unable to develop or engage an effective sales force to successfully market and sell our ACAPODENE® product candidates in the European Territory. In addition, to the extent that we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues are likely to be lower than if we market and sell any products that we develop ourselves.

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

Many patients will not be capable of paying for any products that we may develop and will rely on Medicare and Medicaid, private health insurers and other third-party payors to pay for their medical needs. If third-party payors do not provide coverage or reimbursement for any products that we may develop, our revenues and prospects for profitability may suffer. In December 2003, the President of the United States signed into law the Medicare Prescription Drug, Improvement and Modernization Act of 2003, legislation creating a prescription drug benefit program for Medicare recipients. The prescription drug program established by the legislation may have the effect of reducing the prices that we are able to charge for products we develop and sell through the program. This prescription drug legislation may also cause third-party payors other than the federal government, including the states under the Medicaid program, to discontinue coverage for products that we may develop or to lower the amount that they pay.

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

A primary trend in the United States health care industry is toward cost containment. In addition, in some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization. Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly-approved health care products. In particular, third-party payors may limit the indications for which they will reimburse patients who use any products that we may develop or products we sell. Cost-control initiatives could decrease the price we might establish for products that we may develop or that we sell, which would result in lower product revenues to us.

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

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

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

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

We have product liability insurance that covers our clinical trials and commercial products up to a $20.0 million annual aggregate limit. Insurance coverage is increasingly expensive. We may not be able

to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

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

We face competition from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we may develop. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before us and impair our ability to commercialize our product candidates.

Various products are currently marketed or sold and used off-label for some of the diseases and conditions that we are targeting, and a number of companies are or may be developing new treatments. The occurrence of such off-label uses could significantly reduce our ability to market and sell any products that we may develop. For example, although there are no products that have been approved by the FDA to treat multiple side effects of androgen deprivation therapy, we are aware of a number of drugs marketed by Eli Lilly, Merck, Sanofi-Aventis, Procter & Gamble, Wyeth Pharmaceuticals, Boehringer Ingelheim, Novartis and Bristol Myers Squibb that are prescribed off-label to treat single side effects of this therapy; that external beam radiation is used to treat breast pain and enlargement; and that Amgen is developing a product candidate for the treatment of osteoporosis in prostate cancer patients. While we have the only pharmaceutical product in clinical development to prevent prostate cancer in men with high grade PIN, GlaxoSmithKline is conducting a Phase III study on prostate cancer prevention which purposely excludes the high risk patient group of men with high grade PIN. In addition, there are nutritional supplement studies (for example selenium) investigating prostate cancer prevention in men with high grade PIN. Similarly, while there are no drugs that have been approved by the FDA for the treatment of muscle wasting from cancer, there are drugs marketed by Steris Laboratories and Savient Pharmaceuticals that are being prescribed off-label for the treatment of some types of muscle wasting from cancer. Testosterone and other anabolic agents are used to treat involuntary weight loss in patients who have acute muscle wasting. Also, TAP Pharmaceuticals and Ligand Pharmaceuticals have entered into a collaboration agreement to develop a SARM and may be initiating Phase II studies in 2006. In addition, there are other SARM product candidates at an earlier stage of development that may compete with our product candidates. Wyeth and Amgen have myostatin inhibitors in development which may compete for similar patients as ostarine. This could result in reduced sales and pricing pressure on our product candidates, if approved, which in turn would reduce our ability to generate revenue and have a negative impact on our results of operations.

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

Risks Related to Employees and Growth

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

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

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

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

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

Risks Related to Our Common Stock

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

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

- adverse results or delays in our clinical trials;
- the timing of achievement of our clinical, regulatory and other milestones, such as the commencement of clinical development, the completion of a clinical trial or the receipt of regulatory approval;
- announcement of FDA approval or non-approval of our product candidates or delays in the FDA review process;
- actions taken by regulatory agencies with respect to our product candidates or products, our clinical trials or our sales and marketing activities;
- the commercial success of any product approved by the FDA or its foreign counterparts;
- developments with respect to our collaborations with Ortho Biotech and Ipsen;
- the terms and timing of any collaborative, licensing or other arrangements that we may establish;

- regulatory developments in the United States and foreign countries;
- changes in the structure of health care payment systems;
- any intellectual property infringement lawsuit involving us;
- announcements of technological innovations or new products by us or our competitors;
- market conditions for the biotechnology or pharmaceutical industries in general;
- actual or anticipated fluctuations in our results of operation;
- changes in financial estimates or recommendations by securities analysts;
- sales of large blocks of our common stock;
- sales of our common stock by our executive officers, directors and significant stockholders;
- changes in accounting principles; and
- the loss of any of our key scientific or management personnel.

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

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

As of September 30, 2006, our officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 78.9% of our outstanding common stock. Our officers and directors owned approximately 58.4% of our outstanding common stock as of September 30, 2006. As a result, these stockholders, acting together, will be able to control all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders.

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

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

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

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

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

For the 12 month period ended September 30, 2006, the average daily trading volume of our common stock on the NASDAQ Global Market was approximately 85,000 shares. As a result, future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the then-prevailing market price of our common stock. As of September 30, 2006, we had 31,005,717 shares of common stock outstanding.

Based on information currently available to us, all of the shares of our common stock currently outstanding are eligible for sale in the public market, subject in some cases to volume and other limitations under federal securities laws.

Moreover, J.R. Hyde, III, Oracle Partners, L.P. and Memphis Biomed Ventures I, L.P., three of our largest stockholders, and their affiliates, have rights, subject to some conditions, to require us to file registration statements covering the approximately 11.1 million shares of common stock they hold in the aggregate which are subject to registration rights or to include these shares in registration statements that we may file for ourselves or other stockholders. Additionally, all shares of common stock that we may issue under our employee benefit plans can be freely sold in the public market upon issuance.

ITEM 6. EXHIBITS

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

SIGNATURES

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

GTx, Inc.

Date: November 3, 2006

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

Date: November 3, 2006

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

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EXHIBIT INDEX

Number	Description
3.1	Restated Certificate of Incorporation of GTx, Inc.(1)
3.2	Amended and Restated Bylaws of GTx, Inc.(2)
4.1	Reference is made to Exhibits 3.1 and 3.2
4.2	Specimen of Common Stock Certificate(3)
4.3	Amended and Restated Registration Rights Agreement between Registrant and Oracle Partners, L.P. dated August 7, 2003(3)
4.4	Amended and Restated Registration Rights Agreement between Registrant and J. R. Hyde, III dated August 7, 2003(3)
4.5	Amended and Restated Registration Rights Agreement between Registrant and Memphis Biomed Ventures dated August 7, 2003(3)
10.36*†	Partial Assignment Agreement among Registrant, Orion Corporation and Ipsen Limited dated September 7, 2006
10.37*†	Collaboration and License Agreement between Registrant and Ipsen Limited dated September 7, 2006
31.1*	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a)
31.2*	Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a)
32.1*	Certification of Chief Executive Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350) (4)
32.2*	Certification of Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350) (4)

* Filed herewith.

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

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

(2) Filed as Exhibit 3.4 to the Registrant's registration statement on Form S-1 (File No. 333-109700), filed with the SEC on October 15, 2003, as amended, and incorporated herein by reference.

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

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

[*] = 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 10.36

PARTIAL ASSIGNMENT OF THE AMENDED AND RESTATED LICENSE AND SUPPLY AGREEMENT

THIS PARTIAL ASSIGNMENT AGREEMENT (the "**Partial Assignment**") is made and entered into this 7th day of September, 2006 (the "**Assignment Effective Date**"), amongst **GTx, INC.**, a corporation existing under the laws of the State of Delaware and having its principal offices at 3 North Dunlap Avenue, Van Vleet Building, Memphis, Tennessee 38163, USA ("**GTx**"), **ORION CORPORATION**, a corporation existing under the laws of Finland and having its principal office at Orionintie 1, 02200 Espoo, Finland ("**Orion**"), and **IPSEN LIMITED**, a company organized under the laws of England and having its principal offices at 190 Bath Road, Slough SL1 3XE, United Kingdom, ("**Ipsen**"). GTx, Orion, and Ipsen may hereinafter be referred to individually as a "Party," or collectively as the "Parties."

WHEREAS, GTx and Orion have entered into the Amended and Restated License and Supply Agreement dated the 1st day of January, 2005, which has been further amended on May 26, 2006 and June 30, 2006 (collectively, hereinafter referred to as the "**Orion Agreement**") pertaining to the license and supply of Toremifene based products;

WHEREAS, GTx and Ipsen have entered into a Collaboration and Licensing Agreement, dated as of September 7, 2006 (the "**Sublicense Agreement**"), whereby GTx has sublicensed to Ipsen rights to develop and commercialize Toremifene based products in the European Territory (as hereinafter defined);

WHEREAS, GTx desires to assign to its European partner, Ipsen, certain supply rights and obligations under the Orion Agreement solely as necessary to allow Orion to supply Ipsen with Toremifene based products for sale in the European Territory;

WHEREAS, Orion wishes to consent to this partial assignment and to release GTx from any obligations with respect to the rights assigned to, and obligations assumed by, Ipsen hereunder; and

WHEREAS, the Parties wish that all other terms and conditions of the Agreement shall remain unchanged and shall be retained in full force and effect unless specifically agreed otherwise herein.

NOW, THEREFORE, in consideration of the promises and the mutual covenants contained herein, and for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereto agree as follows:

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[*] = 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.

1. Definitions. Capitalized terms used herein and not otherwise defined shall have the meanings given them in the Orion Agreement.

(a) As used herein, the term "**European Territory**" shall mean the European Union (as defined in Section 1.9 of the Orion Agreement), Switzerland, Norway, Iceland and Lichtenstein and the Commonwealth of Independent States (which for purposes hereof means Russia, Belarus, Ukraine, Moldova, Kazakhstan, Azerbaijan, Armenia, Kyrgyzstan, Uzbekistan, Tajikistan and Georgia).

(b) As used herein, the term "**GTx Territory**" shall mean the United States and all other parts of the world, *except* the European Territory.

2. CONDITIONAL EFFECTIVENESS OF PARTIAL ASSIGNMENT. The effectiveness of this Partial Assignment shall be conditioned on Ipsen and GTx fully executing the Sublicense Agreement.

3. Partial Assignment of Supply Rights and Obligations.

(a) Applicable Territory: This Partial Assignment is being executed by the Parties for the purpose of GTx assigning to Ipsen certain rights and obligations under the Orion License for the ordering, supply and payment of Orion Products within the European Territory, as such rights and obligations are amended in accordance with Appendix 1. The specific rights and obligations assigned to Ipsen, as hereby amended, pertain only to the European Territory and, unless expressly set forth to the contrary in this Assignment or Appendix 1 hereto, any provisions of the Orion Agreement which are assigned to Ipsen by GTx shall continue to apply to GTx to define its rights and obligations within the GTx Territory without regard to the amendments to such provisions set forth in Appendix 1. If Ipsen shall not file its Election for the PIN Indication or if the Sublicense Agreement is terminated pursuant to Sections 12.2(c)(ii), 12.3 and 12.4 of the Sublicense Agreement, then the Parties agree that the amendments to the Orion License set forth in Appendix 1 shall continue to apply to the Orion Products to be developed and commercialized by GTx within the European Territory.

(b) With respect to the European Territory and with effect from the Effective Date, GTx assigns, transfers, conveys and delivers to Ipsen that portion of GTx's rights and obligations to those sections of the Orion Agreement listed in Appendix 1 of this Partial Assignment, as amended in accordance with the amendments specified in Appendix 1(the "**Assigned Ipsen Supply Terms**"), so that a new agreement is entered into between Ipsen and Orion under which Ipsen and Orion will perform the obligations contained in the Assigned Ipsen Supply Terms and be entitled to the rights contained in such Assigned Ipsen Supply Rights (the "**Assigned Supply Agreement**").

(c) Orion hereby consents to the assignment by GTx to Ipsen of the Assigned Ipsen Supply Terms. Orion will, with effect from the Effective Date, observe and perform in favour of Ipsen all liabilities and obligations set out in the Assigned Supply Agreement to the same extent as if Ipsen had been an original party to the Orion Agreement in relation to the Assigned Ipsen Supply Terms, each as arise or fall to be performed on and following the Effective Date.

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(d) GTx shall remain jointly and severally liable with Ipsen towards Orion as regards the payment due by Ipsen in accordance with Section 14.4.2 of the Orion Agreement, as assigned to Ipsen pursuant to Appendix 1 of this Partial Assignment. Ipsen agrees to hold harmless and indemnify GTx for any such payment owing to Orion and agrees to pay within thirty (30) days of GTx's written notice thereof any amounts which GTx shall have to pay to Orion for Ipsen on account of GTx's joint and several liability hereunder, with interest thereon at the rate of interest set forth in Section 3.8 of the Sublicense Agreement.

(e) Any terms and conditions relating to the Fareston Product under Articles 14, 15, 17, 18 and 19 of the Orion Agreement (including any cross-referenced provisions that may be logically applicable by reference or incorporation in such Articles) shall not be assigned or otherwise applicable to Ipsen. For clarity, GTx shall continue to be bound to any such provisions relating to Fareston Product, to the extent such provisions remain in effect and such obligations have not already been fully performed by GTx.

4. PRODUCT DEVELOPMENT AND REGISTRATION. Orion agrees to extend to Ipsen as a GTX Unaffiliated Sublicensee those rights it extends to GTx under Section 7 of the Orion Agreement to assist Ipsen in its Development and regulatory activities within the European Territory, but only to the extent set forth in such Section 7 and further only to the extent such assistance has not previously provided to GTx under the Orion Agreement. The Parties acknowledge that unless Ipsen shall file its Election for the PIN Indication (as such terms are defined in the Sublicense Agreement) within the time period set forth in the Sublicense Agreement, GTx may again assume all rights and obligations in and to the 20 mg Toremifene tablet for the PIN Indication, and this Partial Assignment shall become null and void as to Ipsen with regards to the supply of the 20mg Toremifene tablet.

5. Ipsen's Obligations Under the Assigned Ipsen Supply Terms. With effect as from the Effective Date, Ipsen agrees to assume, perform and be obligated with respect to all of the rights and obligations under the Assigned Ipsen Supply Terms within the European Territory.

6. Confidentiality. Confidentiality and non-use obligations between Orion and GTx are specified in the Orion Agreement, between Gtx and Ipsen in the Sublicense Agreement and between Orion and Ipsen in Appendix 1 of this Assigned Supply Agreement. Orion, GTx and Ipsen understand and agree that relating to this Partial Assignment the Parties may need to exchange information which is confidential and/or proprietary to a Party, including without limitation the terms and conditions of the Partial Assignment. Such confidential information so disclosed shall be disclosed under and subject to the terms and conditions of the aforementioned agreements and shall be kept secret and confidential as defined in those agreements.

7. Reservation of Rights in the GTx Territory. Notwithstanding anything to the contrary set forth herein, GTx reserves all rights under the Orion Agreement with respect to ordering, supply, and payment of Orion Product for sale by or on behalf of GTx of Product in the Field (but excluding the Orion Field) in the GTx Territory.

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8. Consent and Partial Assignment; Release of GTx. Subject to Article 3(d) of this Partial Assignment, Orion hereby consents to the foregoing Partial Assignment and releases GTx from any obligations under the Orion Agreement in respect of the Assigned Ipsen Supply Terms as from the Effective Date.

9. Effect on Orion Agreement. Except as expressly modified hereby, the Orion Agreement shall remain in full force and effect between GTx and Orion, and nothing in this Partial Assignment is intended to impair or alter any other rights, obligations, or remedies of GTx and/or Orion, respectively, under the Orion Agreement. Any future amendments or waivers under the Orion Agreement that pertain to the Assigned Ipsen Supply Terms shall require the written agreement of Ipsen, and Orion provided that no amendment or waiver shall adversely affect any rights of GTx under the Orion Agreement without having first obtained GTx's prior written consent. Ipsen agrees to provide GTx with prompt written notice of any amendment or waiver of the Orion Agreement entered into between Ipsen and Orion which do not otherwise require GTx's prior written consent, as set forth in the preceding sentence. Orion and GTx agree that Ipsen shall have no liability or responsibility for any acts, omissions or failures of performance by Orion and GTx under the Orion Agreement.

10. Term of the Assigned Supply Agreement.

(a) Term of the Assigned Supply Agreement. The Assigned Supply Agreement shall enter into force on the Effective Date and shall expire on a country by country basis until the later of (a) the date of expiration or invalidation of the last to expire or to be invalidated of the GTx Patent Rights (as defined in the Orion Agreement) or (b) the expiration or termination of the last to expire of the marketing or regulatory exclusivity granted by the European Medicines Agency or other equivalent regulatory authority for the Product (as defined in the Orion Agreement) or (c) earlier terminated in accordance with this Section. The Assigned Supply Agreement may be terminated as follows:

(i) Under the terms and conditions set forth in Section 14.9 of the Orion License, as amended and assigned to Ipsen pursuant to Appendix 1 of this Agreement;

(ii) Under the terms and conditions set forth in Section 16.1 of the Orion Agreement, as amended and assigned to Ipsen pursuant to Appendix 1 of this Agreement;

(iii) Under the terms and conditions set for in Sections 21.2.1, 21.2.2 and 21.3 of the Orion Agreement, as amended and assigned to Ipsen pursuant to Appendix 1 of this Agreement;

(iv) In case of material breach of the Partial Assignment;

(v) In case of termination of the Orion Agreement, the Sublicense Agreement and/or the Partial Assignment, except in the event GTx shall again acquire rights to the Orion Products, as stated in the last sentence of Section 3(a) hereof, the Assigned Supply Agreement will continue to apply to the Orion Products to be developed and commercialized by GTx within the European Territory.

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(b) Effect of Termination of the Assigned Supply Agreement. This Partial Assignment is automatically terminated and all Assigned Ipsen Supply Terms as amended and assigned pursuant to Appendix1 shall automatically revert back to GTx and the terms and conditions as set forth in Section 21.5 of the Orion Agreement as amended and assigned to Ipsen pursuant to Appendix 1 shall apply.

(c) Amendments to the Assigned Supply Agreement. Any amendment to the Assigned Supply Agreement shall be agreed in writing between Ipsen and Orion. Subject to Section 9 of this Assignment, such amendment shall be communicated for information purposes to GTx by Ipsen.

11. OTHER AGREEMENTS

Orion and Ipsen (and GTx, for purposes of (b) and (c) hereof) hereby agree to use their commercially reasonable endeavors to negotiate in good faith and under commercially reasonable terms:

(a) [*];

(b) a quality agreement (the "Quality Agreement"), as provided for in Section 15.2 of the Orion Agreement, as amended and assigned to Ipsen pursuant to Appendix 1 to this Agreement;

(c) a safety data exchange agreement, as provided for in Section 19 of the Orion Agreement, as amended and assigned to Ipsen pursuant to Appendix 1 to this Agreement.

12. GENERAL

(a) Assignment. Neither Party may assign this Partial Assignment or any of its rights hereunder, nor delegate any of its duties or obligations hereunder, to any Third Party without the prior written consent of the other Party, except (i) to an Affiliate in accordance with the terms of this Partial Assignment, in which case notification thereof shall be provided to the other Party prior to such assignment to an Affiliate, or (ii) in connection with a merger, consolidation or similar reorganization. For clarity, this Partial Assignment shall survive any such merger, consolidation or reorganization of either Party with or into, another party and no consent for such merger, consolidation or reorganization shall be needed. Neither Party shall unreasonably withhold its consent (which shall be provided promptly after a request is made) to any contemplated assignment if such contemplated assignment is in connection with the sale by either Party of all or substantially all of its assets to a Third Party. Any assignment of this Partial Assignment to an Affiliate of the assigning Party shall not relieve the assigning Party of its responsibilities and obligations hereunder.

(b) Severability. In case one or more of the provisions contained in this Partial Assignment shall, for any reason, be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Partial Assignment, but this Partial Assignment shall be construed by limiting such invalid, illegal or

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unenforceable provision, if such is not possible, by deleting such provision from this Partial Assignment.

(c) Governing law and Dispute Resolution. The Partial Assignment, including the validity, construction, interpretation and performance thereof, shall be governed entirely by the laws of Sweden. It is the specific intent and agreement of the Parties that the United Nations Convention on the International Sale of Goods shall not apply to this Agreement.

Any disputes (excluding any dispute, controversy or claim arising out of or relating to the validity, enforceability, scope or infringement of patent or trademark rights) arising in connection with this Partial Assignment shall be finally settled by binding arbitration under the Rules of the Arbitration Institute of the Stockholm Chamber of Commerce, Stockholm, Sweden in accordance with said Rules then in effect with proceedings to be held in Stockholm, Sweden in the English language. Reasonable submission of evidence shall be permitted in any such proceeding to the extent permitted under and consistent with such Rules. Judgment upon any award rendered by the arbitrator(s) in such proceedings may be issued and enforced by any court having competent jurisdiction. Any disputes arising out of or relating to the validity, enforceability, scope or infringement of patent or trademark rights shall be submitted for resolution by a court of competent jurisdiction.

(d) Execution. This Partial Assignment shall be executed by the Parties in three (3) original counterparts, one (1) original counterpart being retained by each Party and either of which shall be deemed sufficient to prove the existence and terms and conditions hereof. This Agreement may be executed by the Parties by the exchange of facsimile signature pages, with signed original counterparts of the Partial Assignment to be exchanged by the Parties promptly thereafter.

(SIGNATURE PAGE FOLLOWS)

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In Witness Whereof, GTx, Ipsen and Orion have caused this Partial Assignment to be executed and effective as of the Assignment Effective Date.

GTx, Inc.

By: /s/ Mitchell Steiner
Mitchell Steiner, M.D.
Title: Vice-Chairman and CEO GTx, Inc.

By: /s/ Marc Hanover
Marc Hanover
Title: President and COO GTx, Inc.

Ipsen Limited

By: /s/ Alistair Stokes

Name: Alistair Stokes

Title: Director and Chief Executive Officer

Orion Corporation
ORION PHARMA
By: /s/ Timo Lappalainen
Name: Timo Lappalainen
Title: Senior Vice President

By: /s/ Hannu Wennonen
Name: Hannu Wennonen
Title: Director

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ASSIGNED TERMS AND RELATED AMENDMENTS

Any reference to a Section shall be construed as a reference to a Section of the Orion Agreement as amended and assigned to Ipsen pursuant to this Appendix 1. If there is a reference herein to any Section of the Orion Agreement which is not otherwise hereby amended, then in those such Sections any reference to GTx shall be construed to apply to Ipsen.

Section	Terms and amendments
Definitions	**[*]**
2.1.2 Manufacturing Rights Reserved	**[*]**
7.1.2 (b) Orion Activities	**[*]**
8.1 Confidentiality Obligation	**[*]**
8.2 Permitted Disclosure	**[*]**
8.3 Confidential information	**[*]**
8.4 Duration of Confidentiality Obligation	**[*]**
8.5 Publicity and Announcements	**[*]**
14.1.1 Product Supply	**[*]**

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Section	Terms and amendments
14.1.2 Product Delivery	**[*]**
14.1.3 Product Shipping Instructions	**[*]**
14.2 Orion Affiliates and Subcontractors	**[*]**
14.3.1 Rolling Forecasts	**[*]**
14.3.2 Excess quantities	**[*]**
14.3.3 Minimum Quantities	**[*]**
14.4.1 Commercial Pricing Formula	**[*]**
14.4.2 Invoicing and Payment	**[*]**
14.4.3 Price Changes	**[*]**
14.5 Resale Prices	**[*]**
14.6.1 Product Supply for Testing and Registration	**[*]**
14.6.2 Supply of Toremifene	**[*]**
14.7 Agreement Terms Govern	**[*]**
14.9 Termination of Product Supply	**[*]**
15.1 Product Warranties and Limitations	**[*]**

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Section	Terms and amendments
15.2 Certificate of Analysis	**[*]**
15.3.1 Ipsen Inspection and Analysis	**[*]**
15.3.2 Orion Response	**[*]**
15.4 Product storage	**[*]**
15.5.1 Labeling	**[*]**
15.6.1 Orion Indemnification	**[*]**
15.6.2 Ipsen Indemnification	**[*]**
15.7 Conditions for Indemnification	**[*]**
15.8 Liability Insurance	**[*]**
	[*]
	[*]
16.1 Inability to Manufacture or supply	**[*]**
16.2 Back-up manufacturing right	**[*]**

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Section	Terms and amendments
16.3 Maintenance of inventory	**[*]**
17.1 Regulatory inspections	**[*]**
17.2 Orion-initiated manufacturing changes	**[*]**
17.3.1 Ipsen request for manufacturing changes	**[*]**
17.3.2 Required manufacturing changes	**[*]**
17.3.3 Other manufacturing changes	**[*]**
17.4 New dosage strengths and formulation	**[*]**
18. Recall	**[*]**
18.3 Recall costs and expenses in EuropeanTerritory	**[*]**
19. Adverse Drug Experiences	**[*]**
	[*]
21.1 Term	**[*]**
21.1 Termination	**[*]**

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Section	Terms and amendments
for Cause and 21.2.1 Bankruptcy	
21.2.2 Material Breach	**[*]**
21.3 Termination by Mutual Agreement	**[*]**
21.5 Effect of termination	**[*]**
22.1 Manner of giving notices	**[*]**
22.2 Addresses for Notices	**[*]**
23. Integration	**[*]**
24. Assignment	**[*]**
25.1 Governing law	**[*]**
25.2 Dispute resolution	**[*]**
25.3 Effect of commencing dispute resolution	**[*]**
26. Limitation of damages	**[*]**
27. Force majeure	**[*]**
28. Relationships of Parties	**[*]**
29. Severability	**[*]**

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EXHIBIT 10.37

COLLABORATION AND LICENSE AGREEMENT

THIS COLLABORATION AND LICENSE AGREEMENT (the "**Agreement**") is made effective as of the 7th day of September, 2006 (the "**Effective Date**") by and between GTx, Inc., a Delaware corporation having its principal place of business at 3 North Dunlap St., Memphis, Tennessee 38163 ("**GTx**") each on behalf of itself and its Affiliates and Ipsen Limited, a company organized under the laws of England and Wales, with its principal place of business at 190 Bath Road, Slough SL1 3XE, United Kingdom ("**Ipsen**"), each on behalf of itself and its Affiliates. GTx and Ipsen are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**", and references to "**GTx**" and "**Ipsen**" shall include their respective Affiliates.

RECITALS

WHEREAS, Ipsen is a multinational healthcare company with research, development and marketing activities, which desires to obtain additional potential drug products for the prevention of prostate cancer, the treatment of complications arising from androgen deprivation therapy for advanced prostate cancer, and other possible indications;

WHEREAS, GTx is a men's health biotech company, which is developing certain compounds to prevent prostate cancer and treat complications arising from androgen deprivation therapy, including Acapodene®;

WHEREAS, GTx is conducting two clinical studies of Acapodene® for two separate indications in the United States ("**US**") under special protocol assessments ("**SPA**") with the US Food and Drug Administration: (a) a Phase III clinical trial of a 20 mg dose of Acapodene for the prevention of prostate cancer in men with high grade prostatic intraepithelial neoplasia (the "**PIN Trial**"), and (b) a Phase III clinical trial of a 80 mg dose of Acapodene for the prevention of bone fractures and serious side effects of androgen deprivation therapy in men with prostate cancer (the "**ADT Trial**");

WHEREAS, GTx is the exclusive licensee of the compound, Toremifene, the active ingredient of Acapodene, from Orion Corporation, a Finnish pharmaceutical company ("**Orion**"), and the exclusive licensee from the University of Tennessee Research Foundation ("**UTRF**") of certain methods of use patents and patent applications claiming or covering Toremifene and other selective estrogen receptor modulators for the treatment of high grade prostatic intraepithelial neoplasia and the prevention of prostate cancer; and

WHEREAS, GTx desires to exclusively sublicense to Ipsen, and Ipsen desires to exclusively sublicense from GTx, rights under GTx's license agreements from Orion and UTRF

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to Acapodene for all human uses within the European Union (and certain other countries) except for the treatment and prevention of breast cancer, in accordance with the terms and provisions of this Agreement.

Now, Therefore, in consideration of the foregoing premises and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

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 a pharmaceutical product which provide its pharmacological activity (excluding formulation components such as coatings, stabilizers or controlled release technologies).

1.2 "ADT" means androgen deprivation therapy.

1.3 "ADT Indication" means the treatment or prevention of the side effects of ADT in men with prostate cancer.

1.4 "**ADT Trial**" shall have the meaning set forth in the Recitals.

1.5 "**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 Ipsen, as applicable. For the purposes of this Section 1.5, 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.

1.6 "**Agreement**" shall have the meaning set forth in page one.

1.7 "**Bundled Product**" means any combination of a Licensed Product and another pharmaceutical product that is not a Licensed Product where such products are not formulated together but are sold together for a single invoiced price.

1.8 "**Business Day**" means a day on which banking institutions in New York (USA) and London (United Kingdom) are open for business.

1.9 "**Clinical Studies**" means human studies designed to measure the Safety, efficacy, tolerability, pharmacokinetics and appropriate dosage of a Licensed Product. Clinical Studies shall include, without limitation: (a) the PIN Trial and the ADT Trial ; (b) any other clinical studies that GTx determines is necessary or useful to conduct in the GTx Territory for the Initial Products to achieve or maintain Regulatory Approvals in the ADT Indication or the

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PIN Indication, including a Phase IIIB Clinical Trial and/or Phase IV Clinical Trial, as defined herein; or (c) any clinical studies that Ipsen determines is necessary or useful to conduct in the European Territory for the Initial Products to achieve or maintain Regulatory Approvals in the ADT Indication or the PIN Indication.

1.10 "**Combination Product**" means any pharmaceutical product that consists of a Licensed Product that also contains another Active Ingredient that is not Toremifene.

1.11 "**Commercialization Activities**" means activities relating to the marketing and sale of a Licensed Product.

1.12 "**Competing Product**" shall mean **[*]**.

1.13 "**Confidential Information**" shall have the meaning set forth in Section 8.1 of this Agreement.

1.14 "**Control**" or "**Controlled**" means the possession by a Party 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, or 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.

1.15 "Cost of Goods Sold" or **"COGS"** means the sum of (a) the Supply Price, (b) all payments made by Ipsen to Third Party contract manufacturer(s) for supply and delivery to Ipsen of fully packaged and labeled Licensed Products and/or any direct costs incurred internally by Ipsen for the packaging and labeling of the Licensed Products, (c) Royalty Payments to GTx for such Licensed Products, (d) Third Party royalty payments, and (e) any other customary and reasonable overhead costs actually incurred in, and reasonably allocable to, the procurement of Licensed Product, including: import and export duties; applicable taxes assessed on the purchase of such material; port fees and storage fees; shipping and handling; quality control; and quality assurance. The methodology for calculating Cost of Goods Sold shall be consistent with Ipsen's accounting policies and procedures for other products and shall be consistent from year-to-year.

1.16 "**Cover**" shall mean with respect to Patents that, but for a license granted to a Party under such Patents, the manufacture, use, offer for sale, sale or importation of such product would infringe a Valid Claim.

1.17 "Data and Market Protection" means, as to a given country, for the Licensed Product and a given time period, that (a) no Third Party has the right to cross-reference the data generated for the obtaining of the Regulatory Approval of a Licensed Product in a given Indication in order to obtain a Regulatory Approval for a Generic and (b) no Third Party has the right to commercialize a Generic in a given Indication in such country.

1.18 "**Developing Party**" shall have the meaning ascribed to it in Section 4.3(c)(i) of this Agreement.

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1.19 "**Dominating Patent**" means an unexpired patent of a Third Party which has not been invalidated by a court or other governmental agency of competent jurisdiction and which would be infringed by the use, manufacture, sale or import of the Licensed Product under this Agreement.

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

1.22 "Election" and **"Election Fee"** shall have the meaning set forth in Section 4.2(e) of this Agreement.

1.23 "**EMEA**" means the European Medicines Agency or any successor thereto.

1.24 "**EU**" means the European Union and shall include Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, United Kingdom, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, Slovenia, and any such other country or territory that may become part of the European Union after the Effective Date.

1.25 "**European Territory**" means the EU, Switzerland, Norway, Iceland and Lichtenstein and the Commonwealth of Independent States (which for purposes hereof means Russia, Belarus, Ukraine, Moldova, Kazakhstan, Azerbaijan, Armenia, Kyrgyzstan, Uzbekistan, Tajikistan and Georgia).

1.26 "**Executive Officers**" means the Chief Executive Officer of GTx (or another senior officer of GTx designated by GTx's Chief Executive Officer) and the Chief Executive Officer of Ipsen (or another senior officer of Ipsen designated by the Chief Executive Officer of Ipsen).

1.27 "Fareston" means the Orion drug product, containing Toremifene as the Active Ingredient, that is promoted in the US under the brand name "Fareston" by GTx, and in the rest of the world by Orion or its Affiliates, sublicensees and distributors for the treatment and prevention of advanced breast cancer.

1.28 "**FDA**" means the United States Food and Drug Administration or any successor agency thereto having the administrative authority to regulate the marketing of human pharmaceutical products or biological therapeutic products, delivery systems and devices in the United States of America.

1.29 "**FDC Act**" means the Federal Food, Drug and Cosmetic Act, as amended from time to time.

1.30 "**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 **[*]** of work pursuant to the development activities with respect to Licensed Products. Any employee who devotes less than **[*]** shall be

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treated as an FTE on a pro-rata basis calculated by dividing the actual number of hours worked during such calendar year by **[*]**.

1.31 "**FTE Cost**" means the cost to GTx of its scientific, technical, regulatory or clinical personnel directly dedicated to the execution of the development activities (excluding administrative personnel), and shall be calculated by multiplying the FTE Rate by the number of FTEs.

1.32 "**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 **[*]**, with subsequent adjustments on each anniversary thereof). For clarity, said rate includes charges for standard and/or existing lab supplies and equipment and customary business expenses such as insurance.

1.33 "**Generic**" means any pharmaceutical product sold by a Third Party, not authorized by Ipsen, an Affiliate or sublicensee, that contains Toremifene as an Active Ingredient and which can be substituted by the prescriber or dispenser for the Licensed Product for use in the Indications.

1.34 "**GTx Initial Development**" means Initial Development by GTx of the Initial Products for the ADT and PIN Indications in the GTx Territory.

1.35 "**GTx Initial Development Budget**" and "**GTx Initial Development Plan**" shall have the meaning ascribed to it in Section 4.2 (a)(i) of this Agreement.

1.36 "**GTx Invention**" means any Invention made solely by GTx as from the Effective Date including a GTx Product Improvement.

1.37 "**GTx Know-how**" means Information which is within the Control of GTx and is reasonably necessary for the development, import, offer for sale, use or sale of the Licensed Products in the Indications within the European Territory. GTx Know-how shall include Information obtained by GTx under the GTx Licenses, GTx Inventions, GTx Product Improvements, and GTx's interest in any Joint Inventions. Notwithstanding anything herein to the contrary, GTx Know-how shall exclude GTx Patents.

1.38 "**GTx Licenses**" means the Orion License and the UTRF License.

1.39 "**GTx Patent**" means all Patents Controlled by GTx in the European Territory which Cover the Licensed Products. 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 and Patents relating to GTx Inventions.

1.40 "**GTx Product Improvement**" means any Product Improvement Controlled by GTx as from the Effective Date.

1.41 "**GTx Territory**" means the United States and all other parts of the world, *except* the European Territory.

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1.42 "**IND**" shall mean (a) 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 (b) 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.

1.43 "**Indication**" means any disease or condition in humans, *except* the treatment and prevention of breast cancer. The Parties expressly acknowledge that the use of Licensed Products for any disease or condition in animals is excluded from the scope of this Agreement.

1.44 "**Information**" means techniques and data relating to Toremifene, Initial Products or Licensed Products including (but not limited to) inventions, practices, methods, knowledge, know-how, skill, experience, test data including Pre-Clinical Studies and Clinical Studies test data, analytical and quality control data, statistical analyzing plan (SAP), marketing, pricing, distribution, cost, sales data or descriptions, and compounds, compositions of matter, assays and biological materials related thereto.

1.45 "**Initial Development**" means activities relating to obtaining Regulatory Approval of the Initial Products in the ADT Indication and the PIN Indication, in each of GTx's and Ipsen's respective territories. Initial Development includes, but is not limited to, Pre-Clinical Studies, Clinical Studies and regulatory affairs activities.

1.46 "**Initial Development Expenses**" means the expenses incurred by a Party or for its account by a Third Party which are consistent with a Initial Development Plan and Initial Development Budget and are incurred in connection with Pre-Clinical and Clinical Studies (whether conducted internally or by a Third Party, individual investigators or consultants, including Phase IIIB Clinical Trials), toxicological, pharmacological, pharmacokinetic, metabolic, analytical, formulation, chemical studies, and qualification and validation batches of product, as required by the Regulatory Authorities for the purpose of obtaining Regulatory Approval of the Initial Product, and costs (and related fees) for preparing, submitting, reviewing or developing data or information for the purpose of submission to a Regulatory Agency to obtain and/or maintain Regulatory Approval of the Initial Product in the PIN and the ADT Indication.

1.47 "**Initial Development Plan**" shall mean either Ipsen Initial Development Plan or GTx Initial Development Plan.

1.48 "**Initial Election Period**" shall have the meaning ascribed to it in Section 4.2(e)(iii) of this Agreement.

1.49 "**Initial Products**" means the Licensed Products currently being studied in the PIN Trial and the ADT Trial under the appropriate dosages.

1.50 "**Invention**" means any invention relating to Toremifene or Licensed Product (whether patentable or not and including but not limited to Know-How) including without

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limitation a Product Improvement made by the Parties after the Effective Date during the course of, in furtherance of, and as a direct result of the activities of the Parties hereunder.

1.51 "**Ipsen Initial Development**" means all Initial Development by Ipsen of the Initial Products for purposes of obtaining Regulatory Approval within the European Territory for the ADT Indication and the PIN Indication.

1.52 "**Ipsen Initial Development Plan**" shall have the meaning ascribed to it in Section 4.2 (a)(ii) of this Agreement

1.53 "**Ipsen Invention**" shall mean any Invention made solely by Ipsen as from the Effective Date including an Ipsen Product Improvement which development, manufacture, import, sale and use is Covered by a Valid Claim of GTx Patents.

1.54 "**Ipsen Know-how**" means Information relating to the Licensed Product, including Ipsen Inventions, Ipsen Product Improvement and Ipsen's interest in Joint Inventions which is within the Control of Ipsen and which is reasonably necessary for the development, import, offer for sale, use or sale of the Licensed Products in the Indications within the GTx Territory.

1.55 "**Ipsen Patents**" means any Patents relating to an Ipsen Invention which Patents are owned or Controlled by Ipsen. Ipsen Patents shall include Ipsen's interest in Joint Patents.

1.56 "**Ipsen Product Improvement**" means a Product Improvement Controlled by Ipsen as from the Effective Date and which development, manufacture, import, sale and use are Covered by a Valid Claim of GTx Patents.

1.57 "**Joint ADT Initial Development Expenses**" shall have the meaning set forth in Section 4.2(f)(iii) of this Agreement.

1.58 "**Joint Development Committee**" or "**JDC**" means the committee established pursuant to Article II of this Agreement.

1.59 "**Joint Initial Development Expenses**" means Initial Development Expenses incurred by GTx **[*]** relating to the Initial Development of the Initial Products in the ADT Indication and the PIN Indication; *provided however*, that (a) such Joint Initial Development Expenses shall only include Initial Development Expenses incurred in connection with Initial Development activities which are required for or conducted taking into consideration potential requirements for (i) the Initial Development of Initial Products in the ADT Indication and the PIN Indication (subject to Ipsen's Election pursuant to Section 4.2(e)(i) of this Agreement) within the European Territory or (ii) the obtaining of Regulatory Approvals for the Initial Products in the ADT Indication and the PIN Indication (subject to Ipsen's Election pursuant to Section 4.2(e)(i) of this Agreement) in the European Territory or (iii) the maintenance of Regulatory Approvals for the Initial Products in the ADT Indication and the PIN Indication (subject to Ipsen's Election pursuant to Section 4.2(e)(i) of this Agreement) in the European Territory, and (b) such Joint Initial Development Expenses are included in the GTX Initial Development Budget. Such Joint Initial Development Expenses shall include **[*]**.

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1.60 "**Joint Invention**" means any Invention made by the Parties in the course of the Initial Development pursuant to Section 4.2(g) of this Agreement and/or a Joint Subsequent Development pursuant to Section 4.3 (b)(v) of this Agreement.

1.61 "**Joint Patent**" shall mean any Patent Covering a Joint Invention.

1.62 "**Joint PIN Initial Development Expenses**" shall have the meaning set forth in Section 4.2(f)(iii) of this Agreement.

1.63 "**Joint Subsequent Development**" shall have the meaning ascribed to it in Section 4.3(a) of this Agreement.

1.64 "Joint Subsequent Development Budget", "Joint Subsequent Development Costs", "Joint Subsequent Development Plan" shall have the meaning ascribed to it in Section 4.3(b) of this Agreement.

1.65 "**Launch Date**" means the date of the first offer for commercial sale, following Regulatory Approval of a Licensed Product within the European Territory. **[*]**.

1.66 "**Licensed Product**" means a drug product containing Toremifene as an Active Ingredient for use in humans for all Indications, in a form suitable for sale to an end user, and/or for use in conducting Pre-Clinical Studies and Clinical Studies. Licensed Product shall include, without limitation, all doses of the Initial Products and any Product Improvement.

1.67 "Licensed Trademark" means trademarks Controlled by GTx licensed hereunder to Ipsen pertaining to the Initial Products and which are listed in Appendix B.

1.68 "**List Price"** shall mean Ex-manufacturer IMS-MIDAS price list on a per milligram basis.

1.69 "**Major Country**" means any of the following countries: the United Kingdom, France, Germany, Spain and Italy.

1.70 "**Marketing and Sales Committee**" shall have the meaning set forth in Section 6.2 of this Agreement.

1.71 "Marketing and Sales Plan" shall have the meaning set forth in Section 6.3 of this Agreement.

1.72 "**Milestone Event**" shall have the meaning set forth in Section 3.2 of this Agreement.

1.73 "**NDA**" shall mean New Drug Application (as that term is used in Title 21 of the United States Code of Federal Regulations) or any foreign equivalent filed with a Regulatory Agency to market and sell any product for a particular indication.

1.74 "**Net Sales**" means, consistent with, in the European Territory, Ipsen's worldwide

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accounting policies and procedures, and in each such case as consistently applied across the Ipsen pharmaceutical product line, the gross sales invoiced by Ipsen, its Affiliates, and sub-licensees to Third Parties for Licensed Product in the European Territory, less:

(a) credits and allowances or adjustments granted to customers on account of rejections, recalls or returns of Licensed Product previously sold;

(b) any customary and reasonable trade and cash discounts, rebates, including government rebates, granted in connection with sale of Licensed Product to such customers;

(c) sales, tariff duties and/or use taxes directly imposed and with reference to particular sales; and

(d) outbound transportation prepaid or allowed, amounts allowed or credited on returns, export licenses, import duties, value added tax, and prepaid freight.

Sales of Licensed Product by and between Ipsen and its Affiliates, sublicensees are not sales to Third Parties and shall be excluded from Net Sales calculations for all purposes. Sales of Licensed Product for use in conducting clinical trials of Licensed Product candidates in a country within the European Territory in order to obtain applicable Regulatory Approval of the Licensed Product in the European Territory shall be excluded from Net Sales calculations for all purposes.

"Net Sales" of a **Bundled Product.** In the event Licensed Product is sold as part of a Bundled Product in a country within the European Territory, the Net Sales of the Licensed Product, for the purposes of determining payments based on Net Sales, shall be determined by multiplying the Net Sales of the Bundled Product in such country, during the applicable Net Sales reporting period, by the fraction, A/(A+B), where:

A is the average sale price of the Licensed Product by Ipsen (*i.e.* Net Sales divided by units sold), its Affiliates or sublicensees when sold separately in finished form in such country and B is the average sale price by Ipsen, its Affiliates or sublicensees of the other product(s) included in the Bundled Product when sold separately in finished form in such country, in each case during the applicable Net Sales reporting period.

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

C is the average sale price, in such country, of the Licensed Product contained in such Bundled Product when sold separately and D is the average sale price, in such country, for the Bundled Product, in each case during the applicable Net Sales reporting period.

In the event that the Licensed Product is not sold separately in finished form in the country, but all of the other product(s) included in the Bundled Product in such country are sold separately, the Net Sales of the Licensed Product, for the purposes of determining payments based on Net

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Sales, shall be determined by multiplying the Net Sales of the Bundled Product in such country by the fraction (D-E)/D, where:

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

In the event that the Net Sales of the Licensed Product when included in a Bundled 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 Bundled Product by the fraction of F/(F+G) where:

F is the fair market value of the Licensed Product and G is the Fair Market Value of all other pharmaceutical product(s) included in the Bundled Product, as reasonably determined in good faith by the Parties. For the purposes of this Section 1.74, "**Fair Market Value**" shall mean the cash consideration that a willing seller would realize from an unaffiliated, unrelated and willing buyer in an arms' length sale of an identical item sold in the same quantity and at the same time and place of the transaction.

1.75 "**Opt-in**" shall have the meaning set forth in Section 4.3(c)(i) of this Agreement.

1.76 "**Opt-in Information**" shall have the meaning set forth in Section 4.3(c)(ii) of this Agreement.

1.77 "Opt-in Party", "Opt-in Payment", "Opt-in Period", "Opt-in Period 1", "Opt-in Period 2", "Opt-in Period 3", "Opt-in Period 4", "Opt-in Period 5", "Opt-in Notification" , and "Opt-in Payment" shall have the meaning set forth in Section 4.3(c)(iii) of this Agreement.

1.78 "**Opt-out Party**" shall have the meaning set forth in Section 4.3(b)(iv) of this Agreement.

1.79 "**Non-Developing Party**" shall have the meaning set forth in Section 4.3(c)(i) of this Agreement.

1.80 "**Orion**" shall have the meaning set forth in the Recitals.

1.81 "**Orion License**" means the Amended and Restated License and Supply Agreement dated January 1, 2005 by and between GTx and Orion, as the same may be amended from time to time.

1.82 "**Past Initial Development Expenses**" shall have the meaning ascribed to it in Section 4.2(e)(iii) of this Agreement.

1.83 "**Patent**" means (a) United States patents, re-examinations, reissues, renewals, extensions and term restorations, supplemental protection certificates, and foreign counterparts thereof, and (b) pending applications for United States patents, including, without limitation,

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provisional applications, continuations, continuations-in-part, divisional and substitute applications, including, without limitation, inventors' certificates, and (c) foreign counterparts of any of the foregoing.

1.84 "**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, Joint Patents or Ipsen Patents including the costs of Patent interference and opposition proceedings but excluding the costs of any other Patent enforcement proceedings.

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

1.86 "**Phase IIIB Clinical Trial(s)**" means product support clinical trials of a Licensed 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 Licensed Product's label claim. Phase IIIB Clinical Trials shall include GTx's one year extension trial of an 80 mg dose of Initial Products for the ADT Indication.

1.87 "**Phase IV Clinical Trial(s)**" means product support clinical trials, including but not limited to trials for new drug delivery systems, of a Licensed Product with an approved label claim that is commenced after receipt of Regulatory Approval in the country where such trial is being conducted.

1.88 "**PIN**" means high grade prostatic intraepithelial neoplasia.

1.89 "**PIN Indication**" means the prevention of prostate cancer in men with PIN.

1.90 "**PIN Trial**" shall have the meaning set forth in the Recitals.

1.91 "**Pre-Clinical Studies**" means studies of a Licensed Product in animals other than humans, including those studies conducted in whole animals and other test systems, designed to determine the pharmacology, toxicity, absorption, distribution, metabolism, excretion, and immunology of an Active Ingredient.

1.92 "**Pre Opt-in Development Costs**" shall have the meaning set forth in Section 4.3(c)(ii) of this Agreement.

1.93 "Pricing and Reimbursement Approval" means the pricing and reimbursement approval for the Licensed Product from the Relevant Agency, as required.

1.94 "**Primary Endpoint**" means each of the primary efficacy endpoints within the PIN Trial and ADT Trial, respectively, as set forth in the respective SPA approved by the FDA for each such trial and the protocol for each such trial encompassed within each such SPA.

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Primary Endpoints for each of the PIN Trial and ADT Trial are set forth in Exhibit C.

1.95 "**Product Improvement**" shall mean **[*]**.

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

1.97 "**Regulatory Approval**" means any approvals by a Regulatory Agency (with the exception of conditional approvals) that are necessary for the commercial manufacture, use, storage, importation, export, transport or sale of Licensed Products in a regulatory jurisdiction.

1.98 "**Royalty Payment**" shall have the meaning set forth in Section 3.4 of this Agreement.

1.99 "**Royalty Reduction**" and "**Royalty Reduction Cap**" shall have the meaning set forth in Section 3.4 of this Agreement.

1.100 "**Royalty Term**" shall have the meaning set forth in Section 3.8 of this Agreement.

1.101 "**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.

1.102 "**SERM**" means selective estrogen receptor modulator other than Toremifene.

1.103 "**Sole Subsequent Development**" shall have the meaning set forth in Section 4.3(a) of this Agreement.

1.104 "**SPA**" shall have the meaning set for in the Recitals.

1.105 "**Subsequent Development**" shall have the meaning set forth in Section 4.3(a) of this Agreement.

1.106 "**Supply Price**" shall refer to the "**PIN Supply Price"** and the **"ADT Supply Price"** described in Section 3.4 of this Agreement.

1.107 "**Tax**" shall have the meaning set forth in Section 3.12(c) of this Agreement.

1.108 "**Third Party**" means any entity other than GTx or Ipsen, or any of their respective Affiliates.

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1.109 "**Third Party License**" have the meaning set forth in Section 4.3(b)(ii) of this Agreement.

1.110 "**Toremifene**" shall mean **[*]**.

1.111 "**UTRF**" shall have the meaning set forth in the Recitals.

1.112 "**UTRF License**" means the Amended and Restated Exclusive License Agreement dated July 24, 1998, by and between GTx and UTRF (formerly known as the University of Tennessee Research Corporation) exclusively licensing to GTx all UTRF know-how and Patents pertaining to methods of using Toremifene for the PIN Indication, as the same may be amended from time to time

1.113 "**Valid Patent Claim**" means an unexpired claim (a) of any issued 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.

1.114 "**Withholding Royalty Payments**" shall have the meaning set forth in Section 3.9 of this Agreement.

ARTICLE II

JOINT DEVELOPMENT COMMITTEE

2.1 Formation of JDC. Promptly after the Effective Date, GTx and Ipsen shall form a Joint Development Committee ("**JDC**") comprised of equal numbers of reasonably qualified representatives of each Party (not to exceed three (3) representatives of each Party) who have expertise in the clinical development, registration and commercialization of pharmaceutical products, with one such person assigned by each Party as such Party's co-chair (each, a "**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. The formation of the JDC as well as its responsibilities may be amended from time to time by mutual agreement of the Parties.

2.2 Meetings. Meetings of each of the JDC may be called by either Party on **[*]** 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. Notwithstanding the foregoing, the JDC will meet at least quarterly, with face-to-face meetings being required at least twice a year at alternating sites to be designated by GTx and Ipsen, and the other meetings being conducted face-to-face or through teleconference or video conference, as agreed upon by the JDC. With the prior consent of the

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other Party's Co-Chair (such consent not to be unreasonably withheld or delayed), each Party may invite non-members to participate in the discussions and meetings of the JDC, provided that such participants shall have no vote and shall be subject to the confidentiality provisions set forth in Article IX.

2.3 Agendas. Each Party will disclose to the other proposed agenda items for discussion, along with appropriate related Information, at least **[*]** in advance of each meeting of the JDC.

2.4 Responsibilities of the JDC.

(a) The JDC will facilitate communications between the Parties regarding each of the Parties' development of Licensed Products in each of their respective territories (e.g., GTx's development of Licensed Products in the GTx Territory, and Ipsen's development of Licensed Products in the European Territory).

(b) Ipsen shall present to the JDC within **[*]** of the Effective Date the Ipsen Initial Development Plan that relates to the Ipsen Initial Development in the European Territory through 2007 with such level of detail as is necessary and appropriate for all JDC members to fully understand such Ipsen Initial Development Plan.

(c) For each calendar year subsequent to 2007, a revised annual Initial Development Plan and Initial Development Budget for GTx Initial Development in the GTx Territory and a revised Ipsen Initial Development Plan in the European Territory will be prepared by the appropriate Parties and submitted to the JDC before **[*]** of the calendar year proceeding the calendar year for which the revised Initial Development Plans and the revised Initial Development Budget applies.

(d) The JDC will review, discuss and comment on the Initial Development Plans and Initial Development Budget. GTx and Ipsen will each update the JDC periodically, but at least quarterly, of all of their respective material Initial Development activities.

(e) The JDC will review, comment on, and provide recommendations on any Subsequent Development of Product Improvements under the terms set forth in Section 4.3.

(f) All recommendations by the JDC that relate to either GTx Initial Development or Ipsen Initial Development shall be made **[*]**, 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 each such Initial Development Plan and Initial Development Budget. If the JDC is unable to make a **[*]** decision on such matters, the matter will be referred to the Executive Officers of GTx and Ipsen. If such officers do not reach agreement on such matter within **[*]** after it is referred to them, then the decision of **[*]** on matters pertaining to **[*]** (except those related to (i) Initial Development activities conducted by **[*]** which are supportive of the **[*]** and (ii) Joint Initial Development Expenses related thereto) and the decision of **[*]** on matters pertaining to **[*]** will be final and determinative, so long as such

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decision does not contradict or modify the terms of this Agreement. Notwithstanding the preceding sentence, (i) any decision relating to Joint Initial Development Expenses shall require the mutual consent of both Parties and (ii) both Parties agree that before they undertake any Initial Development activities that can materially affect the Initial Development activities of the other Party (including, in particular, Initial Development activities conducted by GTx which are supportive of the Initial Development activities of Ipsen for the European Territory), the Party desiring to conduct such Initial Development activities shall take into account any reasonable suggestion of the other Party. In the event the Parties (through the JDC, or, their Executive Officers) do not reach agreement on matters relating to **[*]**, Ipsen shall have the right not to fund its share of such Joint Initial Development Expenses which GTx shall have the right to undertake. In the event that Ipsen later decides that it wishes to have access to and use the data from such Initial Development activities that Ipsen refused to fund pursuant to its right above, Ipsen shall reimburse GTx **[*]** of Initial Development Expenses pertaining to such Initial Development activities.

2.5 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 Ipsen.

ARTICLE III

LICENSING FEES; MILESTONE PAYMENTS; ROYALTIES; REPORTING

3.1 License Fee, Initial Development Expenses, and Election Fee.

(a) License Fee. As partial consideration for the rights granted by GTx pursuant to this Agreement, Ipsen shall pay to GTx a non-refundable, non-creditable license fee of **[*]** (the "**License Fee**") as follows: (i) **[*]** of such License Fee shall be paid to GTx within **[*]** after the Effective Date of this Agreement; and (ii) the remaining 1.5 Million Euro amount of the License Fee shall be paid in three (3) equal installments of 500,000 Euros each on the 1st, 2nd and 3rd anniversary dates of the Effective Date of the Agreement.

(b) Initial Products Development Expenses Reimbursement. Within **[*]** after the Effective Date, Ipsen shall pay to GTx a non-refundable, non-creditable fee of **[*]** as reimbursement for Initial Development Expenses incurred by GTx in connection with Pre- Clinical Studies and Clinical Studies for the Initial Products that were initiated, conducted, or ongoing prior to the Effective Date.

(c) Election Fee. In the event that Ipsen exercises its Election (as defined in Section 4.2(e)(i) of this Agreement), Ipsen shall pay to GTx an additional fee of **[*]** (the "**Election Fee**") within **[*]** following notice of exercise of such Election to GTx; provided, however, that such Election Fee shall not be due in the event that Ipsen exercises its Election during the Initial Election Period, as provided in Section 4.2(e)(iii).

3.2 Milestone Payments. In addition to the payments due to GTx under Section 3.1, and in consideration for the rights granted by GTx pursuant to this Agreement, Ipsen shall make

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the following non-refundable, non-creditable (except as expressly provided for in the payments described in Milestone Events 5 and 6 below) milestone payments to GTx after the occurrence of each event that follows (each, a "**Milestone Event**"). The payments set forth herein shall each be due and payable by Ipsen within **[*]** following receipt from GTx of a notice and invoice regarding the achievement of each Milestone Event set forth herein.

Milestone Event	Payment (in Euros)
1. Achievement of **[*]**	**[*]**
2. Achievement of **[*]**[1]	**[*]**
3. Filing with the EMEA or with the relevant Regulatory Agency **[*]** for Regulatory Approval of **[*]**[1]	**[*]**
4. Filing with the EMEA or with the relevant Regulatory Agency **[*]** for Regulatory Approval of **[*]**	**[*]**
5. Obtaining a Regulatory Approval by the EMEA/European Commission or by the Regulatory Agency **[*]** of **[*]**[1,2]	**[*]**[4]
6. Obtaining a Regulatory Approval by the EMEA/European Commission or by the Regulatory Agency **[*]** of **[*]**[3]	**[*]**[5]
7. On a **[*]** basis, the determination by the relevant Regulatory Agency of a List Price for **[*]**[1]	**[*]**[6]
8. Obtaining a Regulatory Approval **[*]** for a diagnostic test for **[*]**[1]	**[*]**

1 In the event Ipsen has not made the Election pursuant to Section 4.2(e)(i) of this Agreement at the time any of such Milestone Events (either Milestone Event numbers 2, 3, 5, 7 or 8) are achieved, then the payment associated with each such Milestone Event shall be deferred until no later than thirty (30) calendar days after Ipsen shall have make such Election, at which time all such deferred milestone payments shall become promptly due and payable to GTx.

2 **[*]**.

3 **[*]**.

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4 This total milestone payment shall be allocated among the various Major Countries based on the estimated relative market sizes for the PIN Indication, as follows: the United Kingdom: **[*]**; France: **[*]**; Germany: **[*]**; Italy **[*]**; and Spain: **[*]**.

5 This total milestone payment shall be allocated among the various Major Countries based on the estimated relative market sizes for the ADT Indication, as follows: the United Kingdom: **[*]**; France: **[*]**; Germany: **[*]**; Italy **[*]**; and Spain: **[*]**.

6 This total milestone payment shall be allocated among the various Major Countries based on the estimated relative market sizes, as follows: the United Kingdom: **[*]**; France: **[*]**; Germany: **[*]**; Italy **[*]**; and Spain: **[*]**.

3.3 Limitation on Milestone Payments. Other than the milestone payments recited in Section 3.2, Ipsen shall not be obligated to make any other milestone payments in connection with Initial Products or any other Licensed Product.

3.4 Royalty Payments.

(a) In consideration for the rights granted to Ipsen under this Agreement, Ipsen shall pay to GTx quarterly royalty payments on Net Sales determined as follows (the "**Royalty Payment**") :

(i) For the first calendar year as from the first Launch Date of the Licensed Product in the European Territory ("**Y1**"), Ipsen shall pay, on a country-by-country basis a Royalty Payment equal to the applicable royalty rates set forth in this Section 3.4(a)(i) (the "**Base Royalty Rate**"), multiplied by the Net Sales of Licensed Product for the PIN and ADT Indications (respectively the "PIN Base Royalty rate" and the "ADT Base Royalty Rate") .

(A) the PIN Base Royalty shall be equal to the greater of **[*]** and F, where F is the result of the following calculation:

[*].

(B) the ADT Base Royalty shall be equal to the greater of **[*]** and G, where G is the result of the following calculation:

[*].

For the purposes of calculating Expected Price for the PIN and ADT Indications for the initial calculation of the PIN and ADT Base Royalty, Ipsen shall update its forecast based upon the actual prices received from the appropriate agency upon receiving Pricing and Reimbursement Approval for products that have launched in the first quarter when the Royalty Payment is due.

(ii) Within **[*]** as from the end of the Y1, Ipsen shall determine the following amounts :

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- "**A**" which is equal to the aggregate annual Net Sales of the Licensed Product of Y1 multiplied by the following royalty rates:

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

- "**B**" which is equal to **[*]**
- "**PIN Supply Price**" being equal to **[*]**.
- "**C**" which is equal to **[*]**. For clarity, **[*]**.

(A) In the event B is superior to C, then:

(i) **[*]**;

(ii) **[*]**.

(B) In the event B is inferior to C, then:

(i) **[*]**.

(ii) **[*]**.

For the following calendar years ("**Y**") (notwithstanding the Offset set forth above):

(A) **[*]**;

(B) **[*]**;

(C) **[*]**;

(D) **[*]**;

(E) **[*]**.

Examples Rates are attached hereto as Exhibit D for purposes of further clarification for the calculations described in this Section 3.4.

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(b) Generic Competition. If a Generic is sold in any Major Country of the European Territory and for two (2) succeeding calendar quarters the sales of such Generic in that country equal or exceed **[*]** of the Net Sales of Licensed Products (calculated on a unit basis) in that country by Ipsen, its Affiliates or sublicensees, then the Royalty Payments shall be reduced to **[*]** of the amount of the Royalty Payment otherwise due to GTx on account of Net Sales of such Licensed Product for the ADT Indication or **[*]** of the amount of the Royalty Payment otherwise due to GTx on account of Net Sales of such Licensed Product for the PIN Indication in such country with such reduction to be applicable to the immediately succeeding calendar quarters only.

(c) Dominating Patents. If (i) Ipsen would be prevented from developing, using, selling, or importing the Licensed Products in any country of the European Territory on the grounds that by doing so they would infringe one (or more) Dominating Patent held by a Third Party in said country and (ii) Ipsen licenses rights to such Dominating Patent in said country, then **[*]** of any royalties on Licensed Products sales paid by Ipsen to such Third Party in any calendar year in such country with respect to such Dominating Patent shall be deducted from any Royalty Payments payable to GTx by Ipsen in such calendar year (the "**Royalty Reduction**"), provided, however, that (i) such Dominating Patent relates solely to **[*]** and (ii) GTx has been informed of the Dominating Patent and has had an opportunity to provide input on any related discussion of whether to license such Dominating Patent and negotiation of royalty rates; and (iii) subject to the warranties and representations made by GTx under Section 10.1 (b) of this Agreement, the amount of the Royalty Reduction in any calendar year shall not exceed **[*]** of the Royalty Payments (the "**Royalty Reduction Cap**") that would have otherwise been payable by Ipsen to GTx for such calendar year and for such country. Any amount of the Royalty Reduction which is not offset against Royalty Payments due to GTx from Ipsen (because it exceeds the Royalty Reduction Cap) shall be carried forward to and deducted in subsequent calendar years until the expiration of the Royalty Term.

3.5 Sales by Sublicensees. In the event Ipsen, subject to the provisions of this Agreement, grants licenses or sublicenses to others to market and/or sell Licensed Product, including Initial Products, such licenses or sublicenses shall include an obligation for the licensee or the sublicensee to account for and report its Net Sales of Licensed Product on the same basis as if such sales were Net Sales by Ipsen, and Ipsen shall pay royalties to GTx as if such sales by such sublicensees were the Net Sales of Ipsen, subject to the provisions of this Article III.

3.6 Relief From Certain Marketing Obligations. Notwithstanding anything to the contrary herein, in the event that Ipsen's COGS of a particular Licensed Product for a particular country exceeds **[*]** of the Net Sales of such Licensed Product in such country:

(a) Ipsen shall promptly provide notice to GTx of its belief that the COGS of a particular Licensed Product has exceeded or will exceed **[*]** of Net Sales in such country. Ipsen shall include with any such notice a calculation of such percentage and appropriate documentation and records supporting its calculation of COGS and Net Sales of such Licensed Product in such country.

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(b) The Parties will have **[*]** following GTx's receipt of such notice to discuss in good faith whether an adjustment of the Royalty Payments under Section 3.4 of this Agreement is appropriate so that COGS for such Licensed Product do not exceed **[*]** of Net Sales of such Licensed Product in such country or whether other circumstances exist that may warrant Ipsen continuing to sell such Licensed Product in the country in question. In the event the Parties fail to reach an agreement on any such adjustment, Ipsen shall not have to commercialize the Licensed Products in such country as long as Ipsen reasonably believes circumstances have not sufficiently changed to allow it to have COGS **[*]**.

3.7 Payment of Royalties; Reporting. Within **[*]** after the end of each calendar quarter for which Royalty Payments are payable by Ipsen to GTx with respect to Net Sales by Ipsen, its Affiliates and their respective sublicensees, Ipsen shall pay to GTx by wire transfer the Royalty Payment due for such quarter and 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 Initial Products on a per dose and per Indication basis) made during such calendar quarter, and the calculation prepared by Ipsen to determine the applicable Royalty Payment due for such quarter pursuant to this Article III. Within **[*]** after the end of each calendar year for which Royalty Payments are payable by Ipsen to GTx, Ipsen shall provide to GTx a report, on a country by country basis, reconciling the number of Initial Products sold on a per dose and a per Indication basis to the number of Initial Products consumed per Indication. In the event any payment due to GTx, including the Royalty Payments due hereunder, are late by more than **[*]**, GTx shall have the right to assess interest on the amounts which are then past due and owing to GTx at a rate of interest equal to the prime rate **[*]**.

3.8 Royalty Term. Royalties shall be payable **[*]** (hereinafter, the "**Royalty Term**"). In the event that: (i) a Product Improvement is either jointly developed pursuant to Section 4.3(b) of this Agreement or developed by Ipsen and GTx has opted-in pursuant to Section 4.3(c), (ii) such Product Improvement is covered by an Ipsen Patent or a Joint Patent and (iii) such Product Improvement is commercialized in the European Territory by Ipsen, then, with regards to such Product Improvement, the Royalty Term shall **[*]**.

3.9 [*].

3.10 Ipsen's Rights Upon Expiration of Royalty Term. Upon expiration of the Royalty Term for a Licensed Product on a country-by-country basis as described above, Ipsen shall thereafter have a paid-up, non-exclusive license under the GTx Patents and GTx Know-how to use, sell, offer for sale, have sold and import that Licensed Product in that country.

3.11 Tax Matters.

(a) Ipsen Payments to GTx of Withholding Tax. If provision is made in law or regulation of any country in the European Territory for withholding of Taxes with respect to any amounts payable by Ipsen to GTx pursuant to this Agreement, Ipsen shall promptly pay such Tax on behalf of GTx to the proper governmental authority and Ipsen shall promptly furnish GTx with certificate of Taxes deducted under such withholding tax laws. Ipsen shall have the right to offset any such Tax actually paid from any payment due to GTx or shall be

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promptly reimbursed by GTx if no further payments are due. GTx and Ipsen shall cooperate with each other in obtaining any exemption from or reduced rate of Tax available under any applicable law or tax treaty.

(b) Income and Other Taxes of the Parties. Ipsen and GTx shall pay for their own account all sales, turnover, income, revenue, value added and other taxes levied on account of payments accruing or made under this Agreement. All amounts expressed in this Agreement exclude such taxes where required by law

(c) Tax. Solely for purposes of this Section 3.11, "**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 Ipsen's income, or assessments or fees of any nature (or any interest, penalties or additions thereto) imposed by the FDA or any Regulatory Agencies.

(d) Protest. Ipsen shall promptly notify GTx in writing of any assessment, proposed assessment or other claim for any additional amount of Tax assessed by the US. Notwithstanding any other provision of this Section 3.11, 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. Ipsen 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.

3.12 Currency. Except as specified in the last sentence of this Section, all amounts specified in this Agreement which are to be paid to GTx are to be in Euros, as set forth in Section 15.16 of this Agreement. When calculating Net Sales for Royalty Payments, Ipsen shall convert the amount of invoiced sales in currencies other than Euros into Euros using the exchange rates **[*]**. All payments related to the development costs will be made in the currency of the invoicing party.

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

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 Ipsen from time to time): **[*]**

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ARTICLE IV

DEVELOPMENT AND REGISTRATION

4.1 Development Responsibilities. As a general principle, GTx will be solely responsible for the development of Licensed Products in the GTx Territory and for any communication with Regulatory Agencies in the GTx Territory, and Ipsen will be solely responsible for the development of Licensed Products in the European Territory and for any communication with Regulatory Agencies in the European Territory. Neither Party will undertake to conduct any development activities for Licensed Products in the territory of the other Party without first submitting the proposed development activities to the JDC and receiving the approval of the other Party which shall not be unreasonably withheld or delayed.

4.2 Initial Development.

(a) Initial Development Plan.

(i) GTx Initial Development. The Initial Development of the Initial Products for the ADT Indication and the PIN Indication in the GTx Territory shall be carried out by GTx pursuant to a development plan (the "**GTx Initial Development Plan**") and a development budget (the "**GTx Initial Development Budget**"), both of which are attached as **Exhibit E** of this Agreement. The GTx Initial Development Budget comprises the Initial Development Expenses incurred by GTx as from **[*]** through **[*]** and the forecasted Initial Development Expenses as from **[*]** and until the obtaining of the Regulatory Approval for the Initial Products in the GTx Territory, differentiated between (i) Initial Development Expenses incurred/forecasted for the Development of the ADT Indication and the Initial Development of the PIN Indication and (ii) Joint Initial Development Expenses and other Initial Development Expenses. In the event that there are Joint Initial Development Expenses that are not clearly dedicated to the Initial Development of either ADT Indication or PIN Indication, the sum of such Joint Initial Development Expenses shall be allocated equally as the Initial Development of ADT Indication and PIN Indication. For each calendar year subsequent to 2006, a revised GTx Initial Development Plan and a revised GTx Initial Development Budget will be prepared by GTx and submitted for approval to the JDC before **[*]** of each calendar year, provided, however that any revision of the GTx Initial Development Plan and GTx Initial Development Budget shall not result in an increase of **[*]** of Joint Development Expenses per year, except as otherwise agreed by Ipsen.

(ii) Ipsen Initial Development. The Initial Development of the Initial Products for the obtaining of the ADT Indication and the PIN Indication in the European Territory shall be carried out by Ipsen pursuant to a development plan for the remainder of 2006 and 2007 (the "**Ipsen Initial Development Plan**"). The Ipsen Initial Development Plan will be submitted by Ipsen to the JDC within **[*]** as from the Effective Date. For each calendar year subsequent to 2007, a revised Ipsen Initial Development Plan will be prepared by Ipsen and submitted for information to the JDC before **[*]** of each calendar year.

(b) Content of Initial Development Plan. Each Initial Development Plan

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shall describe the proposed overall program of all the Initial Development of a Party in its respective territory, 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 Initial Development events. Each Initial Development Plan for either GTx Initial Development or Ipsen Initial Development will identify endpoints needed for initiation of the next phase of the Initial Development. Both GTx Initial Development Plan and Ipsen Initial Development Plan will be submitted for comments by GTx to Orion and GTx shall inform Ipsen of all comments made by Orion on the Initial Development Plans. Ipsen agrees to change and/or amend the Ipsen Initial Development Plan to the extent such Ipsen Initial Development Plan could reasonably be deemed to affect adversely Orion's development, commercialization, sales or registration of Fareston by Orion.

(c) Initial Development Efforts. In carrying out Initial Development and its Initial Development Plan in its respective territory, each Party agrees to use commercially reasonable efforts to conduct the Initial Development of the Initial Products in the ADT Indication and the PIN Indication and to conduct the activities set forth in their respective Initial Development Plan in accordance with the timelines set forth therein. A Party's material failure to comply with such diligence obligations shall constitute a breach of this Agreement.

(d) Drug Approval Applications. Consistent with its Initial Development Plan, GTx shall be responsible for the filing of all Drug Approval Applications and seeking Regulatory Approvals for Initial Products in the GTx Territory in the ADT Indication and the PIN Indication, and Ipsen shall be responsible for the filing of Drug Approval Applications and seeking Regulatory Approvals for Initial Products in the European Territory in the ADT Indication and the PIN Indication. If Ipsen does not exercise the Election as set forth in Section 4.2(e) of this Agreement, GTx shall have the right to seek Regulatory Approvals for Licensed Products for the PIN Indication in the European Territory, provided, however, that GTx shall seek such Regulatory Approval under a trademark which is not confusingly similar to the Licensed Trademarks to be used for the commercialization of the Initial Products in the ADT Indication in the European Territory. The Parties shall consult and cooperate in the preparation of each such Drug Approval Application and in obtaining Regulatory Approvals. GTx shall solely own all Drug Approval Applications and Regulatory Approvals for the GTx Territory and Ipsen shall solely own all Drug Approval Applications and Regulatory Approvals for the European Territory. In the event that Ipsen does not exercise its Election, GTx shall solely own all Drug Approval Applications and Regulatory Approvals for Licensed Products for the PIN Indication in the European Territory.

(e) Ipsen's Election to Retain License Rights to Licensed Products for the PIN Indication.

(i) Exercise of Election. Ipsen shall have the option, at its sole discretion, to retain its license rights under Article V in connection with Licensed Products for the PIN Indication, by notifying such election to GTx at any time after the Effective Date and until **[*]** following receipt of the first Regulatory Approval in **[*]** (the "**Election**").

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(ii) Failure to Exercise Election. In the event Ipsen does not make the Election within the period set forth in Section 4.2(e)(i) above or fails to make the payments required under Section 4.2(e)(iii) below, then GTx shall have the right to terminate Ipsen's license and associated rights to Licensed Products for the PIN Indication, and thereafter GTx shall have the exclusive right to commercialize the Licensed Product in the European Territory for the PIN Indication, provided however that such commercialization shall be made under a trademark which shall not be confusingly similar to the Licensed Trademarks to be used for the commercialization of the Initial Products in the ADT Indication. Upon termination of such rights:

(1) Ipsen shall grant to GTx an exclusive, royalty-free license under any Ipsen Inventions which would directly result from the conduct of the Ipsen Initial Development activities for the PIN Indication to Develop, use, sell, have sold, offer for sale, import, export, and distribute the Licensed Product for the PIN Indication in the European Territory;

(2) Within **[*]** of such termination, Ipsen shall transfer to GTx all data from Preclinical Studies and Clinical Studies and other related Information as Ipsen may then Control pertaining to such Licensed Product for the treatment of the PIN Indication, including any IND or similar Regulatory Agency documents Ipsen may then Control for the purposes of conducting Clinical Studies within the European Territory for the PIN Indication;

(3) Ipsen shall use commercial reasonable efforts to transfer to GTx all Regulatory Approvals relating to the Licensed Product in the PIN Indication obtained in the European Territory; and

(4) Ipsen shall cease all on-going Initial Development of the Licensed Product in the PIN Indication in the European Territory and shall not be obligated to make any payment pursuant to Section 4.2(e)(iii) below.

(iii) Election Fee and Payment of Past Initial Development Expenses. In the event Ipsen makes such Election, Joint PIN Indication Development Expenses (as defined in Section 4.2(f)(iii)(2) of this Agreement) shall be considered part of Joint Initial Development Expenses, and Ipsen will be required to make the following payments : (i) within **[*]** as from the date of Election, the Election Fee (as provided for in the chart below), (ii) within **[*]** as from the date of Election, the reimbursement of the Joint PIN Initial Development Expenses which shall have accrued from the date at which the aggregate Joint Initial Development Expenses (now inclusive of Joint PIN Initial Development Expenses) incurred by GTx exceeded **[*]** in the aggregate and until the date of Election (such costs during such period, the "**Past Initial Development Expenses**") with a premium as shown in the chart below and (iii) the payment of the Joint PIN Development Expenses as provided for in Section 4.2(f)(iii)(2) of this Agreement.

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Adjusted Payments with Premium for PIN Initial Development Expenses

Election Date	Premium on IPSEN share of Past Initial Development Expenses	IPSEN share of Past Initial Development Expenses	Election Fee
A. Prior to the expiry of a **[*]** period as from Effective Date(the **"Initial Election Period"**)	**[*]**	**[*]**	**[*]**
B. Between the date of expiry of the Initial Election Period and receipt by Ipsen of interim data from Phase III trial G300104 (IND **[*]**)	**[*]**	**[*]**	**[*]**
C. Between receipt by Ipsen of G300104 Phase III interim data and receipt by Ipsen of G300104 (IND **[*]**) final data	**[*]**	**[*]**	**[*]**
D. Between receipt by IPSEN of G300104 (IND **[*]**) final data and 90 days after receipt by IPSEN of G300104 (IND **[*]**) final data, and in any case, prior to obtaining Regulatory Approval in European Territory or in any Major Country for PIN Indication	**[*]**	**[*]**	**[*]**
E. Between 90 days after receipt by IPSEN of G300104 (IND **[*]**) final data and **[*]** after obtaining of Regulatory Approval in European Territory or in any Major Country for PIN Indication	**[*]**	**[*]**	**[*]**

By way of example only, in the event that GTx has expended more than **[*]** in Joint Initial Development Expenses, and Ipsen exercises its Election after the expiration of the Initial Election Period but before Ipsen's receipt of G300104 (IND **[*]**) final data, it shall owe a payment to GTx that is the sum of **[*]** of Past Initial Development Expenses, as well as an Election Fee of **[*]**.

(f) Initial Development Expenses.

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(i) Initial Development Expenses Solely Borne by Ipsen. Ipsen shall be solely responsible for paying all Initial Development Expenses that are not Joint Initial Development Expenses relating to the obtaining of Regulatory Approvals in the European Territory for the Initial Products for the ADT Indication and the PIN Indication (subject to the provisions of Section 4.2(e)(ii) of this Agreement), which shall include the costs for any additional Pre-Clinical Studies and Clinical Studies required exclusively by the EMEA or other Regulatory Agencies to grant Regulatory Approvals for Initial Products within the European Territory.

(ii) Initial Development Expenses Solely Borne by GTx. GTx shall be solely responsible for paying all Initial Development Expenses that are not Joint Initial Development Expenses relating to the obtaining of Regulatory Approvals for the Initial Products in the GTx Territory, including the Initial Products for the ADT Indication and the PIN Indication (subject to the provisions of Section 4.2(e)(ii) of this Agreement), which shall include the costs for any additional Pre-Clinical Studies and Clinical Studies required exclusively by the FDA or other Regulatory Agencies to grant Regulatory Approvals for the Initial Products within the GTx Territory**.**

(iii) Joint Initial Development Expenses. GTx shall bear the **[*]** of Joint Initial Development Expenses. Thereafter, Joint Initial Development Expenses shall be allocated between GTx and Ipsen as follows: **[*]** of Joint Initial Development Expenses shall be paid by GTx, and **[*]** of Joint Initial Development Expenses shall be paid by Ipsen as set forth below.

(1) Joint Initial Development Expenses for the Initial Products in the ADT Indication. At such time as Joint Initial Development Expenses incurred by GTx exceed **[*]**, GTx shall invoice Ipsen on a quarterly basis for **[*]** of the Joint Initial Development Expenses relating to the Initial Development of the Initial Products for the treatment of the ADT Indication (such Initial Development Expenses referred to as the "**Joint ADT Initial Development Expenses**"). Ipsen shall reimburse GTx for such costs within **[*]** of its receipt of such invoice.

(2) Joint Initial Development Expenses for Initial Products in the PIN Indication. Ipsen shall not be responsible for paying any Joint Initial Development Expenses incurred in relation to the Initial Development of the Initial Products for the treatment of the PIN Indication ("**Joint PIN Initial Development Expenses**"), unless and until such time as Ipsen exercises its Election as set forth in Section 4.2(e)(i). As from the Election and at such time as Joint Initial Development Expenses (including Joint PIN Initial Development Expenses) incurred by GTx exceed **[*]**, GTx shall invoice Ipsen on a quarterly basis for **[*]** of the on-going Joint PIN Initial Development Expenses and Ipsen shall reimburse GTx for such costs within **[*]** of its receipt of such invoice.

(3) Reports and Adjustment. Within **[*]** after the end of each calendar quarter, GTx shall provide Ipsen with a report detailing all GTx FTEs actually utilized by GTx during such calendar quarter (by names and major tasks) and external costs (for which invoices were received and approved for payment by GTx), as well as a comparison of

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such expenditures with the relevant provisions of the GTx Initial Development Budget. Within **[*]** of the end of 2006, and each calendar year thereafter, GTx shall provide to Ipsen an accounting report of the actual Joint Initial Development Expenses incurred during the previous calendar year including without limitation all detailed GTx FTE Costs as well as all invoiced external costs. In the event Ipsen has overpaid or underpaid any amount in excess of its **[*]** share in the Joint Initial Development Expenses as set forth in this report, GTx and Ipsen agree to reimburse one another such amounts as are appropriate within **[*]** from the date of receipt by Ipsen of this report. GTx agrees to maintain appropriate and accurate records of all Joint Initial Development Expenses incurred by it.

(iv) Audits. Upon the written request of Ipsen (which shall be no more than **[*]**), GTx and Ipsen shall agree on a mutually acceptable date on which to permit an independent certified public accounting firm of an internationally recognized standing **[*]** to have access during normal business hours to such of the records of GTx as may be reasonably necessary to verify the accuracy of the reports and to audit the records as provided for in Section 4.2(f)(iii) of this Agreement. The accounting firm shall disclose to GTx and Ipsen whether the reports/records are correct or incorrect, the specific details concerning any discrepancies and such other information that should properly be contained in an accounting report required under this Section. If such accounting firm concludes that additional amounts relating to Ipsen's share in Joint Initial Development Expenses were owed, Ipsen shall pay such additional amounts within **[*]** of the date Ipsen delivers to GTx such accounting firm's written report so concluding. In the event such accounting firm concludes that amounts relating to Ipsen's share in Joint Initial Development Expenses were overpaid by Ipsen, GTx shall repay Ipsen the amount of such overpayment within **[*]** of the date Ipsen delivers to GTx such accounting firm's written report so concluding. The fees charged by such accounting firm shall be paid by Ipsen; provided, however, if the audit reveals that Ipsen has overpaid by more than **[*]** Ipsen's share of Joint Initial Development Expenses due hereunder for the period being reviewed, then the fees and expenses of the accounting firm for the audit shall be paid by GTx. Upon the expiry of **[*]** following the end of any calendar year for which Ipsen has made payment of Joint Development Expenses with respect to such calendar year, and in the absence of gross negligence or willful misconduct of GTx or a contrary finding by an accounting firm pursuant to this Section, such calculation shall be binding and conclusive upon the Parties, and GTx shall be released from any liability or accountability with respect to any over payment by Ipsen for Joint Development Expenses for such calendar year.

(g) Inventions under the Initial Development and license grant.

In the event any Party makes an Invention during the course of the conduct of the Initial Development, any such Invention shall be considered as a "**Joint Invention"**.

Ipsen shall grant GTx an exclusive, royalty-free license on Ipsen's interest in such Joint Invention to develop, use, sell, have sold, offer for sale, import, export and distribute the Initial Product in the GTx Territory.

4.3 Subsequent Development.

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(a) Subsequent Development Proposals.

Each Party acknowledges that no development of a GTx Product Improvement or an Ipsen Product Improvement shall be made without first having been proposed to the other Party in accordance with the provisions of this Section 4.3.

The Party (the "**Proposing Party**") intending to conduct the development of respectively an Ipsen Product Improvement or a GTx Product Improvement (the "**Subsequent Development**") shall notify the JDC of such intent and shall provide to JDC all necessary information relating to the concerned Product Improvement and the related Subsequent Development in order to enable the other Party to reasonably assess the scientific, technical and commercial implications of the proposed Subsequent Development. Within **[*]** from receipt of all such information, the other Party shall notify the Proposing Party its decision or not to participate in the Subsequent Development.

In the event the other Party decides not to participate in the Subsequent Development, the Proposing Party shall be free to conduct the Subsequent Development at its own cost and expenses (the "**Sole Subsequent Development**") subject to the other Party's right to decide at a later stage to opt-in in such Subsequent Development in accordance to Section 4.3(c).

In the event the other Party decides to participate to the Subsequent Development, the Parties shall jointly perform and fund such Subsequent Development (the "**Joint Subsequent Development**") as set forth in Section 4.3(b) of this Agreement.

(b) Joint Subsequent Development

(i) Joint Subsequent Development Plan and Budget.

Following the other Party's notification to join in the Subsequent Development, the Parties working through the JDC shall agree upon a plan and a budget for the conduct of the Joint Subsequent Development (respectively, the "**Joint Subsequent Development Plan**" and the "**Joint Subsequent Development Budget**") which shall include at least the following items:

(A) research and development activities to be performed by each Party for the purpose of obtaining Regulatory Approval for the Product Improvement in each Party's respective territory;

(B) specific tasks, location of work, milestones, estimated timelines, immediate objectives and long term objectives;

(C) the global budget for the Joint Subsequent Development and the estimated budget for the development activities of each Party under the Joint Subsequent Development Plan. The costs of the development activities of the Parties (the "**Joint Subsequent Development Costs**") will be determined in accordance with Section 4.3(b)(ii) of this Agreement.

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Once agreed by the Parties within the JDC, each Party undertake to use its reasonable commercial efforts to conduct its development activities under the Joint Subsequent Development Plan. The Joint Subsequent Development Plan and the Joint Subsequent Development Budget shall be updated annually by the JDC at a time decided by the JDC and suitable for both Parties' planning and budgeting processes, provided however that any update or amendment of the Joint Subsequent Development Plan and the Joint Subsequent Development Budget shall be approved by both Parties within the JDC.

(ii) Determination of Subsequent Development Costs

All research and development activities conducted by the Parties under the Joint Subsequent Development Plan shall be valued as follows:

(A) internal costs: **[*]**;

(B) external costs: **[*]**.

In the event the Parties reasonably agree that there is a need to enter into an agreement with a Third Party having intellectual property rights which would be infringed by the development and commercialization of the Product Improvement which is the subject matter of the Joint Subsequent Development (the "**Third Party License**"), the Parties shall reasonably cooperate to negotiate and enter into the Third Party License. Any payments to be made to this Third Party under the Third Party License during the Joint Subsequent Development shall be included in the Joint Subsequent Development Budget as Joint Subsequent Development Costs.

(iii) Funding of Joint Subsequent Development

All activities undertaken by the Parties pursuant to the Joint Subsequent Development Plan shall be funded by the Parties in the following proportion : Ipsen shall be responsible for **[*]** of all Joint Subsequent Development Costs and GTx shall be responsible for **[*]** of all Joint Subsequent Development Costs, only to the extent the foregoing Joint Subsequent Development Costs are set forth in the Joint Subsequent Development Budget or revisions thereof. Within **[*]** of the end of each calendar quarter, each Party will notify the JDC in writing of the Joint Subsequent Development Costs incurred by such Party during such calendar quarter, and the JDC shall aggregate such Joint Subsequent Development Costs and allocate them to the Parties in accordance with the percentages set forth in the foregoing sentence. Where needed in order to reflect such allocated Joint Subsequent Development Costs, corresponding "true up" payments will be made by the Party underpaying its share of Joint Subsequent Development Costs to the Party having overpaid its share, quarterly within **[*]** following the end of each calendar quarter.

(iv) Disagreement and Opt-out of the Joint Subsequent Development

In case of failure of the Parties within the JDC to agree upon the Joint Subsequent Development Plan, the Joint Subsequent Development Budget and any

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revisions thereof or the terms and conditions of a Third Party License, such disagreement shall be referred to the Executive Officers. In case the Executive Officers fail to reach an agreement within **[*]** as from the date such matter was referred to them, then each Party shall have the right to opt-out of the Joint Subsequent Development, subject to a **[*]** notice period.

The decision to opt-out shall be notified to the JDC. The Party exercising this opt-out right (the "**Opt-Out Party**") shall continue all development activities under the Joint Subsequent Development Plan during the **[*]** notice period, fund the Joint Subsequent Development in accordance with the provisions of Section 4.3(b)(iii) of this Agreement during such period and enable the other Party to take over, if the other Party wishes to, such development activities to avoid any disruption of the Joint Subsequent Development.

The Opt-Out Party shall grant to the other Party an exclusive royalty-free license under the Opt-Out Party's interest in any Joint Inventions for the sole purpose of the development of the Product Improvement in the other Party's territory.

After the expiry of the **[*]** notice period, in the event the other Party decides to continue the development of the Product Improvement at its own cost and expenses, such development shall be considered as a Sole Subsequent Development and the provisions of Section 4.3(c) shall apply including the right for the Opt-Out Party to Opt-In under the terms and conditions of this Section.

(v) Inventions under the Joint Subsequent Development

All Inventions made by the Parties during the course of, or in furtherance of, and as direct result of the development activities of the Parties in the Joint Subsequent Development shall be deemed Joint Inventions. For the avoidance of doubt, any Ipsen Invention and GTx Invention which does not directly result from the development activities under the Joint Subsequent Development shall be or remain owned by Ipsen or GTx, as the case may be.

(vi) Commercialization of the Product Improvement developed under a Joint Subsequent Development

Each Party shall have the right to obtain Regulatory Approval and commercialize the Product Improvement in its respective Territory provided that:

(A) each Party shall grant to the other Party a royalty-free, exclusive license on its interest in the Joint Inventions in the other Party's territory ;

(B) in the event the Parties have entered into a Third Party License, each Party shall pay to such Third Party any royalty due with respect to each Party's respective territory. In the event any other payment would be due to this Third Party, any such payment will be allocated **[*]** GTx/Ipsen;

(C) in the event a Party Controls Patents which are not GTx Patent Rights or Joint Patent Rights and which would be infringed by the manufacture, use or

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commercialization of the Product Improvement in the other Party's territory, the Parties shall negotiate in good faith the terms and conditions of a royalty-bearing license agreement relating to those Patent Rights for the other Party's territory.

(c) Sole Subsequent Development and Opt-in

(i) Decision for Sole Subsequent Development. In the event that the Parties have not agreed to jointly perform or fund any Subsequent Development, either Party may pursue and fund at its own cost and expenses the Subsequent Development (the "**Developing Party**"), subject to the other Party's (the "**Non-Developing Party**") right to opt-in in the conduct and funding of the Subsequent Development (the "**Opt-in**").

(ii) Conduct of the Sole Subsequent Development

(1) Reporting. The Developing Party shall provide the JDC with quarterly reports outlining the results of each completed material pre-clinical and clinical study during the preceding calendar quarter. Notwithstanding the foregoing, the Developing Party shall not be required to continue any Sole Subsequent Development or to complete any tasks therein, prior to the time the other Party exercises its rights to Opt-in.

(2) Territorial Restrictions. If Ipsen is the Developing Party, it shall only carry out the development activities under the Sole Subsequent Development in the European Territory or, outside the European Territory, but only with the prior written consent of GTx which shall not be unreasonably withheld or delayed. If GTx is the Developing Party, it shall only carry out development activities under the Sole Subsequent Development in the GTx Territory or, in the European Territory, but only with the prior written consent of Ipsen which shall not be unreasonably withheld or delayed.

(3) Development Costs under Sole Subsequent Development. The Developing Party shall be responsible for all development costs related to such Sole Subsequent Development, subject to Opt-in by the other Party and sharing of costs pursuant to Section 4.3(c)(iii)(3) below (the "**Pre Opt-in Development Costs**"). The Developing Party shall record separately in its books in an auditable manner, all its Pre Opt-in Development Costs including costs of acquiring ownership or Control of Patents or Know-How in relation to the New Product.

(4) Provision of Information. The Developing Party shall provide to the Non-Developing Party, on a continuing basis, all relevant information relating to the Sole Subsequent Development through the JDC (the "**Opt-in Information**"). Such information shall include but is not limited to: **[*]**. The Non-Developing Party shall only use such Opt-in Information to decide whether to exercise an Opt-in.

If Non-Developing Party does not exercise an Opt-in, such Party shall not use such Opt-in Information for any other purpose, shall return the same to the Developing Party and shall maintain its confidentiality, provided that such information qualifies as Know-How of the Developing Party.

The Non-Developing Party may request additional information

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which would be reasonably material for it to make an Opt-in decision and the Developing Party shall supply such information to the extent it is reasonably available and necessary for the Opt-in decision.

(5) Third Party License. In the event the Developing Party decides to enter into a Third Party License, such Developing Party shall so inform in advance the Non-Developing Party and provide the Non-Developing Party with the opportunity to make any reasonable recommendation with respect to the terms and conditions of the Third Party License, provided however, that the Developing Party shall have the sole right to negotiate and execute the Third Party License.

(6) Inventions under the Sole Subsequent Development. Any Inventions made by the Developing Party during the course of, or in furtherance of, and as direct result of the development activities in the Sole Subsequent Development shall be owned by the Developing Party and shall be considered as an Ipsen Invention if the Developing Party is Ipsen and a GTx Invention if the Developing Party is GTx.

(iii) Opt-in.

(1) Opt-In Period. With respect to each Sole Subsequent Development Plan, the Non-Developing Party (the "**Opt-in Party**") shall have the right to Opt-in in the performance and the funding of such Subsequent Development at such times during the performance of the Sole Subsequent Development as are set forth below (each, an "**Opt-in Period**"):

(A) **[*]** ("**Opt-in Period 1"**);

(B) **[*]** ("**Opt-in Period 2"**);

(C) **[*]** ("**Opt-in Period 3**");

(D) **[*]** ("**Opt-in Period 4**");

(E) **[*]** ("**Opt-in Period 5**").

As used above with respect to a clinical trial, "receipt of data following completion" shall mean the receipt by the Non-Developing Party of the results from the completed clinical trial at issue in the form of a final report fully compliant with applicable regulatory requirements, signed by Chief Research Officer and delivered to the Non-Developing Party.

In such event of Opt-in, the Non-Developing Party shall notify its exercise of its right to Opt-in in writing to the JDC (the "**Opt-in Notification**").

(2) Extension of the Opt-in Period. In the event a Developing Party is required to supply additional information pursuant to Section 4.3(c)(ii)(4) above and there are fewer than **[*]** remaining in the relevant Opt-in Period, such Opt-in Period shall be extended to

such date that is **[*]** after the provision of such additional information. The Non-Developing Party may, at its sole discretion, notify the Developing Party in writing before the expiration of its rights set forth herein, that it waives such rights and such Opt-in rights shall thereby terminate.

(3) Opt-in Payment. The Opt-in Party shall reimburse to the Developing Party its share of the Pre Opt-in Development Costs determined as follows (the "**Opt-in Payment").**

(A) Calculation of the Opt-in Payment

The Opt-in Payment will be equal to the relevant percentage as set forth below applied to (i) **[*]** and (ii) **[*]**

(A) The relevant percentage shall be **[*]** if the Opt-in Party exercises its Opt-in during Opt-in Period 1;

(B) The relevant percentage shall be **[*]** if the Opt-in Party exercises its Opt-in during Opt-in Period 2;

(**C**) The relevant percentage shall be **[*]** if the Opt-in Party exercises its Opt-in-during Opt-in Period 3;

(**D**) The Opt-in Payment shall be **[*]** if the Opt-in Party exercises its Opt-in during Opt-in Period 4;

(E) The Opt-in Payment shall be **[*]** if the Opt-in Party exercises its Opt-in during Opt-in Period 5.

(B) Timing of Reimbursement of Pre Opt-in Development Costs. Within **[*]** as from the Opt-in Notification, the Opt-in Party shall pay to the Developing Party the Opt-in Payment.

(C) Disputes. The Opt-in Party may audit Pre Opt-in Development Costs submitted by the Developing Party pursuant to this Agreement or may appoint internationally-recognized professional accountants to do so. In the event that the Opt-in Party reasonably disputes specific items contained in the Developing Party's calculation of Pre Opt-in Development Costs, the Opt-in Party shall pay the amounts not in dispute or in question and such disputed or questioned amounts shall be submitted to the JDC which shall promptly meet or confer to resolve such disputes or questions. Within **[*]** following resolution of such matters, one Party shall pay or reimburse to the other Party the appropriate remaining balance. In the event the JDC is not able to resolve a dispute concerning the Opt-in Payment under this Section, the dispute shall be referred to the Executive Officers and in case of failure of the Executive Officers to resolve this dispute, the Parties shall follow the dispute resolution procedure in Article XIV of this Agreement.

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(iv) Joint Development After Opt-in. After any Opt-in, the Parties shall agree upon a Joint Subsequent Development Plan and a Joint Subsequent Development Budget relating to the development to be conducted jointly. The provisions of Section 4.3(b) of this Agreement shall apply to the Subsequent Development as from the Opt-in Notification.

(v) Non-Exercise of Opt-in by the Non-Developing Party. In the event the Non-Developing Party does not Opt-in, the Developing Party shall have the right to use, import and commercialize the Product Improvement in the Developing Party's territory and in the Non-Developing Party's territory, provided, however, that the Developing Party shall commercialize the Product Improvement in the Non-Developing Party's territory under a trademark other than the Licensed Trademarks.

For this purpose:

(A) if the Non-Developing Party is Ipsen, the Parties shall negotiate in good faith the terms and conditions of an exclusive, royalty-bearing license under any Ipsen Patent Rights which would Cover the Product Improvement in the European Territory and the GTx Territory ;

(B) if the Non-Developing Party is GTx, the Parties shall negotiate in good faith the terms and conditions of an exclusive, royalty-bearing license under any GTx Patent Rights which would Cover the Product Improvement in the GTx Territory.

4.4 Documentation and Data.

(a) Ipsen Access to GTx Know-How. GTx shall provide Ipsen with copies of the GTx Know-How and Ipsen shall be authorized to use and reference the same in its applications for Regulatory Approvals and regulatory compliance activities in relation to such Regulatory Approvals. GTx shall, upon reasonable request therefore by Ipsen, provide appropriate authorization letters to relevant regulatory bodies in the European Territory within sixty (60) days from such request to enable Ipsen to reference any Licensed Product Active Substance Master Files ("**ASMFs**") Controlled by GTx for the purposes of Ipsen's applications for Regulatory Approval and regulatory compliance activities in the European Territory. If requested by Ipsen, GTx shall also provide Ipsen with an appropriate authorization letter from Orion to enable Ipsen to reference all applications or filings for Regulatory Approvals for Fareston and related ASMFs (as defined and identified in Article 7.5.3 and Schedule E of the Orion License) for the purpose of applying for and supporting Regulatory Approval of Licensed Products within the European Territory. In case of Ipsen's requests to be provided with copies of GTx Know-How which is controlled by a Third Party and for which Orion would charge to GTx direct out-of-pocket costs for making such copies and providing such GTx Know-How, Ipsen shall reimburse GTx for these costs.

(b) Each Party to Provide the Other With Information Necessary for Development. Each Party shall provide the other Party, within thirty (30) days from request, copies of, which may be in partially or wholly electronic form, or access to relevant documentation, information, data and reports related to its Development in its respective territory

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of any of the Licensed Products, to the extent such information and documentation are under the disclosing Party's Control and possession (and such information and documentation is freely disclosable), in each case to the extent reasonably necessary or useful to Develop and Market such Licensed Products in each of the Party's respective territories

ARTICLE V

LICENSES

5.1 Non-Exclusive Licenses to Conduct Development. Subject to the terms and conditions of this Agreement, GTx grants to Ipsen a non-exclusive, royalty-free license under the GTx Patents and GTx Know-how to conduct development of Licensed Product for any Indication.

5.2 Exclusive License to Conduct Commercialization Activities. Subject to the terms and conditions of this Agreement, GTx hereby grants to Ipsen an exclusive (except as to GTx's rights under Section 4.2(e) as to the PIN Indication), royalty-bearing license, with the right to grant sublicenses, under GTx Patents and GTx Know-how to develop, use, sell, have sold, offer for sale, import, export, and distribute Licensed Product for any Indication within the European Territory. For clarity, GTx retains rights under the GTx Patents and GTx Know-how to use, sell, have sold, offer for sale, import, export, and distribute Licensed Product for any Indication within the GTx Territory.

5.3 Exclusive License Under Licensed Trademarks. GTx hereby grants to Ipsen an exclusive, royalty-free license, with the right to grant sublicenses, under Licensed Trademarks, to develop, use, sell, have sold, offer for sale, and distribute Licensed Product for any Indication within the European Territory, provided that the license rights relating to the Licensed Trademark pertaining to the PIN Indication (as long it is different from the Licensed Trademark for the ADT Indication) shall terminate in the event Ipsen shall fail to make the Election.

5.4 Sublicensing. Ipsen may grant sublicenses under Sections 5.1, 5.2 and 5.3 of this Agreement without GTx's prior written consent. Any sublicense granted by Ipsen in accordance with Section 5.1, 5.2 and Section 5.3 of this Agreement shall be granted pursuant to a written agreement that subjects such sub-licensee to all relevant restrictions, limitations and obligations in this Agreement. Ipsen shall be responsible for failure by its sub-licensees to comply with, and Ipsen guarantees to GTx, the compliance by each of its sub-licensees with, all relevant restrictions, limitations and obligations in this Agreement. In the event of a material default by any sub-licensee under a sublicense agreement, Ipsen will inform GTx and take such action, after consultation with GTx, that, in the sublicensing Party's reasonable business judgment, is required to address such default.

5.5 Independent Research. Each Party is free to develop other pharmaceutical products independent of this Agreement, including without limitation, any other SERM products that are not Licensed Products. Neither Party has an obligation to disclose Information relating

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to medicinal chemistry nor other topics relating to SERMs, except to the extent such Information relates to Licensed Product.

5.6 Obligations With Respect to Competing Products.

(a) [*].

(b) [*].

[*].

5.7 Ipsen's Right of First Negotiation.

(a) GTx undertakes to regard Ipsen as its preferential partner for the development, marketing, sale and distribution of SERMs in the field of the prevention and treatment of prostate cancer or side effects related thereto or any other Indication in which the Parties jointly develop or commercialize a Licensed Product (the "**Field**"). Consequently, in the event GTx acquires, gains Control or develops a SERM that can be used in the Field, GTx grants to Ipsen a right of first negotiation to negotiate in good faith an agreement(s) under commercially reasonable terms and conditions regarding the development, marketing, sale and distribution of such SERM that can be used in the Field in the European Territory.

(b) [*].

5.8 GTx's Right of First Negotiation.

(a) Ipsen undertakes to regard GTx as its preferential partner for the development, marketing, sale and distribution of SERMs in the field of the prevention and treatment of prostate cancer or side effects related thereto or any other Indication in which the Parties jointly develop or commercialize a Licensed Product (the "**Field**"). Consequently, in the event Ipsen acquires, gains Control or develops a SERM that can be used in the Field, Ipsen grants to GTx a right of first negotiation to negotiate in good faith an agreement(s) under commercially reasonable terms and conditions regarding the development, marketing, sale and distribution of such SERM that can be used in the Field in the GTx Territory.

(b) [*].

5.9 Further Negotiations.

(a) [*].

(b) [*]

(c) [*].

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ARTICLE VI

COMMERCIALIZATION; REGULATORY COMPLIANCE

6.1 Commercialization and Marketing Responsibilities. Subject to Ipsen's failure to make the Election pursuant to Section 4.2(e)(iii) of this Agreement pertaining to the PIN Indication, Ipsen shall have the sole right and obligation to market all Licensed Products within the European Territory, and shall therefore have full and exclusive decision making authority with respect to all Commercialization Activities for all Licensed Product within the European Territory, including pricing decisions. GTx shall have the sole right and obligation to market all Licensed Products within the GTx Territory, and shall therefore have full and exclusive decision making authority with respect to all Commercialization Activities for all Licensed Product within the GTx Territory, provided that such decisions are consistent with this Agreement. Notwithstanding the foregoing, each Party shall consider in good faith any comments or concerns expressed by the other Party regarding such Commercialization Activities that would materially affect the other Party's development, marketing, and commercialization of Licensed Products in its respective territory. No Party shall be required to undertake any activity under this Agreement which it believes, in good faith, may violate any law.

6.2 Marketing and Sales Committee. GTx and Ipsen will form a Marketing and Sales Committee at **[*]** prior to the first anticipated Launch Date of a Licensed Product in the European Territory. The Marketing and Sales Committee shall be comprised of equal numbers from each Party **[*]** of reasonably qualified representatives, and shall meet from time to time **[*]**, at mutual agreeable times and locations, to discuss Ipsen's proposed Marketing and Sales Plan for Licensed Product. Ipsen will have the final responsibility, with the cooperation and assistance of GTx, for defining the resources required for the Marketing and sale of the Licensed Product within the European Territory, and for establishing marketing and promotion strategies with respect to the Licensed Product and budgets therefor. **[*]**.

6.3 Marketing and Sales Plan and Reports. At **[*]** prior to the first anticipated Launch Date, Ipsen shall submit to GTx a Marketing and Sales Plan for its review and comment provided that GTx shall not have approval rights with respect to such Marketing and Sales Plan. The Marketing and Sales Plan shall set forth, among other items, the projected Annual Net Sales and the projected advertising and promotion budgets for such year. The Marketing and Sales Plan shall be updated at least annually by Ipsen and submitted to GTx for review and comment by **[*]** of each calendar year. In addition, within **[*]** at the end of each calendar year, Ipsen shall provided a marketing and sales report for each Major Country in which a Licensed Product is launched, which report shall include a description of sales, marketing and promotion activities and a list of scientific conferences or other events involving the Licensed Product in which Ipsen has participated.

6.4 Medical Inquiries. Ipsen shall respond to all medical questions or inquiries relating to Licensed Product within the European Territory, which are directed to its respective sales representatives or other personnel, including Affiliates or sublicensees, unless such question or inquiry can be answered by reference to EMEA's or other Regulatory Agencies' approved labeling and package insert. Ipsen and GTx agree that they will share with each other

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all relevant medical information and inquiries pertaining to Licensed Product in order for each Party to be able to comply with all applicable law, including the requirements of any Regulatory Agency, and to facilitate the exchange of medical information, each Party agrees to designate a medical liaison to whom medical questions or inquiries relating to Licensed Product may be directed.

6.5 Regulatory Contact. At any time during the term, each Party shall notify the other Party's Regulatory Affairs Department upon being contacted by the FDA, the EMEA or any other Regulatory Agency with respect to Licensed Product and shall specify the nature of such inquiry. GTx shall retain responsibility for communicating with the FDA provided that GTx agrees to take into account any reasonable suggestion of Ipsen in the event the inquiry may affect any development activities conducted by GTx which is supporting the development activities conducted by Ipsen. During the term, Ipsen shall retain responsibility for communicating with all Regulatory Agencies in the European Territory provided that Ipsen agrees to take into account any reasonable suggestion of GTx in the event the inquiry may affect any development activities conducted by GTx for any Licensed Product.

6.6 Regulatory Compliance. Ipsen shall comply in all material respects with all applicable laws, rules, and regulations in the development and commercialization of Licensed Products in the European Territory under this Agreement. Ipsen shall retain exclusive authority and responsibility for handling, in any manner it deems appropriate, any disputes or law suits with any Regulatory Agencies regarding the regulatory status of Licensed Product within the European Territory. Notwithstanding the foregoing, Ipsen shall consider in good faith any comments or concerns communicated by GTx to Ipsen regarding such regulatory disputes that would materially affect GTx's development, Marketing, and commercialization of Licensed Products in the GTx Territory.

6.7 Commercialization Efforts. On a country by country basis, during the period commencing with Regulatory Approval and Pricing and Reimbursement Approval in a Major Country, and for the remainder of the Term, Ipsen, its Affiliates and/or sublicensees shall use commercially reasonable efforts to promote, market, distribute and sell the Licensed Product in such Major Country and in other countries within the European Territory where Regulatory Approval and Pricing and Reimbursement Approval has been obtained for the Licensed Product. **[*]**:

(i) [*];

(ii) [*];

(iii) [*]

(iv) [*]; and

(v) [*].

6.8 Product Launch.

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(a) Timing of Launch. Ipsen shall use commercially reasonable efforts to launch the Licensed Product in any Indication **[*]** in every Major Country of the European Territory and other countries within the European Territory where Ipsen, its Affiliates and/or sublicensees have obtained Regulatory Approval and Pricing and Reimbursement Approval for the Licensed Product in such Indication. Notwithstanding the foregoing, Ipsen, its Affiliate or a sublicensee may, acting in good faith in the exercise of its reasonable business judgment, determine either to delay the launch of the Licensed Product for use in a given Indication or not to launch the Licensed Product for use in a given Indication in any given country in the European Territory other than a Major Country, which decision to delay or not to launch shall not be deemed a failure to use commercially reasonable efforts. Further, Ipsen's, its Affiliates' or a sublicensee's decision to delay the launch of the Licensed Product for use in a given Indication in any Major Country for up to **[*]** after Ipsen or its Affiliates shall have obtained Regulatory Approval and Pricing and Reimbursement Approval in such country, will not be deemed a failure to use commercially reasonable efforts pursuant to Section 6.7 to the extent that Ipsen can demonstrate that such delay was attributable to bona fide business reasons affecting the Licensed Product.

(b) Decisions Not to Launch. Notwithstanding the provisions of Section 3.6 of this Agreement**,** Ipsen shall promptly notify GTx in writing if Ipsen, its Affiliate or a sublicensee, as applicable, determines to delay the launch of the Licensed Product for use in a given Indication in any Major Country after obtaining Regulatory Approval and Pricing and Reimbursement Approval of Licensed Product therefor. If such decision is due to any reasons other than the potential for, or the existence of, adverse business effects in such Major Country, or under the conditions set forth in Section 3.6 of this Agreement, then such decision shall be deemed a material breach of this Agreement.

6.9 Commercialization in European Territory. Ipsen shall set all prices for all Licensed Product within the European Territory, shall obtain Pricing and Reimbursement Approvals for Licensed Product as may be required, shall be responsible for distribution of each Licensed Product within the European Territory and shall book all sales for Licensed Product within the European Territory.

6.10 Advertising and Promotion. With respect to printed promotional materials or printed educational materials for Licensed Product within the European Territory, Ipsen shall be solely responsible for the content of such materials and the preparation thereof, at its sole expense.

6.11 Additional Support by GTx. If either Party desires the other Party to participate in marketing activities, such as by participating in global marketing programs, providing medical liaison support or other Licensed Product specialty support, the Parties shall discuss the proposed activities. If the Party being requested to participate or provide services agrees in writing to participate or conduct such activities, the Marketing and Sales Plan shall be revised to reflect such activities and the Party making the request shall reimburse the other Party on an FTE Cost plus out-of-pocket cost basis for such support, provided however that in the case such marketing activities shall benefit both Parties, each Party shall be responsible for paying its own costs and expense.

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ARTICLE VII

SUPPLY OF LICENSED PRODUCT

7.1 Manufacture and Supply of Licensed Product. Ipsen, GTx and Orion shall enter into a partial assignment agreement whereby GTx shall assign to Ipsen all rights and obligations pertaining to the manufacture and the supply of Licensed Product for the European Territory. As the result of such assignment, Ipsen shall directly purchase the Licensed Product from Orion and GTx shall have no responsibility whatsoever with respect to such supply.

7.2 Technology Transfer in Event of Termination of Supply by Orion. In the event that Orion terminates supply of Licensed Product to GTx and Ipsen for any reason whatsoever, then the Parties agree to collaborate with one another in good faith to establish one or more alternate manufacturing sites (either itself or through its Affiliates or Third Parties) to manufacture and supply Licensed Product in the manner and to the extent necessary and appropriate to meet the needs of both Parties, provided that in case of disagreement of the Parties on the manufacturing sites, each Party shall have the right to select such alternate manufacturer(s) and site(s) for its own supply.

ARTICLE VIII

CONFIDENTIALITY

8.1 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;

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(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, use of or access to Confidential Information of the other Party as shown by competent documentary evidence.

8.2 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 on a need to know basis 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. 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.

8.3 Survival. Sections 8.1 through 8.3 of this Article shall survive the termination or expiration of this Agreement for a period of **[*]**.

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8.4 Publications. Except to the extent set forth in Sections 8.2 and 8.5 of this Agreement, each Party (the "**Publishing Party**") shall provide to the other Party (the "**Reviewing Party**") the opportunity to review any proposed scientific/technical publications or scientific presentations which relate to Toremifene and/or Licensed Product as early as reasonably practical, but at least **[*]** prior to the intended submission for publication (except with the written consent of the Reviewing Party). The Reviewing Party will provide the Publishing Party with its response to its request to publish within **[*]** of receipt of such request. In the event that the Reviewing Party identifies any Confidential Information of the Reviewing Party contained within or referenced in such publication and the Reviewing Party requests the Publishing Party to remove such Confidential Information, the Publishing Party shall comply with such request. No publication shall be made by the Publishing Party without the written agreement of or approval from the Reviewing Party. However, the failure of the Reviewing Party to respond to such request within such **[*]** 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 a Licensed Product may be made by the Publishing Party even if the Reviewing Party does not approve, provided that the Reviewing Party may request a reasonable delay on such publication to seek patent protection on any patentable inventions disclosed therein.

8.5 Public Disclosures. Subject to the further provisions of this Article VIII, each Party shall not 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, without first obtaining the other Party's prior written approval, which shall not be unreasonably withheld or delayed, provided that in the event the Parties shall have previously approved the form of a press release or other publicly disseminated disclosure, either Party shall be free to disclose publicly substantially the same information in subsequent public releases without having to obtain other Party's consent thereto. Additionally, the Parties acknowledge that as public companies certain information is required by law to be filed by the Parties with certain agencies or authorities. In connection herewith, Ipsen acknowledges that GTx will have to file the Agreement with the U.S. Securities and Exchange Commission ("SEC") as a "material agreement" of GTx, but GTx shall do so under a request for confidential treatment which shall be submitted to Ipsen for its approval (not to be unreasonably withheld or delayed) prior to submission. Once information is disclosed to the SEC, any similar information which is not subject to confidential treatment may be disclosed by GTx in subsequent public filings or in public disclosures without having to first obtain Ipsen's prior written approval.

ARTICLE IX

OWNERSHIP OF INTELLECTUAL PROPERTY AND PATENT RIGHTS

9.1 Ownership. Each Party shall solely own, and that Party alone shall have the right to apply for, Patents for any Ipsen Inventions or GTx Inventions. Joint Inventions shall be owned jointly by GTx and Ipsen, without a duty of accounting. For clarity, either Party shall be free to grant licenses or other rights under Joint Inventions, to the extent consistent with the

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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.

9.2 Invention Disclosures. Each Party shall promptly provide to the other Party 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.

9.3 Disclosure of Provisional and Non-Provisional Patent Applications. 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 9.3 covering an Invention solely owned by such Party shall be deemed the Confidential Information of the Party providing such application.

9.4 Patent Filings.

(a) Ipsen Patent, GTx Patent and Joint Patent Filings. Each Party, at its sole discretion, responsibility, and cost shall prepare, file, prosecute and maintain its own Patents. GTx shall file, prosecute and maintain Patents to cover Joint Inventions. Ipsen and GTx shall pay fifty percent (50%) of all costs associated with the preparation, prosecution and maintenance of Joint Patents unless the Parties otherwise agree. The determination of the countries in which to file Joint Patents shall be made jointly by the Parties. GTx shall have the right to direct and control all material actions relating to the prosecution or maintenance of Joint Patents, subject to Ipsen's ability to comment on such filings and GTx's reasonable consideration of such comments. GTx shall provide prior written notice to Ipsen of the countries in which it intends to file, including conflict proceedings, reexaminations, reissuance, oppositions and revocation proceedings, provided, however, that Ipsen shall have the right to file or continue prosecution in countries in which GTx determines it wishes to abandon or not file such Joint Patent.

(b) Ipsen and GTx Patent Strategy. GTx shall keep Ipsen apprised of the status of each Joint Patent for which it is responsible and shall seek the advice of Ipsen 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 covering Licensed 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 any aspect of patent prosecution of a Joint Patent or a Patent covering a Licensed Product, each Party at its expense shall be free to take whatever action it deems appropriate to protect the Joint Invention or Licensed 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 Licensed Product to which the Party has license rights under this Agreement to lapse

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or become abandoned without having first filed a substitute, the filing Party shall, whenever practicable, notify the other Party of such intention at least sixty (60) calendar days prior 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 Ipsen 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, GTx shall notify Ipsen upon receipt of Regulatory Approval to market a Licensed Product in the United States, and Ipsen shall notify GTx upon receipt of Regulatory Approval to market a Licensed Product in the EU. Both Parties agree to timely file such applications as they feel are appropriate or required to extend the patent term of the GTx Patents pertaining to Licensed Product. 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 of the GTx Patents in the United States shall be made by GTx.

9.5 Third Party Patent Rights. Except as expressly provided in Section 10.1 of this Agreement, 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 Licensed 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 Toremifene or any Licensed Product.

9.6 Enforcement Rights.

(a) Notification of Infringement. If either Party learns of any infringement or threatened infringement by a Third Party of a GTx Patent or a Joint Patent, 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 (including Joint Patents) covering the manufacture, use, importation, exportation, sale or offer for sale of Licensed Product by reason of the manufacture, use or sale of products competitive with Licensed Product, using counsel of its own choice. Ipsen 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 within a period of one hundred

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eighty (180) calendar days of notice by Ipsen to GTx requesting action, Ipsen 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.

(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 XIV.

(d) Damage Award or Settlement Payments. Any damage award or settlement payments made to either or both of GTx or Ipsen in connection with any such action relating to infringement of a GTx Patent or a Joint Patent, whether obtained by judgment, settlement or otherwise shall be allocated, (i) first, to the Party which initiated and prosecuted the action to recoup all of its costs and expenses incurred in connection with the action, (ii) second, to the other Party, to recover all of its costs and expenses incurred in connection with the action, and **[*]**.

(e) 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 Licensed Product, GTx shall have the first right, but not the obligation, to defend the Parties against any claim by a Third Party that the development, use, sale, offer for sale, export or import of Licensed Product in the European Territory infringes Third Party intellectual property rights but no settlement may be entered into without the written consent of Ipsen if such settlement would materially and adversely affect Ipsen's interests in any Licensed Product. Ipsen shall have the right to participate in the defense of such claim at its cost and expense but shall not take any position inconsistent with GTx's position on such issues. In the event GTx chooses at in its sole discretion not to defend such suit, Ipsen shall have the right but not the obligation to defend such suit, provided that Ipsen shall not settle any action pursuant to this Section without GTx's consent, such consent not to be unreasonably withheld.

9.7 Allocation of Patent Expenses. On a country-by-country basis, Patent Expenses arising from GTx Patents shall be borne solely by GTx, Patent Expenses arising from Ipsen Patents shall be borne solely by Ipsen and Patent Expenses arising from Joint Patents shall be borne equally by the Parties, unless otherwise agreed.

9.8 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.

9.9 Trademarks.

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(a) The Licensed Product will be marketed in the European Territory under the Licensed Trademark, provided, however that (i) if the Licensed Product is subject to a centralized Regulatory Approval process with the EMEA, the Licensed Product will be marketed in the European Territory under the Licensed Trademark if approved by the EMEA or any other trademark as determined jointly by the Parties and approved by the EMEA and (ii) in specific countries of the European Territory where the use of the Licensed Trademark is not permitted by law or is not appropriate including for reasons relating to language or custom, Ipsen shall have the possibility to use a different trademark, subject to GTx's prior written approval which shall not be unreasonably withheld or delayed. GTx shall be responsible for securing and for maintaining registrations for the Licensed Trademark in the European Territory and shall use reasonable commercial efforts in that regard, provided, however, that GTx shall not be deemed to have breached this Agreement if it is unable to obtain registration of the Licensed Trademark in every country in the European Territory. In the event, despite its reasonable commercial efforts, GTx is unable to obtain or maintain registrations for the Licensed Trademark in some country(ies) in the European Territory, the Parties shall negotiate in good faith concerning the use of such other trademarks as may be available for marketing the Licensed Product in those countries.

(b) GTx and Ipsen shall cooperate with each other and use reasonable efforts to protect the Licensed Trademark from infringement by Third Parties. Without limiting the foregoing, each Party shall promptly notify the other Party of any known, threatened or suspected infringement, imitation or unauthorized use of or unfair competition relating to the Licensed Trademark. GTx shall have the first right to determine in its discretion whether to and to what extent to institute, prosecute and/or defend any action or proceedings involving or affecting any rights relating to the Licensed Trademark. Upon GTx's reasonable request, Ipsen shall cooperate with and assist GTx in any of GTx's enforcement efforts with respect to the Licensed Trademark. GTx shall promptly inform Ipsen if GTx elects not to take action against any actual or suspected infringement of the Licensed Trademark, in which case, Ipsen shall then have the right, but not the obligation, to bring or assume control of any action against the allegedly infringing third party as Ipsen determines may be necessary, provided, however, that Ipsen shall not enter into any settlement or compromise of any claim relating to the Licensed Trademark without the prior written consent of GTx. In the event that Ipsen brings or assumes control of any such action, then GTx agrees to reasonably assist Ipsen in connection therewith. In either case, the Party that initiated and prosecuted, or maintained the defense of the action shall bear all of the costs and expenses (including reasonable attorneys' fees) incurred in connection with the action and shall be entitled to recoup those amounts in the event of recovery, by settlement or otherwise. The amount of any recovery remaining shall be shared equally by the Parties.

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ARTICLE X

REPRESENTATIONS AND WARRANTIES

10.1 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, provided that for purposes hereof, 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) Compliance with Laws. It shall comply with all applicable local, state, national, regional and governmental laws and regulations relating to its activities under this Agreement.

(iii) No Debarment. It has not been and will not be debarred under Section 306 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 335a(a) or (b). In the event that such Party becomes aware of, or receives notice of, the debarment of any individual, corporation, partnership, or association performing activities which relate to the Products, it shall notify the other Party immediately and address the issue as directed by the other Party.

(b) GTx Representations and Warranties to Ipsen. GTx hereby represents and warrants to Ipsen as follows:

(i) GTx Patents. GTx warrants and represents that, to the best of its knowledge as of the Effective Date, (A) Exhibit A of this Agreement sets forth all of GTx Patents as of the Effective Date which are directed to the composition of matter or use of Toremifene in Licensed Products, (B) the GTx Patents which have been granted and for which any period for filing a protest shall have expired are valid, in full force and enforceable, (C) there are no existing valid Third Party patents in the European Territory that might be infringed by the sale of the Initial Products by Ipsen under this Agreement and (D) the use and/or sale of the Licensed Products in the ADT and PIN Indications in the European Territory will not in the absence of a license from GTx infringe any patents owned or Controlled by GTx other than the 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 Initial Products, and it is not aware that the manufacture, use or sale

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of Initial Products 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 to its knowledge it owns (in whole or in part) or otherwise Controls all Patents and Know-How that are the subject of the licenses granted to Ipsen herein.

(iv) UTRF and Orion Consents. GTx expressly represents and warrants that no consents are required to be obtained from UTRF and Orion under the GTx Licenses relating to the execution of this Agreement other than the consent of Orion for the assignment of supply rights to Ipsen for the European Territory.

(v) GTx Prior Obligations. As at the Effective Date, GTx is obligated under only the GTx Licenses to pay to any Third Party royalties with respect to Licensed Products for any Indication.

(vi) GTx Licenses. GTx warrants that as of the Effective Date, (i) the GTx Licenses are in full force and in effect in accordance with their terms, (ii) GTx is not in default or breach in any material respect of the GTx Licenses and (iii) to GTx's knowledge, there is no cause of early termination of the GTx Licenses. GTx shall (i) comply with and observe in all material respects its obligations under the GTx Licenses and (ii) not terminate or otherwise modify any terms or conditions of the GTx Licenses in any manner that would materially adversely affect Ipsen's rights under this Agreement without the prior written consent of Ipsen.

(c) Ipsen Representations and Warranties to GTx. Ipsen hereby represents and warrants to GTx as follows:

(i) Acceptance of Obligations and Duties. Ipsen acknowledges receipt of copies of the GTx Licenses and agrees to be bound by the terms thereof as far as these terms are applicable to Ipsen.

(ii) Ipsen's Power and Authority. Ipsen 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.

10.2 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.

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ARTICLE XI

INFORMATION AND REPORTS

11.1 Information and Reports During Development and Commercialization. Ipsen 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, quality, regulatory, commercial, marketing, promotion, pricing, sales and other Information, including copies of all preclinical and clinical reports, known by Ipsen or GTx that directly concern Licensed Product, as provided for in this Agreement. Each Party will use commercially reasonable efforts to disclose to the other Party all significant Information relating to Licensed Product promptly after it is learned or its significance is appreciated. GTx shall own and maintain the combined database of clinical trial data accumulated from all clinical trials of Licensed Product and of adverse drug event information for all Licensed Product. 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 Licensed Product.

11.2 Complaints. Each Party shall maintain a record of all complaints it receives with respect to any Licensed Product and shall inform the other Party of the receipt of such complaint.

11.3 Safety Data Exchange Agreement. Within [*] calendar days of the Effective Date, the Parties and Orion will negotiate in good faith and execute a pharmacovigilance safety data exchange agreement, which shall include adverse event reporting, with terms and conditions that are customary in the industry.

11.4 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, 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. In connection herewith, Ipsen agrees that it shall maintain accurate records reflecting the actual purchases of Licensed Product made from Orion during the term of this Agreement, on a country by country basis, and the sales of each Licensed Product in each such country, including copies of invoices reflecting purchases of Licensed Product and other data supporting the consumption of such Licensed Product in each of the countries within the European Territory. 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, for a period of **[*]** from creation of individual records. Upon the written request of GTx, Ipsen and GTx shall agree on a mutually acceptable date on which to permit an independent certified public accountant firm of an internationally recognized standing and selected by GTx to examine such records at its expense (not more often than once each year), for the sole purpose of verifying the accuracy of

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calculations, amounts and classifications of such revenues, costs or payments made under this Agreement. The accounting firm shall disclose to GTx and Ipsen whether the calculations were correct or incorrect, the specific details concerning any discrepancies and such other information that should properly be contained in any reports required under this Agreement. In the absence of material discrepancies (i.e., in those instances where discrepancy is less than **[*]** of the amounts payable under this Agreement) identified in any such audit, the accounting expenses shall be paid by GTx. If material discrepancies are identified by the independent accountant, the audited Party shall bear all accounting expenses. If such accounting firm concludes that additional royalties or other amounts were owed by Ipsen, Ipsen shall promptly pay any amounts due to the GTx. Upon the expiry of **[*]** following the end of any calendar year for which Ipsen made payment in full of all royalties and other amounts payable with respect to such calendar year, and in the absence of gross negligence or willful misconduct of Ipsen or a contrary finding by an accounting firm pursuant to this Section, such calculation shall be binding and conclusive upon the Parties and Ipsen shall be released from any liability or accountability with respect to royalties or other payments for such calendar year.

(b) Any records or accounting information received by a Party from the other Party shall be Confidential Information for purposes of Article VIII of this Agreement. Results of any such audit shall be provided to both Parties, subject to Article VIII of this Agreement.

ARTICLE XII

TERM AND TERMINATION

12.1 Term. This Agreement shall commence as of the Effective Date and, unless sooner terminated as provided in this Article XII of this Agreement, (a) the provisions relating to development and Commercialization shall continue in effect until the Parties are not developing or Commercializing any Licensed Product within the European Territory; and (b) the provisions relating to Commercialization shall continue in effect until the date on which Ipsen is no longer obligated to pay Royalty Payments to GTx on Net Sales of Licensed Product.

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12.2 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 **[*]** 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 thirty (30) 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 **[*]** 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 XIV of this Agreement. 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 XIV of this Agreement 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 XIV of this Agreement. To the extent that it is determined pursuant to a final and non-appealable decision under Article XIV of this Agreement 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 XIV of this Agreement 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 of this Agreement. If a final and non-appealable decision is made under Article XIV of this Agreement that no material breach was committed by the Accused Breaching Party, then the decision maker under Article XIV of this Agreement 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 12.2(a) and (b) of this Agreement, then the following provisions shall apply:

(i) If the Non-Breaching Party that terminates this Agreement is Ipsen, then Ipsen's license under Section 5.2 of this Agreement shall survive, subject, however, to the rights and interests of Orion and UTRF under the GTx Licenses. The Royalty Payments

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required to be paid to GTx by Ipsen under Article III of this Agreement shall survive but shall be offset by any damages incurred by Ipsen in connection with such material breach.

(ii) If the Non-Breaching Party that terminates this Agreement is GTx, then the effects of termination as set forth in Section 12.5 of this Agreement shall apply.

(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.

12.3 Termination by Ipsen. Ipsen may terminate this Agreement upon the following circumstances :

(a) For any reason whatsoever, with **[*]** prior written notice to GTx; provided, however, that in the event that termination is the result of a legitimate and documented concern over Safety, termination shall be effective **[*]** after written notice to GTx; and

(b) With **[*]** prior written notice, in case of early termination of the Orion License (except in the event of the termination of the Orion License due to Orion's breach pursuant to Section 21.2.2 of the Orion License) and/or the UTRF License (on account of the PIN Indication); provided, however, that in the case of the termination of the Orion License (except in the event of the termination due to Orion's breach as herein provided) and/or the UTRF License (on account of the PIN Indication), GTx shall use its commercially reasonable efforts to ensure that, upon request from Ipsen, Orion and/or UTRF will agree to discuss with Ipsen with a view to negotiate the terms and conditions under which Orion and/or UTRF would be willing to collaborate with regard to the further development and commercialization of Licensed Product in the Indications in which GTx and Ipsen were previously developing and commercializing such Licensed Products, provided that any such further development and/or commercialization of the Licensed Products by Orion and Ipsen would be subject to and conditioned on a definitive written agreement to be negotiated between and executed by Orion and Ipsen.

12.4 Bankruptcy. Either Party may terminate this Agreement, in whole or in part as applicable, effective immediately upon receipt of written notice to the other Party if such other Party is adjudged bankrupt or has had filed against it any petition under any bankruptcy, insolvency or similar laws or has had a receiver appointed for its business or property, and in each case such petition or appointment of receiver shall not have been dismissed within ninety (90) days of such filing or appointment, or each Party makes a general assignment for the benefit of its creditors.

12.5 Effect of Termination by GTx Under Section 12.2 of this Agreement or Termination by Ipsen Under Section 12.3 of this Agreement. If GTx terminates this Agreement for Material Breach by Ipsen pursuant to Section 12.2 of this Agreement or if Ipsen

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terminates this Agreement pursuant to Section 12.3 of this Agreement, Ipsen shall continue to be obligated during the termination notice period to perform all of its obligations under this Agreement, including its obligation to pay Initial Development Expenses. In addition, as a result of any such termination:

(a) [*]

(b) [*]

(c) [*]

(d) [*]

(e) [*]

(f) [*]

(g) [*] and

(h) [*]

12.6 Permitted or compulsory assignment other than to Affiliate or by merger or reorganization. [*].

12.7 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 is necessary to permit their complete fulfillment or discharge. Without limiting the foregoing, Sections 3.10, 8.1, 8.2, 8.3, 9.1, 11.4, 12.2 and 12.3 (as to activities occurring during the term of the Agreement), 12.4, 12.5, 12.6, 12.7, 13.1-13.4 (if applicable to such termination),13.5, and Articles 14 and 15 shall survive expiration or termination of this Agreement.

ARTICLE XIII

INDEMNIFICATION

13.1 Ipsen and GTx. Ipsen 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 (a) the material breach by such Party in the performance of any obligation of a Party in this Agreement or of any warranty, representation, or agreement made by such Party in this Agreement, (b) the intentional misconduct of such Party, its Affiliates, or their respective officers, directors or employees (each an "Actionable Party"), or (c) the negligent acts or

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omissions of an Actionable Party, but only to the extent such negligent acts or omissions materially contributed to the Claims.

13.2 Ipsen. Ipsen further agrees to defend, indemnify and hold harmless GTx, its officers, directors, agents, employees and Affiliates ("**GTx Indemnitees**"), from and against 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 packaging, labeling, sale, use, storage, transportation, distribution or handling of Licensed Product in the European Territory; provided, however, that Ipsen shall not be required to defend, indemnify, or hold harmless GTx Indemnitees from any such Claims to the extent they result from GTx's, its officers', directors', employees' or Affiliates' gross negligence or willful misconduct, GTx's sales of Licensed Product in the GTx Territory or material breach of this Agreement.

13.3 GTx. GTx further agrees to defend, indemnify and hold harmless Ipsen, its officers, directors, agents, employees and Affiliates ("**Ipsen Indemnitees**"), from and against any Claims relating to personal injuries (including death) or product liability or other loss or damage by Third Parties resulting from or relating to packaging, labeling, sale, use, storage, transportation, distribution or handling of Licensed Product in the GTx Territory, provided, however, GTx shall not be required to defend, indemnify of hold harmless Ipsen Indemnitees from any such Claims to the extent they result from Ipsen's, it officers', directors', employees' or Affiliates' gross negligence or willful misconduct, Ipsen's sales of Licensed Product in the European Territory or material breach of this Agreement.

13.4 Procedure. The Party seeking indemnification (the "**Indemnified Party**") shall inform the other Party promptly of any such Claim which is brought against it and shall, to the extent such Claim is brought by a Third Party, at the other Party's request, cooperate fully with the other Party in defending such 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 (a) provides for any relief other than the payment of monetary damages for which the Indemnifying Party shall be solely liable and (b) 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.

13.5 Insurance.

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(a) Each Party agrees during the term of the Agreement and for a period of at least three (3) years thereafter to maintain commercial general liability insurance covering each Party's activities contemplated in this Agreement on a claims made form having limits of not less than and **[*]** per occurrence. All insurance companies must be rated A or better in the most recent AM Best Rating Guide. Each party, upon request, agrees to provide the other Party with a certificate of insurance evidencing its retention of such insurance coverage and any updates thereto.

(b) Each Party shall ensure that their subcontractors, if any, are properly insured against the risks related to their own activities, for damages of any kind, caused to the other Party or to Third Party, for an amount proportionate to the activities carried out by such subcontractors hereunder. The insurance must be subscribed with a financially sound company of international repute.

ARTICLE XIV

DISPUTE RESOLUTION

14.1 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.

14.2 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 within fourteen (14) calendar days after such issue is submitted for resolution to such officers.

14.3 Resolution of Dispute by Alternate Means. In the event the designated Executive Officers are not able to resolve such dispute, such dispute shall be resolved through binding arbitration, which arbitration may be initiated by either Party at any time after the conclusion of such period, on the following basis:

(a) The place of arbitration shall be **[*]**.

(b) The arbitration shall be made in accordance with the **[*]**.

(c) The governing law shall be **[*]** .

(d) Judgment upon the award rendered by such arbitrator shall be binding on the Parties and may be entered by any court or forum having jurisdiction.

(e) Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Further, either Party also may, without waiving any remedy under this Agreement, seek from any

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court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of such Party pending the arbitration award.

(f) [*].

(g) Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' and any administrative fees of arbitration.

(h) Except to the extent necessary to confirm an award or as may be required by law, neither Party nor any arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties.

(i) In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable statute of limitations.

14.4 Patent and Trademark Dispute Resolution. Any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any patent rights covering the manufacture, use or sale of any Licensed Product or of any trademark rights relating to any Licensed Product shall be submitted to a court of competent jurisdiction in the territory in which such Patent or trademark rights were granted or arose.

14.5 Injunctive Relief. Nothing herein may prevent either Party from seeking preliminary injunction or temporary restraint order in order to prevent any Confidential Information is disclosed without appropriate authorization under this Agreement.

ARTICLE XV

MISCELLANEOUS

15.1 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) Non-Affiliates. Except as provided in subsection (b)(ii) below, neither Party shall 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.

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

(d) 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.

15.2 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.

15.3 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.

15.4 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.

15.5 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.

15.6 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.

15.7 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: **[*]**

With a copy to: **[*]**

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If to Ipsen: [*]

With a copy to: [*]

15.8 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.

15.9 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.

15.10 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.

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

15.12 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.

15.13 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.

15.14 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

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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.

15.15 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.

15.16 Currency Exchange. Except as set forth in Section 3.12 of this Agreement, all payments to be made by Ipsen to GTx shall be made in Euros, to a GTx bank account able to receive Euros.

IN WITNESS WHEREOF, GTx and Ipsen 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

Title: CEO and Vice Chairman

IPSEN Ltd

Signed By: /s/ Alistair Stokes

Title: Director and Chief Executive Officer

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EXHIBITS PROVIDED SEPARATELY

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EXHIBIT A

Patents & Patent Applications Controlled by GTx, Inc.
in the European Territory which cover the Licensed Products

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EXHIBIT A (cont.)

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EXHIBIT B

European Community Trademark Registration

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EXHIBIT C

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EXHIBIT D

Example Calculation to Clarify Section 3.4

1. **[*]**

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EXHIBIT E

ADT DEVELOPMENT PLAN

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EXHIBIT E (cont.)

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EXHIBIT E (cont.)

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EXHIBIT E (cont.)

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EXHIBIT 31.1

CHIEF EXECUTIVE OFFICER CERTIFICATION

I, Mitchell S. Steiner, certify that:

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

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 3, 2006

/s/ Mitchell S. Steiner

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

EXHIBIT 31.2

CHIEF FINANCIAL OFFICER CERTIFICATION

I, Mark E. Mosteller, certify that:

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

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 3, 2006

/s/ Mark E. Mosteller

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

EXHIBIT 32.1

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

In connection with the Quarterly Report of GTx, Inc. (the "Company") on Form 10-Q for the three months ended September 30, 2006, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mitchell S. Steiner, Chief Executive Officer of the Company certify, pursuant to Rule 13a-14(b) or Rule 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 3, 2006

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

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

EXHIBIT 32.2

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

In connection with the Quarterly Report of GTx, Inc. (the "Company") on Form 10-Q for the three months ended September 30, 2006, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mark E. Mosteller, Chief Financial Officer of the Company certify, pursuant to Rule 13a-14(b) or Rule 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 3, 2006

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

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