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

FORM 10-K

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

For the fiscal year ended December 31, 2007

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)	(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	The NASDAQ Stock Market, LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No ☑

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

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

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

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

The aggregate market value of common stock held by non-affiliates of the registrant based on the closing sales price of the registrant's common stock on June 29, 2007 as reported on the NASDAQ Global Market was $199,944,800.

There were 36,236,263 shares of registrant's common stock issued and outstanding as of March 5, 2008.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, in connection with the Registrant's 2008 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "could," "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, uncertainties and other important factors. We discuss many of these risks, uncertainties and other important factors in this Annual Report on Form 10-K in greater detail in the section entitled "Risk Factors" under Part I, Item 1A below. Given these risks, uncertainties and other important factors, 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 Annual Report on Form 10-K. You should read this Annual Report on Form 10-K and the documents that we incorporate by reference in and have filed as exhibits to this Annual Report on Form 10-K, 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.

PART I

ITEM 1. BUSINESS

Overview

GTx, Inc., a Delaware corporation incorporated on September 24, 1997, is a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules that selectively target hormone pathways to treat cancer, osteoporosis and bone loss, muscle wasting and other serious medical conditions. 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 multiple 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. In February 2008, we announced that the Phase III clinical trial results for ACAPODENE® 80 mg for the treatment of multiple serious side effects of ADT showed that ACAPODENE® 80 mg reduced new morphometric vertebral fractures and met other key endpoints of bone mineral density, or BMD, lipid profiles and gynecomastia. In March 2008, we announced that the results from this Phase III clinical trial also showed that ACAPODENE® 80 mg demonstrated a reduction in hot flashes in a subset analysis. We expect to file a New Drug Application, or NDA, for ACAPODENE® 80 mg for the treatment of multiple serious side effects of ADT with the U.S. Food and Drug Administration, or FDA, in 2008. We have licensed to Ipsen Limited, or Ipsen, exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States, which we collectively refer to as the European Territory, to develop and commercialize ACAPODENE® and other products containing toremifene in all indications which we have licensed from Orion Corporation, or Orion, which include all indications in humans except breast cancer outside of the United States. In addition to ACAPODENE®, we are developing selective androgen receptor modulators, or SARMs, with Merck and Co., Inc., or Merck. In November 2007, we entered into an exclusive license and collaboration agreement with Merck establishing a global strategic collaboration for the discovery, development and commercialization of SARMs, including Ostarine™. We believe that Ostarine™ and other SARM candidates, including GTx-838, have the potential to treat a variety of indications associated with muscle wasting and bone loss, including frailty, muscle loss associated with aging, also known as sarcopenia, muscle wasting in cancer patients, known as cancer cachexia, osteoporosis, and chronic kidney disease muscle wasting. We are currently evaluating Ostarine™ in a Phase II clinical trial for the treatment of cancer cachexia.

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

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

Our most advanced product candidate, ACAPODENE®, is being developed to treat multiple serious side effects of ADT and to prevent prostate cancer in high risk men with high grade PIN. ADT is the most common treatment for advanced, recurrent or metastatic prostate cancer, and we believe that it is currently used to treat approximately 800,000 men in the United States. ADT is hormone therapy that works by reducing testosterone and estrogen. The low estrogen levels unintentionally caused by ADT can lead to multiple serious side effects including: severe bone

loss, or osteoporosis, resulting in skeletal fractures; hot flashes; lipid profile changes that lead to higher rates of cardiovascular disease; and breast pain and enlargement, or gynecomastia. There are currently no drugs approved by the FDA for the treatment of these multiple serious side effects of ADT. We commenced a pivotal Phase III clinical trial of ACAPODENE® 80 mg under a Special Protocol Assessment, or SPA, with the FDA for this indication in November 2003. A SPA is designed to facilitate the FDA's review and approval of drug products by allowing the agency to evaluate the proposed design and size of clinical trials that are intended to form the primary basis for determining a drug product's efficacy. The primary endpoint was new morphometric vertebral fractures measured by x-ray, and the secondary endpoints included BMD, lipid profile changes, gynecomastia and hot flashes. The last patient completed the ADT clinical trial in November 2007. In February 2008, we announced that the results of the Phase III clinical trial showed that ACAPODENE® 80 mg reduced new morphometric vertebral fractures and met other key endpoints of BMD, lipid profiles and gynecomastia. Also, in March 2008, we announced that the results from this Phase III clinical trial of ACAPODENE® 80 mg demonstrated a reduction in hot flashes. We expect to file a NDA for ACAPODENE® 80 mg for the treatment of multiple serious side effects of ADT with the FDA in 2008.

In the United States, prostate cancer is one of the most commonly diagnosed cancers and the second leading cause of cancer-related deaths in men. Men who have high grade PIN are at high risk of developing prostate cancer (we believe that more than 40% of men with high grade PIN detected on a prostate biopsy develop prostate cancer within three years). In the United States, there are over 115,000 new cases of high grade PIN diagnosed each year and an estimated 14 million men under the age of 80 may unknowingly harbor this condition. Currently, there is no approved treatment to prevent prostate cancer in high risk men with high grade PIN. In January 2005, we initiated a pivotal Phase III clinical trial of orally administered ACAPODENE® 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, which is being conducted under a SPA with the FDA. We will evaluate efficacy endpoints for the clinical trial at 36 months after completion of enrollment, and we anticipate conducting a planned efficacy interim analysis after a certain number of cancer events have been recorded among study patients, which we currently expect to occur by the end of the first quarter of 2008. If the efficacy results from the planned interim analysis achieve the statistical outcome specified in the SPA (a £ 0.001), we plan to file a NDA with the FDA. If we are able to file a NDA based on the results of the efficacy interim analysis, we will continue to collect efficacy data and safety data during the review process to satisfy the FDA's safety requirements set forth in the SPA. If the efficacy results from the planned interim analysis do not satisfy the specified statistical requirements in the SPA, we plan to continue the clinical trial.

In our third clinical program, Ostarine™, a SARM, is being developed to treat a variety of medical conditions relating to muscle wasting and/or bone loss. In December 2006, we announced that Ostarine™ met its primary endpoint in a Phase II proof of concept, double blind, randomized, placebo controlled clinical trial in 60 elderly men and 60 postmenopausal women. We initiated a Phase II randomized, double blind, placebo controlled clinical trial evaluating Ostarine™ for the treatment of cancer cachexia in 150 patients diagnosed with non-small cell lung cancer, colorectal cancer, non-Hodgkin's lymphoma, or chronic lymphocytic leukemia. The clinical trial is being conducted at approximately 50 clinical sites in the United States, Argentina and Canada and we expect to receive data from this trial during the summer of 2008.

In November 2007, we entered into an exclusive license and collaboration agreement with Merck which governs our and Merck's joint research, development and commercialization of SARM compounds and related SARM products, including SARMs currently being developed by us and Merck and those yet to be discovered, for all potential indications of interest. Under the agreement, we will conduct preclinical research of SARM compounds and products, and Merck will be primarily responsible for conducting and funding development and commercialization of products developed under the agreement. We received an upfront licensing fee of $40.0 million in January 2008 and Merck has agreed to pay us $15.0 million in guaranteed cost reimbursements for research and development activities in equal annual installments over a three year period beginning on the first anniversary of the effective date of the agreement. We are also eligible to receive up to $422.0 million in future milestone payments associated with the development and regulatory approval of a lead product candidate, including Ostarine™, as defined in the agreement, if multiple indications are developed and receive required regulatory approvals, as well as additional milestone payments for the development and regulatory approval of other product candidates developed under the agreement, upon the achievement of such development and regulatory approval milestones and assuming the continued effectiveness of the agreement. Merck also has agreed to pay us tiered royalties on net sales of products that may be developed under the agreement. On the date the agreement became effective in December 2007, we issued to Merck 1,285,347 newly-issued shares of our common stock for an

aggregate purchase price of approximately $30.0 million. We and Merck, through our SARM collaboration, will determine the development strategy of Ostarine™, GTx-838 and other collaboration compounds.

In September 2006, we entered into a collaboration and license agreement with Ipsen pursuant to which we granted Ipsen exclusive rights in the European Territory to develop and commercialize ACAPODENE® and other products containing toremifene in all indications that we have licensed from Orion. In accordance with the terms of the agreement, Ipsen paid us €21.5 million as a license fee and expense reimbursement and is paying us €1.5 million in equal installments over a three year period from the date of the agreement. Pursuant to the agreement, we are also entitled to receive from Ipsen up to an aggregate of €39.0 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 the 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.

Scientific Background on Estrogens and Androgens

Both estrogens and androgens are hormones that play critical roles in men's and women's health, regulating not only the reproductive system, but also having important effects on the muscular, skeletal, cardiovascular, metabolic and central nervous systems. In order for the body to function properly, a balance must exist between estrogens and androgens.

Estrogens prevent osteoporosis, reducing the risk of skeletal fractures, may be cardioprotective by having a favorable effect on lipid profile and may reduce hot flashes. As testosterone levels decrease in aging men, there is also a gradual increase in estrogen levels in the blood relative to testosterone levels which may promote BPH, initiate prostate cancer and cause gynecomastia.

Testosterone, the predominant androgen in men, is important for mental well-being and for masculine physical characteristics, such as muscle size and strength and bone strength. Male reproductive health is also dependent on testosterone to maintain sexual interest, fertility, erectile function and normal prostate function. Testosterone is converted into a more potent androgen, dihydrotestosterone, or DHT, which also stimulates sebaceous and hair glands and may cause unwanted effects like acne and hair loss. DHT is the primary androgen involved in BPH. In aging men, there is a gradual decline in testosterone levels, which contributes to a loss of muscle mass and strength, and decreased bone mineralization, which may result in osteoporosis and bone fractures, erectile dysfunction, decreased sexual interest, depression and mood changes.

Estrogens and androgens perform their physiologic functions by binding to and activating their hormone receptors located in various tissues. Once a hormone binds with its receptor, this activates a series of cellular events that results in estrogenic or androgenic tissue effects.

Pharmaceuticals that target estrogen or androgen receptors have been used medically for over 50 years. The drugs that have been used to stimulate androgen receptors are either natural or synthetic hormones, known as steroids. Steroids activate hormone receptors in all tissue types in a non-selective manner resulting in not only beneficial effects but also in unwanted clinical effects. In men, the absence of selectivity and conversion of testosterone to DHT may result in unwanted side effects, such as the potential stimulation of latent into clinical prostate cancer, and may enhance BPH, cause acne, cause loss of hair in men and hair growth in women and cause gynecomastia. Currently, no orally available testosterone products have been approved for use in the United States, and those testosterone products that are available must be administered by intramuscular injections or by transdermal patches or gels that may not be convenient for patients and, in some cases, can result in inconsistent blood levels of testosterone.

There are also classes of small molecules that are not steroids that can bind to the same hormone receptors. These nonsteroidal small molecules may either stimulate or block hormone receptors depending on the type of tissue in which the receptor is found and the interaction of the small molecule with the receptor. A drug that has the ability to either block or stimulate the hormone receptor is called a selective hormone receptor modulator. A selective hormone receptor modulator that can either block or stimulate a hormone receptor in a tissue-selective manner may be able to mimic the beneficial, while minimizing the unwanted, effects of natural or synthetic steroid hormones.

A SERM is a nonsteroidal small molecule that binds to and selectively modulates estrogen receptors. SERMs have the ability to either stimulate or block estrogen's activity in different tissue types. SERMs have been shown to mimic estrogen's beneficial action in bone and lipid profiles, and we believe that SERMs have the potential to block estrogen's harmful activity in the prostate and the breast. Examples of SERMs currently on the market include toremifene, which is FDA approved to treat advanced female breast cancer, and raloxifene, which is used to prevent and treat postmenopausal female osteoporosis.

A SARM is a small molecule that binds to and selectively modulates androgen receptors, the primary receptor to which testosterone binds. In men, SARMs potentially have beneficial action in bone and muscle while blocking testosterone's unwanted action in the prostate and skin. We further believe that SARMs can be designed to either cross or not cross into the central nervous system and to selectively modulate androgen receptors in the brain to affect mood and sexual interest. Although no SARMs have been commercialized to date, we believe that SARMs without testosterone's or other exogenous anabolic steroid therapies' harmful side effects can be developed to treat a range of medical conditions, including: (1) muscle wasting conditions of chronic diseases, such as cancer, AIDS, chronic kidney disease, end-stage renal disease, neurodegenerative disorders, trauma and burns; (2) muscle wasting conditions associated with aging such as frailty and sarcopenia; (3) the prevention and/or treatment of osteoporosis; (4) prostate disorders, such as BPH and prostate cancer; (5) disorders of the central nervous system, such as low libido, depression and other mood disorders; (6) low testosterone conditions, such as primary and secondary hypogonadism; (7) male reproductive functions, such as infertility, male contraception and erectile dysfunction; and (8) other conditions, such as anemia and male hair loss.

Marketed Product

FARESTON®

We currently market FARESTON® (toremifene citrate 60 mg) tablets, which have been approved by the FDA for the treatment of metastatic breast cancer in postmenopausal women in the United States. Toremifene is a SERM owned and manufactured by Orion. On January 1, 2005, we entered into a revised license and supply agreement with Orion to exclusively license toremifene for all indications in the United States and for all indications in humans except breast cancer outside of the United States. Toremifene is the active pharmaceutical ingredient in ACAPODENE®, our lead product candidate currently in two separate clinical programs for two indications, and FARESTON®.

We currently sell FARESTON® primarily through wholesale drug distributors. The top three distributors, McKesson Corporation, Cardinal Health, Inc. and AmerisourceBergen Corporation, accounted for approximately 93% of our gross product sales generated from the sale of FARESTON® for the year ended December 31, 2007. The loss of any of these three distributors could have a material adverse effect on continued FARESTON® sales. FARESTON® net product sales accounted for 15%, 18% and 65% of our total revenue for the years ended December 31, 2007, 2006 and 2005, respectively.

Product Candidates

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

Program	Product Candidate/ Indication	Development Phase	Status
		Clinical	
SERM	**ACAPODENE®** **80 mg** Multiple serious side effects of ADT	Pivotal Phase III clinical trial	Phase III clinical trial, which was conducted under a SPA, completed in February 2008 ; achieved primary endpoint of reduction of new morphometric vertebral fractures
	ACAPODENE® **20 mg** Prevention of prostate cancer in high risk men with high grade PIN	Pivotal Phase III clinical trial	Phase III clinical trial ongoing under a SPA; attained enrollment goal; planned efficacy interim analysis by the end of the first quarter 2008
SARM	**Ostarine™** Cancer cachexia	Phase II clinical trial	Phase II proof of concept clinical trial completed in December 2006; Phase II clinical trial to treat cancer cachexia ongoing
		Preclinical	
SARM	**GTx-838**	Preclinical	We and Merck, through our SARM collaboration, will determine the clinical development strategy of GTx-838
LH inhibitor	**GTx-758** Advanced Prostate Cancer	Preclinical	Phase I clinical testing planned by the end of 2008
Estrogen receptor beta agonist	**GTx-878** BPH	Preclinical	Phase I clinical testing planned in the first half of 2009

ACAPODENE® (toremifene citrate)

Our most advanced product candidate, ACAPODENE®, is a SERM. ACAPODENE® is being developed as a once-a-day oral tablet to (1) treat multiple serious side effects of ADT (80 mg dose) and (2) prevent prostate cancer in high risk men (20 mg dose). In January 2005, we exclusively licensed toremifene, the active ingredient in ACAPODENE®, for all indications in humans, except breast cancer outside of the United States. We licensed rights to toremifene based on our belief that a SERM can treat estrogen related complications resulting from ADT and reduce the incidence of prostate cancer in high risk men with high grade PIN and toremifene's established record of safety in the treatment of postmenopausal women with advanced breast cancer. Under a license and supply agreement with Orion, Orion manufactures and supplies us with FARESTON®, the 60 mg dose of toremifene citrate, for sale in the United States to treat advanced breast cancer, as well as ACAPODENE® 20 mg dose of toremifene

citrate for our Phase III clinical trial for the prevention of prostate cancer in high risk men with high grade PIN.

In September 2006, we licensed to Ipsen exclusive rights to develop and commercialize ACAPODENE® and other products containing toremifene in the European Territory in all indications that we have licensed from Orion.

ACAPODENE® 80 mg for the Treatment of Multiple Serious Side Effects of ADT

Scientific Overview. ADT is the most common treatment for patients who have advanced, recurrent or metastatic prostate cancer. ADT reduces testosterone, a primary growth factor for prostate cancer, to levels similar to that of castrated men. ADT is accomplished either surgically by removal of the testes, or chemically by treatment with LH releasing hormone agonists, or LHRH agonists. LHRH agonists work by shutting off LH secretion by the pituitary gland, which stops testosterone production by the testes. Examples of commercially marketed LHRH agonists are Lupron® (leuprolide acetate), Zoladex® (goserelin acetate),Viadur® (leuprolide acetate) and Eligard® (leuprolide acetate). The reduction in testosterone from ADT also results in very low estrogen levels in men, because estrogen is derived from testosterone in men.

Estrogen related side effects associated with ADT include bone loss, which may lead to osteoporosis and skeletal fractures, hot flashes, gynecomastia, adverse lipid changes that may lead to higher risk of cardiovascular diseases, depression, and memory loss. Bone loss leading to osteoporosis and possible skeletal fractures is a significant clinical problem because clinical studies have shown that prostate cancer patients who develop skeletal fractures have 39 month shorter survival rates. Hot flashes occur because of reduced estrogen levels in the brain. Hot flashes experienced by prostate cancer patients on ADT tend to be severe, frequent and protracted and is the side effect most frequently mentioned by prostate cancer patients on ADT.

Based on the results of our Phase III clinical trial, our two Phase II clinical trials and our preclinical testing of ACAPODENE® 80 mg, as well as preclinical and clinical information known about toremifene, ACAPODENE® has estrogenic activity both in bone, which treats osteoporosis, and in the brain, which may reduce hot flashes. Toremifene has been shown to improve lipid profiles in postmenopausal women and, based on data received from our Phase III clinical trial, ACAPODENE® improves lipid profiles in men undergoing androgen deprivation therapy for prostate cancer. ACAPODENE® also can block estrogen's action in the male breast, which may prevent and treat gynecomastia. As a consequence, we believe that ACAPODENE® 80 mg has the potential to treat serious estrogen related side effects of LHRH agonists: osteoporosis and fractures, hot flashes, adverse lipid changes and gynecomastia. Importantly, as evidenced by our two Phase II clinical trials and our Phase III clinical trial, ACAPODENE® has not been shown to stimulate prostate cancer growth or increase luteinizing hormone in men on ADT.

Potential Market. In the United States, we believe approximately 800,000 prostate cancer patients are currently being treated with ADT, and over 100,000 new patients are started on this therapy each year. An increasing number of prostate cancer patients are being treated by androgen deprivation with LHRH agonists earlier than in the past because of two main factors: first, medical studies have shown that early ADT prolongs the survival of prostate cancer patients, and second, the serum test for prostate specific antigen, or PSA, is detecting advanced prostate cancer earlier than in the past. The net effect of prostate cancer being treated sooner and for longer periods is that the multiple serious side effects of ADT have now been shown to contribute significantly to morbidity, and in some cases may lead to increased mortality. Physicians are currently prescribing certain drugs on an off-label basis to help ameliorate some of the specific serious side effects of ADT. These drugs include bisphosphonates for osteoporosis, Megace® (megestrol acetate) and antidepressants for hot flashes and tamoxifen for gynecomastia. Radiation is also used to treat gynecomastia. However, no single therapy is available to treat multiple serious side effects of ADT.

Clinical Trials. We have completed two Phase II clinical trials of ACAPODENE® for the treatment of osteoporosis and hot flashes in patients with advanced, recurrent or metastatic prostate cancer. The first Phase II trial was conducted at five clinical sites across the United States and treated 43 patients with advanced, recurrent or metastatic prostate cancer shortly after initiation of treatment with LHRH agonists. The second of these trials was conducted at three clinical sites across the United States and treated 46 patients with advanced, recurrent or metastatic prostate cancer who had been receiving LHRH agonists for more than 12 months. In each trial, participants were randomized to either a daily oral dose of ACAPODENE® or a placebo for six months. The

primary endpoint of both trials was BMD. The secondary endpoint of both trials was the incidence of hot flashes. We measured BMD and hot flash symptoms at entry into each of the clinical trials and at six months. We did not evaluate the effects of ACAPODENE® on gynecomastia in either of these trials.

In our first Phase II clinical trial, which evaluated 43 patients shortly after initiation of treatment with LHRH agonists, patients who received ACAPODENE® at the highest tested dose on average experienced an approximately 2% decrease in lumbar vertebral spine BMD at six months, while the patients who received the placebo on average experienced an approximately 4% decrease in lumbar vertebral spine BMD at six months. At the lower tested doses, ACAPODENE®, as compared to the placebo, did not have a meaningfully different effect on lumbar vertebral spine BMD. There was no significant difference between ACAPODENE® and the placebo in the incidence of hot flashes at any tested dose.

In our second Phase II clinical trial, which evaluated 46 patients who had been receiving LHRH agonists for more than 12 months, patients who received ACAPODENE® at the highest tested dose experienced a 3.5% average increase in lumbar vertebral spine BMD, an indicator of bone strength, while the patients who received the placebo experienced a 0.24% average increase in lumbar vertebral spine BMD. The difference in these measurements had a p-value of less than 0.05. A p-value of 0.05 or less generally represents a statistically significant difference in treatments. The BMD changes in the hip were not significant vs. placebo. Only 12.5% of the patients in this trial who received ACAPODENE® at the highest tested dose, compared to 50% of the patients who received the placebo, reported experiencing an increase in the frequency of hot flashes during the clinical trial. The magnitude of the BMD changes seen in patients treated with ACAPODENE® in this Phase II clinical trial were similar to those reported for each of raloxifene and bisphosphonates in postmenopausal women with osteoporosis and bisphosphonates being prescribed off-label to men with prostate cancer. However, bisphosphonates have not been shown to have any effect on hot flashes or gynecomastia. At the lower tested doses, ACAPODENE®, compared to the placebo, did not demonstrate a meaningful effect on lumbar vertebral spine BMD or frequency of hot flashes.

In November 2003, we initiated a pivotal Phase III clinical trial of orally administered ACAPODENE® 80 mg dose in patients undergoing ADT for advanced, recurrent or metastatic prostate cancer under a SPA, from the FDA. We designed this pivotal Phase III clinical trial principally based on the results of our second Phase II clinical trial that evaluated patients who had been receiving LHRH agonists for more than 12 months. The primary endpoint of the trial was new morphometric vertebral fractures measured by x-ray, and the secondary endpoints of the trial included BMD, hot flashes, lipid profile changes and gynecomastia. We reached our enrollment goal in the fall of 2005 and randomized approximately 1,400 patients into the trial with advanced, recurrent or metastatic prostate cancer who had been receiving ADT for at least six months and who had significant existing bone loss, or were greater than 70 years of age. The patients were randomized to receive either a placebo or a daily 80 mg dose of ACAPODENE® for 24 months. We conducted the trial in approximately 150 sites in the United States and Mexico. In December 2005 and in accordance with the SPA, we completed a planned interim BMD analysis among the first 197 patients who completed one year of treatment. Patients treated with ACAPODENE® 80 mg demonstrated statistically significant increases in BMD compared to placebo in all three skeletal sites measured, with lumbar spine showing an improvement of 2.3 percentage points ($p<0.001$), hip, a 2.0 percentage point improvement ($p=0.001$), and femoral neck, a 1.5 percentage point improvement ($p=0.009$). For perspective, a study of raloxifene, a SERM, in postmenopausal osteoporosis in women showed a lumbar spine BMD increase of 2.0 percentage points after one year which resulted in a 55% fracture reduction in three years. In June 2006, we conducted a lipid interim analysis of the same 197 patients. Patients treated with ACAPODENE® 80 mg 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.

A Data Safety Monitoring Board, or DSMB, meets every six months to review unblinded data from the ACAPODENE® 80 mg ADT and ACAPODENE® 20 mg PIN clinical trials. In January 2007 and July 2007, the DSMB reviewed safety data from approximately 2,900 and 3,000 patients, respectively, and recommended to continue both trials.

The last patient completed the ADT clinical trial in November 2007. In February 2008, we announced that the Phase III clinical trial results for ACAPODENE® 80 mg for the treatment of multiple serious side effects of ADT showed that ACAPODENE® 80 mg reduced new morphometric vertebral fractures and met other key endpoints of BMD, lipid profiles and gynecomastia. In the modified intent to treat analysis which included all patients with at

least one evaluable study radiograph and a minimum of one dose of study drug or placebo, ACAPODENE® 80 mg demonstrated a 50% reduction in new morphometric vertebral fractures ($p<0.05$; 5% fracture rate in the placebo group). The estimated two year fracture rate for new morphometric vertebral fractures in the placebo group was 6.2%. In an intent to treat analysis which included all patients randomized into the trial, ACAPODENE® 80 mg demonstrated a 53% reduction in new morphometric vertebral fractures ($p=0.034$; 3.6% fracture rate in the placebo group). In prespecified subset analyses, in study patients who were greater than 80% treatment compliant, ACAPODENE® 80 mg reduced new morphometric vertebral fractures by 61% ($p=0.017$). When study patients who had greater than 7% bone loss at one year and new morphometric vertebral fractures were considered as treatment failures, ACAPODENE® 80 mg compared to placebo demonstrated a 56% reduction ($p=0.003$).

Patients treated with ACAPODENE® 80 mg compared to placebo demonstrated statistically significant increases in BMD in the lumbar spine, hip, and femur skeletal sites (each site demonstrating $p<0.0001$). ACAPODENE® 80 mg treatment compared to placebo also resulted in a decrease in total cholesterol ($p=0.011$), LDL ($p=0.018$), and triglycerides ($p<0.0001$), and an increase in HDL ($p=0.001$). There were also statistically significant improvements in gynecomastia ($p=0.003$). In March 2008, we announced that in an analysis of hot flashes in a subset of patients in the Phase III ADT clinical trial experiencing six or more hot flashes per day at baseline and not being treated with megestrol acetate (Megace(R)), ACAPODENE® 80 mg treatment reduced the number of hot flashes by an average of 4.7 hot flashes per day compared to placebo patients who had a reduction of 1.6 hot flashes per day ($p=0.03$). The reduction of hot flashes in patients treated with ACAPODENE® 80 mg was durable for at least 12 months.

ACAPODENE® 80 mg had a favorable safety profile and was well tolerated. Among the most common adverse events that occurred in over 2% of study subjects were joint pain (treated 7.3%, placebo 11.8%), dizziness (treated 6.3%, placebo 5.0%), back pain (treated 5.9%, placebo 5.2%), and extremity pain (treated 5.0%, placebo 4.4%). Venous thromboembolic events, or VTEs, which included both deep venous thrombosis and pulmonary embolism, were 17 (2.4 %) in the ACAPODENE® 80 mg treated group and 7 (1.02 %) in the placebo group. The risk for VTE's was similar between the ACAPODENE® 80 mg treated group and the placebo group in the second year of treatment. The majority of VTEs occurred in men at high risk for a VTE including: age >80 years or history of VTE. In men without major risk factors for VTE, there were 3 (1.3%) VTE in the ACAPODENE® 80 mg treated group and 2 (1.0%) VTE in the placebo group.

NDA Filing. We expect to file a NDA for ACAPODENE® 80 mg for the treatment of multiple serious side effects of ADT with the FDA in 2008.

ACAPODENE® 20 mg for the Prevention of Prostate Cancer in High Risk Men with High Grade PIN

Scientific Overview. Patients who have an abnormal serum PSA test, a prostate cancer blood test that is commonly administered to men as part of physical examinations, or an abnormal digital rectal examination routinely undergo a prostate biopsy to determine whether they have prostate cancer. Precancerous prostate lesions known as high grade PIN, rather than prostate cancer, are detected in approximately 15% of the patients who undergo prostate biopsies. Over the last 17 years, scientific evidence has established that men who have high grade PIN are at high risk for developing prostate cancer. More than 40% of these men will progress to prostate cancer within three years. We believe that this strong correlation between high grade PIN and prostate cancer makes these men an appropriate population to treat to prevent prostate cancer. Currently, there is no approved treatment to prevent prostate cancer in men who are diagnosed with high grade PIN.

Testosterone and estrogens together are important for the initiation of prostate cancer. Estrogens may promote the development of prostate cancer by stimulating high grade PIN and causing it to progress into prostate cancer. Estrogen receptors are found in the normal prostate and in high grade PIN lesions. In animal models of prostate cancer, blocking estrogens' action has been shown to reduce the incidence of prostate cancer. Because ACAPODENE® blocks estrogen receptors, we believe that it has the potential to reduce the incidence of prostate cancer in high risk men with high grade PIN.

Potential Market. In the United States, prostate cancer is one of the most commonly diagnosed cancers and the second leading cause of cancer-related deaths in men. There are approximately 186,000 new cases of prostate cancer diagnosed each year and 27,000 prostate cancer deaths annually in the United States. In addition, there are over 115,000 new cases of high grade PIN diagnosed each year, with an estimated 14 million men under the age of

80 who unknowingly harbor high grade PIN.

Patients who are diagnosed with high grade PIN may undergo repeat biopsies following the diagnosis in order to detect the progression of high grade PIN into prostate cancer. Prostate biopsies are performed through an ultrasound probe placed in the rectum. Hollow needles are then inserted through the probe through the rectum into the prostate to obtain sample cores of tissue. Complications from this procedure include bleeding, pain, prostate infection and, in rare instances, life-threatening blood infection (sepsis). Because the prostate biopsy technique randomly samples the prostate gland with a relatively thin needle, both prostate cancer and high grade PIN may be missed by the biopsy. Patients with high grade PIN are exposed to the potential complications and the discomfort of invasive, repeat prostate biopsies and are subject to the mental anguish of fearing that a diagnosis of prostate cancer may be imminent.

We have entered into separate collaboration agreements with diagnostic companies, including Hybritech, Inc., a wholly owned subsidiary of Beckman Coulter, Inc., diaDexus, Inc., MacroArray Technologies, LLC, Onconome, Inc. (formerly known as Tessera, Inc.), and Gen-Probe, Inc., to provide clinical samples to these companies from our Phase IIb clinical trial and our ongoing Phase III clinical trial of ACAPODENE® 20 mg for the prevention of prostate cancer in high risk men with high grade PIN. Information resulting from these collaborations will be used to evaluate whether a commercial test using blood or urine may be effectively developed to detect high grade PIN and/or prostate cancer. By continuing to collaborate with leading diagnostic labs, we hope to have a urine or blood test developed to detect high grade PIN in the millions of American men who may unknowingly harbor high grade PIN and/or prostate cancer.

Clinical Trials. In 2004, we completed a randomized, double blind, placebo controlled, dose finding Phase IIb clinical trial of ACAPODENE® in men diagnosed with high grade PIN to determine the efficacy and safety of a daily dose of ACAPODENE® for 12 months. The trial enrolled 514 men and was conducted at 64 clinical sites across the United States. The primary efficacy endpoint of this trial was incidence of prostate cancer at 12 months. Participants were randomized to receive a 20 mg, 40 mg or 60 mg dose of ACAPODENE® or placebo. A screening prostate biopsy was performed on each trial participant before enrollment into the trial, and eligibility was limited to participants who were diagnosed with high grade PIN and had no evidence of prostate cancer. A second biopsy was performed six months after enrollment in an effort to identify trial participants who had prostate cancer that was not detected by the initial biopsy. The intent to treat population consisted of all patients initially enrolled in the trial who returned for their six-month biopsy. We also analyzed trial results in a predefined subgroup of patients that excluded patients showing biopsy evidence of prostate cancer at six months and patients who did not complete the full course of therapy in the trial (completer's analysis).

We analyzed the results of this Phase IIb clinical trial on a stratified basis, in which we assessed the effect of individual clinical sites on the overall statistical analysis of the trial results, and on an unstratified basis, in which we did not assess such effect. In the stratified analysis of the per protocol population, which is the intent to treat population less two patients in the group that received 20 mg of ACAPODENE® who were deemed to be not compliant with the protocol, the cumulative, or overall, risk of prostate cancer was 24.4% in the group that received 20 mg of ACAPODENE® compared with 31.2% in the group that received placebo. The p-value for this result was less than 0.05. Thus, the cumulative risk of prostate cancer based on a stratified analysis of the per protocol population was 22.0% lower in the 20 mg treatment group, which would imply an annualized rate of prevention of cancers of 6.8 per 100 men treated. The p-value in the unstratified analysis of the per protocol population for the comparison between the group that received 20 mg of ACAPODENE® and the group that received placebo was 0.132. In the stratified analysis of the intent to treat population, the cumulative risk of prostate cancer was 24.9% in the group that received 20 mg of ACAPODENE® compared with 31.2% in the group that received placebo. The p-value for this result was 0.081, which was statistically significant under the protocol for this trial. Statistical significance under the protocol was defined as a p-value of 0.10 or less. The p-value in the unstratified analysis of the intent to treat population for the comparison between the group that received 20 mg of ACAPODENE® and the group that received placebo was 0.148.

In a stratified analysis of the subgroup of patients who had no biopsy evidence of prostate cancer at their initial screening biopsy or their six-month biopsy and completed the full course of therapy in the trial, the cumulative risk of prostate cancer was 9.1% in the group that received 20 mg of ACAPODENE® compared with 17.4% in the group that received placebo, a 48.2% reduction. The p-value for this result was less than 0.05. For the 40 mg and 60 mg

treatment arms, in the intent to treat population, the per protocol population and the predefined patient subgroup, the cumulative risk of cancer was lower than the placebo group, although these results were not statistically significant.

The overall rates of drug-related adverse events and serious adverse events did not differ to a significant degree between any of the ACAPODENE® dose groups and placebo. The results of our pivotal Phase III clinical trial of ACAPODENE® 20 mg for this indication may not be the same as the results of this Phase IIb clinical trial.

In January 2005, we initiated a randomized, double blind, placebo controlled pivotal Phase III clinical trial of orally administered ACAPODENE® 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, which is being conducted under a SPA with the FDA. Approximately 130 clinical sites across the United States and Canada are participating in this trial. We have randomized a total of 1,590 patients into the trial, 330 patients above our enrollment goal of 1,260 patients. These additional patients are also participating in bone and ocular studies requested by the FDA under the SPA. We will evaluate efficacy endpoints for the clinical trial at 36 months after completion of enrollment, and we anticipate conducting a planned efficacy interim analysis after a certain number of cancer events have been recorded among study patients, which we currently expect to occur by the end of the first quarter of 2008. If the efficacy results from the planned interim analysis achieve the statistical outcome specified in the SPA (a £ 0.001), we plan to file a NDA with the FDA. If we are able to file a NDA based on the results of the efficacy interim analysis, we will continue to collect efficacy data and safety data during the review process to satisfy the FDA's safety requirements set forth in the SPA. If the efficacy results from the planned interim analysis do not satisfy the specified statistical requirements in the SPA, we plan to continue the clinical trial.

In January 2008, the DSMB reviewed safety data from approximately 1,500 patients participating in the trial and recommended to continue the Phase III clinical trial for the prevention of prostate cancer in high risk men with high grade PIN, which we believe suggests that there are no clinically significant trends of serious side effects related to ACAPODENE®.

OSTARINE™

In our third clinical program, Ostarine™, a SARM, is being developed for the treatment of a variety of medical conditions relating to muscle wasting and/or bone loss. Testosterone and other anabolic steroids have been proven to beneficially treat involuntary muscle wasting in acute and chronic diseases caused by aging, burns and trauma, cancer, chronic kidney disease/end-stage renal disease, chronic obstructive pulmonary disease and other similar diseases. Testosterone and other anabolic steroids, however, may cause unwanted side effects, including stimulating prostate cancer growth in men and masculinization in women. Ostarine™ is an oral nonsteroidal agent designed to have anabolic activity on muscle and bone without unwanted side effects on prostate and skin.

In November 2007, we and Merck entered into a global strategic SARM collaboration. Under this collaboration we and Merck will work together to discover, develop and commercialize current, as well as future SARM compounds.

Ostarine™ for the Treatment of Cancer Cachexia

Scientific Overview. Cancer cachexia is defined as the unintentional loss of lean body mass or muscle. Cancer causes the body to go into a starvation-like state that results in the preferential loss of muscle. Loss of muscle may lead to weakness, fatigue, diminished response and greater toxicity to chemotherapy, and in some cases, death. Approximately one-third of newly-diagnosed cancer patients have cancer cachexia which accounts for approximately 20% of cancer deaths. Weight loss is one of the most important indicators of how long a cancer patient will live since the survival of a patient with cancer is greatly impacted by the degree and rate of muscle wasting. A greater lean body weight may increase strength, activity levels, quality of life, response to chemotherapy and, ultimately, survival.

Testosterone increases lean body weight in both men and women. One of the causes of cancer cachexia may be reduced levels of testosterone. Testosterone therapy, however, is not used for the treatment of cancer cachexia for two reasons. First, the available delivery methods for testosterone may not be convenient for patients, and testosterone can have a number of undesirable side effects in men, such as the potential stimulation of latent prostate

cancer, aggravation of existing BPH and gynecomastia, and in women, masculinizing effects such as acne and facial hair.

We believe that Ostarine™ is similar to testosterone in activating androgen receptors in muscle, thereby promoting lean body weight, but does not stimulate sebaceous glands, the cause of hair growth and acne, or the prostate, which may exacerbate BPH or stimulate prostate cancer. In addition, Ostarine™ is being developed in an oral dosage form, which patients may find is more convenient to take.

Potential Market. There are approximately 1.3 million patients diagnosed with cancer each year in the United States. It has been estimated that cancer cachexia afflicts approximately 410,000 patients. Over 30 clinical trials of supplemental nutritional support alone have reported little or no benefit in counteracting cachexia in cancer patients receiving chemotherapy or radiation. There are no drugs that have been approved by the FDA for the treatment of cancer cachexia. Although there are two commercially available anabolic steroids being prescribed off-label for the treatment of cancer cachexia, chronic use of these drugs may result in liver toxicity. Also, Megace®, an appetite stimulant which has been used off-label for cancer patients, has not been shown to increase lean body mass in spite of increasing appetite.

Clinical Trials. We have clinical data from two Phase I clinical trials and one Phase II clinical trial of Ostarine™. In our first Phase I clinical trial, a double blind, placebo controlled, single ascending dose study in 96 healthy male volunteers, Ostarine™ was well tolerated and there were no drug-related serious adverse events. This clinical trial demonstrated that the half life of Ostarine™ was approximately 24 hours.

The second Phase I clinical trial was a double blind multiple ascending dose 14 day study to evaluate the safety, tolerability, pharmacokinetics, and specific pharmacodynamic characteristics of Ostarine™ in 48 healthy male volunteers between 18 and 45 years of age and 23 elderly males with an average age of 68 years. Measurements included routine blood chemistry and hematology, sex hormones and gonadotropins, serum prostate specific antigen, metabolic markers of bone and muscle, cutaneous sebum analysis and DEXA scanning for body composition. Overall, clinical laboratory values and hormonal effects for the 71volunteers were consistent with anabolic activity. Comparisons of DEXA assessments from the beginning of the study to DEXA assessments after 14 days showed positive changes in body composition at clinically relevant doses; increases in lean body mass and decreases in fat mass were observed. Ostarine™ did not appear to have unwanted side effects on the prostate (serum PSA) or the skin (sebum analysis). Ostarine™ was well tolerated with no drug-related serious adverse events. However, Phase I clinical trials are not designed to show efficacy, and the results of future clinical trials may not be the same as these early observations.

In May 2006, we initiated a Phase II proof of concept, double blind, randomized, dose finding placebo controlled clinical trial in 60 elderly men and 60 postmenopausal women. The trial was designed to evaluate Ostarine™ treatment in building muscle, as well as to assess safety in both elderly men and postmenopausal women. Enrollment was completed in July 2006, and in December 2006, we reported the top line results. Without a prescribed diet or exercise regimen, all subjects treated with Ostarine™ had dose dependent increases in the primary endpoint total lean body mass. Treatment with Ostarine™ also resulted in a dose dependent improvement in functional performance, a secondary endpoint, measured by a stair climb test. Ostarine™ had a favorable safety profile, with no serious adverse events reported. Ostarine™ also exhibited tissue selectivity with beneficial effects on lean body mass and performance and with no apparent change in measurements of serum PSA, sebum production, or serum LH. We initiated a Phase II randomized, double blind, placebo controlled clinical trial evaluating Ostarine™ for the treatment of cancer cachexia in 150 patients diagnosed with non-small cell lung cancer, colorectal cancer, non-Hodgkin's lymphoma, or chronic lymphocytic leukemia. The clinical trial is being conducted at approximately 50 clinical sites in the United States, Argentina and Canada and we expect to receive data from this trial during the summer of 2008.

Ostarine™ for the Treatment of Frailty or Sarcopenia

Scientific Overview. Every year after age 30, people lose on average a half pound of muscle and gain a pound of fat. A typical man may lose 35% of muscle between the ages of 30 and 90 years of age. A contributing factor to muscle loss in men is that testosterone levels decrease by 1% every year after the age of 30 years. Muscle plays several important roles: muscle provides strength and endurance, supports the skeletal system, plays an important

role in metabolism, and helps protect the body by providing protein for the immune system. During an illness or trauma to the body, the energy demands of the body increase, and the body breaks down muscle to get protein to fuel the body's needs, to repair damaged organs, and to replenish immune system cells. As people lose muscle, they become fatigued more easily, making it more difficult for them to rehabilitate and recover. Loss of muscle can cause frailty, loss of independence and can worsen other conditions of aging such as osteoarthritis and osteoporosis. People who are fatigued may become more sedentary, which can lead to a reduction in their quality of life. Loss of muscle and bone with age is sometimes referred to as frailty whereas loss of bone only is referred to as osteoporosis. A 2001 study among more than 5,000 elderly adults found that over a three-year period the death rate among the frail elderly was 18%, versus a 3% mortality rate in the non-frail elderly. The frail were also far more likely to experience falls, hospitalizations and loss of independence.

We believe that Ostarine™ can build muscle and bone by improving: (1) the body's efficiency at metabolizing protein from food, (2) the body's ability to recycle protein, (3) the body's ability to burn fat and build muscle and (4) the body's ability to maintain and promote bone. We believe that Ostarine™ can increase muscle size and strength, resulting in improved function, quality of life and speed of recovery, and can prevent osteoporosis and fractures. Ostarine™ has been designed to have anabolic properties in muscle and bone without unwanted side effects, such as the stimulation of prostate cancer in men and masculization in women. In preclinical studies of intact animals, Ostarine™ has been shown to build muscle and bone while shrinking the prostate.

Potential Market. There are approximately 17 million people over the age of 65 in the United States who have age related loss of muscle mass. In the United States in 2003, there were approximately 13.2 million hospital discharges among the 35 million people over the age of 65 years. It has been shown that from the time of the onset of their illness, approximately 50% of the elderly declined in health after their hospital stay. Muscle wasting is a contributing factor in their inability to completely recover. Current anabolic agents available in the market may be experiencing limited acceptance by patients due to concerns about their potential undesirable side effects, and inconvenient dosing. Testosterone is not available as an oral tablet in the United States and topical gels and patches are the most utilized forms of delivery for testosterone currently.

GTx-838

GTx-838 is another of our SARMs that is currently in preclinical development for the treatment of a variety of medical conditions relating to muscle wasting and/or bone loss. We and Merck, through our SARM collaboration, will determine the clinical development strategy of GTx-838 and other collaboration SARMs.

GTx-758 for the Treatment of Advanced Prostate Cancer

GTx-758 is an oral LH inhibitor that is currently in preclinical development for the treatment of advanced prostate cancer. In preclinical models, GTx-758 induced androgen deprivation and we believe GTx-758 can minimize certain unwanted side effects. We are planning to initiate Phase I clinical testing for GTx-758 by the end of 2008.

GTx-878 for the Treatment of BPH

GTx-878 is an estrogen receptor beta agonist that is currently in preclinical development for the treatment of BPH. In preclinical models, GTx-878 has demonstrated three activities that may be beneficial to treat BPH. We believe that GTx-878 has the potential to inhibit prostate growth, relax prostate smooth muscle tone, and reduce inflammation. We are planning to initiate Phase I clinical trials for GTx-878 in the first half of 2009.

Drug Discovery and Other Research and Development

Steroid hormone therapies, which include estrogen and testosterone therapies, have been used to treat humans for many years. Steroid hormones by their nature have unselective effects in various tissues. As a result, they have unintended side effects, which limit their clinical value.

SERM-based drugs, such as toremifene, tamoxifen and raloxifene, have achieved commercial success in

treating women as nonsteroidal small molecules that modulate hormone estrogen receptors in a tissue selective way and minimize some of the side effects of the natural estrogen hormone to treat breast cancer (toremifene and tamoxifen) or to treat postmenopausal osteoporosis (raloxifene). We believe that the previous commercial and scientific success of SERMs indicates that it is possible to design and develop classes of nonsteroidal small molecule drugs to modulate hormone receptors in addition to estrogen receptors.

We believe that our drug discovery expertise will allow us to sustain our clinical pipeline through the design and development of nonsteroidal small molecule drugs that selectively modulate hormone receptors. Our in-house medicinal chemists and scientists provide us with significant discovery and development expertise. Using our capabilities in hormone receptor biology and medicinal chemistry, we are able to target many hormone receptors and generate compounds that are designed to address the shortcomings of natural hormone therapies.

We design and synthesize new compounds based on computer, or *in silico*, models and crystal structures of a hormone receptor's binding sites. We continually modify and improve these models to reflect our study of the activity of new compounds in the laboratory, in which we determine the link between chemical structures and biological activity, or structure-activity relationships.

We also have significant medicinal scale-up and high throughput capabilities, which facilitate our rapid synthesis and evaluation of new compounds. Throughout our discovery process, we build diversity into our chemistry structures in order to improve our likelihood of success in developing novel compounds that have the potential to treat multiple indications. Through this approach, we have generated clinical product candidates for the androgen receptor such as Ostarine™, a nuclear hormone receptor modulator. We also have conducted research and development efforts focused on other SERM and SARM compounds, other hormone receptor modulator compounds and anticancer agents.

Our Strategy

Our objective is to discover, develop and commercialize small molecules that selectively target hormone pathways to treat cancer, osteoporosis and bone loss, muscle wasting and other serious medical conditions. Key elements of our strategy to achieve this objective are to:

Obtain Regulatory Approval of ACAPODENE®. We have completed our Phase III clinical trial of ACAPODENE® to treat multiple side effects of ADT, which was conducted under a SPA, and expect to file a NDA with the FDA in 2008. In addition, we are conducting our Phase III clinical trial of ACAPODENE® for the prevention of prostate cancer in high risk men with high grade PIN under a SPA from the FDA. We are focused on obtaining regulatory approval and preparing for the potential commercial launch of ACAPODENE® for these two distinct indications in men's health.

To Commercialize ACAPODENE® in the United States and Establish Sales and Marketing Infrastructure. We have commercial rights to ACAPODENE® in the United States. We believe that we can effectively market ACAPODENE® to the target physician audience of urologists and medical oncologists in the United States through a specialty sales force that we plan to build.

Partner Commercial Rights to ACAPODENE® in Europe, Asia and the Rest of the World. In September 2006, we licensed to Ipsen exclusive rights in the European Territory to develop and commercialize ACAPODENE® and other products containing toremifene for all indications which we have licensed from Orion. We are currently pursuing a similar partnership for ACAPODENE® in Asia and other markets outside of the United States and Europe. We and Ipsen also intend to apply for market exclusivity and regulatory extensions of patent life under applicable European and U.S. laws, as appropriate, to protect our exclusive rights in ACAPODENE® for the indications that we are currently testing in clinical trials.

Develop Diagnostic Tests for High Grade PIN. We are currently collaborating with several diagnostics companies, including Hybritech, Inc., a wholly owned subsidiary of Beckman Coulter, Inc., diaDexus, Inc., MacroArray Technologies, LLC, Onconome, Inc. (formerly known as Tessera, Inc.), and Gen-Probe, Incorporated to develop an accurate blood or urine test to detect high grade PIN. We will continue to seek additional

collaborations with other companies with promising high grade PIN diagnostics. We believe that men would be more willing to be tested for high grade PIN if the diagnostic test were less invasive than a prostate biopsy. In February 2007, MacroArray Technologies reported in *Clinical Cancer Research* the development of a urine test to non-invasively detect high grade PIN. Given the large number of patients with undiagnosed high grade PIN, we believe that the development of a blood or urine test would increase the detection of high grade PIN and thereby expand the already large potential market for ACAPODENE® 20 mg.

Maintain Commercial Sales of FARESTON®. We intend to continue to market FARESTON® in the United States.

Pursue Clinical Development of SARMs with Merck. In December 2007, we and Merck formed a global strategic collaboration for the discovery, development and commercialization of SARMs. We and Merck have pooled our programs and compounds and intend to work together to discover, develop and commercialize current, as well as future SARMs.

Build Upon Our Other Drug Discovery Capabilities to Sustain Our Small Molecule Product Candidate Pipeline to Selectively Target Hormone Pathways. While our clinical development efforts to date have focused on SERM and SARM technologies, we have the capability to discover and develop additional drug candidates that target other hormone receptors. We intend to develop new molecules to treat diseases that affect large numbers of patients and are underserved by available alternatives. We have selected two new molecules, GTx-758 and GTx-878, for human clinical testing. We anticipate initiating Phase I clinical testing for GTx-758, an oral LH inhibitor for advanced prostate cancer, by the end of 2008. We anticipate initiating Phase I clinical testing for GTx-878, an estrogen receptor beta agonist for BPH, in the first half of 2009.

Licenses and Collaborative Relationships

In addition to our internally-developed and discovered small molecules, we have established and intend to continue to pursue licenses from and collaborative relationships with pharmaceutical companies and academic institutions to further the development and commercialization of our small molecule product candidates.

Merck & Co., Inc.

On November 5, 2007, we and Merck entered into an exclusive license and collaboration agreement governing our and Merck's joint research, development and commercialization of SARM compounds and related SARM products, including SARMs currently being developed by us and Merck and those yet to be discovered, for all potential indications of interest. Our agreement with Merck became effective in December 2007.

Under the agreement, we granted to Merck an exclusive worldwide license under our SARM-related patents and know-how. We will conduct preclinical research of SARM compounds and products, and Merck will be primarily responsible for conducting and funding development and commercialization of products developed under the agreement. We received an upfront licensing fee of $40.0 million in January 2008, and Merck has agreed to pay us $15.0 million in guaranteed cost reimbursements for research and development activities in equal annual installments over a three year period beginning on the first anniversary of the effective date of the agreement, subject to the collaboration not being terminated for cause and not occurring certain change of control events involving us during this three-year period. We are also eligible to receive under up to $422.0 million in future milestone payments associated with the development and regulatory approval of a lead product candidate, including Ostarine™, as defined in the agreement, if multiple indications are developed and receive required regulatory approvals, as well as additional milestone payments for the development and regulatory approval of other product candidates developed under the agreement. Merck has also agreed to pay us tiered royalties on net sales of products that may be developed under the agreement. We are responsible for any payments owed to the University of Tennessee Research Foundation, or UTRF, resulting from the collaboration with Merck. On the date the agreement became effective in December 2007, we issued Merck 1,285,347 newly-issued shares of our common stock for an aggregate purchase price of approximately $30.0 million.

Unless terminated earlier, the collaboration agreement with Merck will remain in effect in each country of sale

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

Ipsen Group

In September 2006, we entered into a collaboration and license agreement with Ipsen pursuant to which we granted Ipsen exclusive rights in the European Territory to develop and commercialize ACAPODENE® and other products containing toremifene in all indications that we have licensed from Orion, which include indications for all diseases or indications in humans except the treatment and prevention of breast cancer. 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 upon 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 €23.0 million as a license fee and expense reimbursement, of which €1.5 million is to be paid in equal installments over a three year period from the date of the agreement. In October 2006, we received €21.5 million (approximately $27.1 million) from Ipsen as initial payment for the license fee and expense reimbursement. In September 2007, we received €500,000 (approximately $688,000) from Ipsen as the first annual installment payment. Pursuant to the agreement, we are also entitled to receive from Ipsen up to an aggregate of €39.0 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 are responsible for paying upstream royalties on ACAPODENE® to both Orion and UTRF for the PIN indication and to Orion only for the ADT indication. Ipsen will purchase the bulk drug product supply directly from Orion and is responsible for the packaging and labeling of the final product.

Orion Corporation

In March 2000, we entered into a license and supply agreement with Orion to develop and commercialize products containing toremifene, the active pharmaceutical ingredient in FARESTON® and ACAPODENE®. Our rights under the original license agreement were limited to specific disease fields pertaining to prostate cancer. In December 2004, we entered into an agreement with Orion to purchase specified FARESTON® related assets which Orion had re-acquired from another licensee. We also entered into an amended and restated license and supply agreement with Orion which replaces the original license agreement. We paid Orion approximately $5.2 million under the 2004 agreements for the assets and related license rights.

Under the amended and restated license and supply agreement, we obtained an exclusive license from Orion to develop and commercialize toremifene-based products, including FARESTON® and ACAPODENE®, for all human indications worldwide, except breast cancer outside of the United States. We are required to pay Orion a royalty on sales by us and our affiliates of FARESTON® for breast cancer in the United States. We are also required to pay Orion a royalty on sales by us, our affiliates and third-party sublicensees of other toremifene-based products, including ACAPODENE® if approved for commercial sale. Our license and supply agreement with Orion requires that Orion will manufacture and supply all of our and our sublicensees' needs for clinical trial and commercial grade material for toremifene-based products developed and marketed in the United States and abroad, including ACAPODENE® globally and FARESTON® in the United States. Orion may terminate its supply obligations under specified circumstances. However, we have specified rights to assume manufacture of toremifene if Orion terminates its supply of toremifene because it has ceased to manufacture toremifene, although we would have to engage another supplier to do so. The term of the amended and restated license and supply agreement lasts, on a country-by-country basis, until the later of expiration of our own patents claiming the method of use or manufacture of toremifene for prostate cancer or the end of all marketing or regulatory exclusivity which we may obtain for toremifene-based products. Orion may terminate the agreement as a result of our uncured material breach or bankruptcy.

University of Tennessee Research Foundation

In July 2007, we and UTRF entered into a consolidated, amended and restated license agreement to consolidate and replace our two previously existing SARM license agreements with UTRF and to modify and expand certain rights and obligations of each of the parties under both license agreements. Pursuant to this agreement, we were granted exclusive worldwide rights in all existing SARM technologies owned or controlled by UTRF, including all improvements thereto, and exclusive rights to future SARM technology that may be developed by certain scientists at the University of Tennessee or subsequently licensed to UTRF under certain existing inter-institutional agreements with The Ohio State University. Unless terminated earlier, the term of this agreement will continue for the longer of 20 years or until the expiration of the last valid claim of any licensed patent in the particular country in which a licensed product is being sold. UTRF may terminate the agreement for our uncured breach or upon our bankruptcy.

In September 2007, we and UTRF entered into an Amended and Restated License Agreement to replace our previously existing exclusive worldwide license agreement for ACAPODENE®. Pursuant to this agreement, we were granted exclusive worldwide rights to UTRF's method of use patents relating to SERMs, including ACAPODENE® for chemoprevention of prostate cancer as well as future related SERM technologies that may be developed by certain scientists at the University of Tennessee. Unless terminated earlier, the term of this agreement will continue in a particular country for the longer of 20 years from the effective date of our previously existing exclusive worldwide license agreement with UTRF for ACAPODENE® or until the expiration of the last valid claim of any licensed patent in such country. UTRF may terminate the agreement for our uncured breach or upon our bankruptcy.

Under the agreements with UTRF, we agreed to pay to UTRF a one-time, upfront fee of $290,000 per agreement as consideration for entering into the agreements. We are also obligated to pay UTRF annual license maintenance fees and royalties on sublicense revenues and net sales of products. We also agreed to pay all expenses to file, prosecute and maintain the patents relating to the licensed SARM and SERM technologies, and are obligated to use commercially reasonable efforts to develop and commercialize products based on the licensed SARM and SERM technologies.

Ortho Biotech

In March 2004, we entered into a joint collaboration and license agreement with Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, for andarine, one of our proprietary SARM compounds, and specified backup SARM compounds. Under the terms of the agreement, we received in April 2004 an upfront licensing fee and expense reimbursement totaling $6.7 million. The upfront licensing fee and expense reimbursement were deferred and amortized into revenue on a straight-line basis over the estimated five year andarine development period. In December 2006, we reacquired full rights to develop and commercialize andarine and all backup compounds

previously licensed to Ortho Biotech, and the joint collaboration and license agreement was terminated by mutual agreement of the parties. In connection with the termination of the Ortho Biotech agreement, we recognized the associated $3.1 million balance of deferred revenue as additional collaboration revenue.

Manufacturing

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of FARESTON®, ACAPODENE® or any of our SARMs. We currently rely and expect to continue to rely on third parties for the manufacture of our product candidates or products that we may develop.

We have agreed to purchase from Orion our worldwide requirements for toremifene citrate, the active pharmaceutical ingredient in ACAPODENE® and FARESTON® under an exclusive license and supply agreement providing for Orion to supply our requirements for clinical and commercial product. Orion has agreed to supply us with, and we have agreed to purchase from Orion, our worldwide requirements of toremifene citrate in specified doses in finished tablet form at specified transfer prices. Similarly, Ipsen has agreed to purchase from Orion, ACAPODENE® tablets for clinical testing and commercial sale in the European Territory under an amended supply agreement with Orion. As such, both we and Ipsen rely on Orion as the single source supplier of ACAPODENE®. Orion's manufacturing facility also produces commercial quantities of toremifene tablets for FARESTON® and complies with the FDA's current Good Manufacturing Practice regulations. The raw materials necessary to manufacture toremifene citrate tablets are readily available, but Orion is our only supplier of toremifene tablets. Our license and supply agreement with Orion does not provide us with the current right to manufacture toremifene. In addition, under the terms of our agreement with Orion, we have agreed to purchase our requirements for toremifene tables from Orion during the term of the agreement, which extends for the life of our patent rights, beyond the term of Orion's patents with respect to the composition of matter of toremifene.

Orion may terminate its obligation to supply us and Ipsen with toremifene if Orion permanently ceases the manufacture of toremifene subject to giving us and Ipsen proper notice or Orion may terminate its obligation to supply us with toremifene if marketing approval for ACAPODENE® for use in any of the licensed fields, except breast cancer, is not granted in the United States prior to December 31, 2009. There are a number of circumstances in which Orion is required to grant manufacturing rights to us and Ipsen, including following termination of its supply obligation as set forth above, failure by Orion to supply product to us for 90 days or to supply product in dosages or formulations other than the dosages and formulations specified in the agreement or termination of the agreement by us following a breach by Orion. Also, under certain circumstances, if additional manufacturing capacity is needed to supply our increasing need for product, we have the right at certain sales levels to require Orion to qualify an additional manufacturing site at our expense. Under these circumstances, we and Ipsen would need to make arrangements for an alternative supply which would still have to be made with a qualified alternative supplier with the appropriate FDA approval in order for us to obtain our supply requirements for ACAPODENE®. However, in the event that Orion terminates the license agreement as a result of our bankruptcy or a material breach of the agreement by us that is not cured, we would not have the right to manufacture toremifene for ACAPODENE® until Orion's patents with respect to the composition of matter of toremifene expire in the United States. 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. 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.

There are no complicated chemistries or unusual equipment required in the manufacturing process for our SARMs. The active ingredient in Ostarine™ and our other SARMs is manufactured using a four-step synthetic process that uses commercially available starting materials and raw materials for each step. We have contracted with third party vendors for the manufacture of Ostarine™ drug substance and the supply of Ostarine™ drug product for our Phase II clinical trial for the treatment of muscle wasting in cancer patients, known as cancer cachexia. However, Merck has assumed primary manufacturing responsibility for Ostarine™ and other SARM products developed under our license and collaboration agreement with Merck.

Competition

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, 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. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize similar products that are safer, more effective, have fewer side effects or are less expensive than any products that we and/or our collaborators may develop. 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.

ACAPODENE® 20 mg for the Prevention of Prostate Cancer in High Risk Men with High Grade PIN

Currently, there are no drug products that would compete with ACAPODENE® 20 mg for the treatment of high grade PIN to reduce the incidence of prostate cancer. There are government sponsored studies looking at the ability of nutritional supplements to prevent prostate cancer in men with high grade PIN. These studies are much smaller than the ACAPODENE® 20 mg Phase III trial and may not have enough clinical patients to show a statistically significant benefit. Avodart® (dutasteride), from GlaxoSmithKline, is being evaluated in a Phase III clinical trial in prostate cancer prevention in men with elevated PSA, but men with high grade PIN were excluded from the Avodart trial.

ACAPODENE® 80 mg for the Treatment of Multiple Serious Side Effects of ADT

Currently, there are no products that have been approved by the FDA to treat multiple serious side effects of ADT. We are aware of a number of drugs that are marketed or prescribed off-label for the treatment of single side effects. For example, Evista® (raloxifene hydrochloride), a SERM marketed by Eli Lilly, Fosamax® (alendronate sodium), a bisphosphonate marketed by Merck, Zometa® (zoledronic acid) a bisphosphonate marketed by Novartis, and Actonel® (risendronate sodium), a bisphosphonate marketed by Sanofi-Aventis and Procter & Gamble, are each prescribed for the treatment of osteoporosis. Amgen has an investigational drug, denosumab, in Phase III clinical trials for the treatment of osteoporosis in men undergoing ADT. Effexor® (venlafaxine hydrochloride), marketed by Wyeth Pharmaceuticals, Catapres® (clonidine hydrochloride), marketed by Boehringer Ingelheim, and Megace® (megesterol acetate), marketed by Bristol Myers Squibb, are prescribed off-label to treat hot flashes caused by ADT. External beam radiation and tamoxifen are both used to treat gynecomastia. There can be significant side effects associated with the use of these drugs and radiation treatment. Most patients would need to take several different drugs and potentially receive radiation treatments to treat multiple serious side effects of ADT. In contrast, we believe that ACAPODENE® 80 mg as a single product candidate has the potential to treat multiple serious side effects.

SARMs for the Treatment of Cancer Cachexia and Frailty, or Sarcopenia

There are currently no drugs that have been approved by the FDA for the treatment of cancer cachexia. Although there are two commercially available drugs, nandrolone and oxandrolone, that are being prescribed off-label for the treatment of some types of cancer cachexia, chronic use of these drugs may result in bleeding liver cysts and liver cell tumors. Nandrolone is an oral steroid that is available from Steris Laboratories, a subsidiary of Watson Pharmaceuticals. Oxandrin® (oxandrolone) is indicated as an adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections and severe trauma and in some patients who without pathophysiologic reasons fail to maintain normal weight but has also been prescribed off-label for cancer cachexia. Oxandrin® was marketed by Savient Pharmaceuticals and generated approximately $60 million in annual sales. Savient has discontinued production of Oxandrin® following the introduction of an authorized generic. Oxandrin® has a black box warning for liver toxicity and has warnings and precautions related to increasing the risk

for prostate cancer and virilization in women.

Testosterone products have been used off-label to treat andropause and muscle wasting. Owing to its potentially unwanted effects in the prostate, and possible inconvenient dosing, we believe that testosterone products have had a limited impact on the market for muscle wasting. TAP Pharmaceuticals and Ligand Pharmaceuticals have announced a collaboration to develop a SARM and have been conducting Phase I clinical studies. Other pharmaceutical companies are also developing SARMs. Wyeth and Amgen have myostatin inhibitors in development which may compete for similar patients as Ostarine™. Megace® (megesterol acetate) and Marinol® (dronasinol) are appetite stimulants approved for AIDS patients which are used off-label for cancer cachexia. Neither Megace® nor Marinol® increase muscle and neither have been shown to improve physical function.

FARESTON® for the Treatment of Breast Cancer

There are a number of drugs that have been approved by the FDA for the treatment of breast cancer. Tamoxifen, which is marketed by AstraZeneca and several generic manufacturers, has been approved by the FDA for the treatment of advanced breast cancer and the reduction of breast cancer in women at high risk for developing the disease. The aromatase inhibitors, or AIs, such as anastrozole, letrozole and exemestane, are used to treat breast cancer in postmenopausal women. The AIs are growing at the expense of SERMs due to clinical trials such as the clinical trial entitled “Arimidex and Tamoxifen: Alone or in Combination” which has shown efficacy and tolerability advantages for AIs compared to tamoxifen.

Sales and Marketing

In order to commercialize any future products, we must broaden our sales and marketing infrastructure or collaborate with third parties with sales and marketing experience and personnel. We plan to build a small, highly-focused, specialty sales and marketing infrastructure, which we expect to include 50 to 100 sales representatives, to market ACAPODENE® to the relatively small and concentrated community of urologists and medical oncologists in the United States and to market FARESTON® to targeted prescribers, principally medical oncologists and other key specialists targeted in the United States. We believe that the urology and medical oncology markets in the United States are readily accessible by a limited sales and marketing presence due to the concentration of prescribing physicians. We have partnered with Ipsen to commercialize ACAPODENE® in Europe. We are currently seeking partners to market ACAPODENE® in Asia and other markets outside of the United States and Europe.

If Ostarine™ or another of the SARMs under development by us and Merck is approved by the FDA, Merck will commercialize the drug and we will have the opportunity to participate in commercialization through medical affairs and potentially also through copromotion.

Intellectual Property

We will be able to protect our technology from unauthorized use by third parties only to the extent it is covered by valid and enforceable patents or is effectively maintained as trade secrets. Patents and other proprietary rights are an essential element of our business.

For ACAPODENE® in the United States and internationally, we have entered into an amended and restated license and supply agreement with Orion Corporation granting us an exclusive license under Orion’s patents covering the composition of matter of toremifene, the active pharmaceutical ingredient in ACAPODENE®, for all uses in humans in the United States, and for all human uses outside the United States other than to treat breast cancer. The patent for toremifene will expire in the United States in 2009 and will expire in Australia, Italy, Sweden and Switzerland in 2008. This patent has already expired in other European countries and in Japan and is likely to expire in countries outside the United States before we commercialize ACAPODENE®. As a result, outside of the United States and in the United States after 2009, we will need to rely primarily on the protection afforded by the method of use patents that either have been already issued or other patents that may later be issued in respect of our owned and/or licensed patent applications relating to the use of ACAPODENE® for the relevant indications we seek.

We have licensed from UTRF method of use patents for specific disease indications and doses in the United States and issued and pending patent applications internationally related to the use of ACAPODENE® 20 mg for the reduction in the incidence of prostate cancer in high risk men with high grade PIN. The method of use patents issued in the United States related to the use of ACAPODENE® for this indication will begin expiring in 2019.

We have our own pending method of use patent applications in the United States and internationally related to the use of ACAPODENE® 80 mg for the treatment of osteoporosis, gynecomastia and hot flashes as multiple serious side effects of ADT in men with prostate cancer. A method of use patent related to the use of ACAPODENE® for the treatment of ADT-induced osteoporosis and bone fractures in men with prostate cancer is issued in the United States and will expire in 2023.

In all countries in which we hold or have licensed rights to patents or patent applications related to ACAPODENE®, the composition of matter patents for toremifene, the active pharmaceutical ingredient of ACAPODENE®, will expire before the method of use patents. Furthermore, with respect to the method of use of ACAPODENE® 80 mg for the treatment of osteoporosis, hot flashes and gynecomastia as multiple serious side effects of ADT in men with prostate cancer worldwide and the method of use of ACAPODENE® 20 mg for the reduction in the incidence of prostate cancer in high risk men with high grade PIN outside the United States, we have some patents issued and many more pending patent applications. Method of use patents for compounds where the composition of matter patents have expired carry the risk of individual physician prescribed off-label use of the subject compounds.

In the event that patents issued in respect of 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 generic versions of toremifene at doses and in formulations that are bioequivalent to FARESTON® (toremifene citrate 60 mg) for uses other than the indications for ACAPODENE® covered by these pending method of use patent applications, and individual physicians would be permitted to prescribe generic versions of toremifene for indications that are protected by our or our licensors' method of use patents and pending patent applications. Assuming ACAPODENE® receives appropriate marketing approval, after the expiration of the patent covering the composition of matter of toremifene in a particular country, if patents do not issue in respect of our pending method of use patent applications related to the use of ACAPODENE® 80 mg for the treatment of osteoporosis, hot flashes and gynecomastia as multiple serious side effects of ADT in men with prostate cancer worldwide and the method of use of ACAPODENE® 20 mg for the reduction in the incidence of prostate cancer in high risk men with high grade PIN outside the United States, competitors could market and sell generic versions of toremifene at doses and in formulations that are bioequivalent to FARESTON® (toremifene citrate 60 mg) tablets for these indications.

Until January 2005, our license from Orion was limited to the use of toremifene for the prevention and treatment of prostate cancer and the prevention and treatment of osteoporosis, hot flashes and gynecomastia as multiple serious side effects of ADT in the treatment of prostate cancer. We have since acquired the rights from Orion to market, sell and distribute a 60 mg toremifene tablet under the trademark FARESTON® for the treatment of advanced breast cancer in the United States and the rights to market, sell and distribute toremifene for all other indications in humans in the United States and in the rest of world except for breast cancer outside of the United States.

For Ostarine™ and our other SARMs, including GTx-838, we have an exclusive license from the UTRF under its issued patents and pending patent applications in the United States and internationally covering the composition of matter of the active pharmaceutical ingredient in these product indications, pharmaceutical compositions and formulations and methods of synthesizing the active pharmaceutical ingredients. We also have licensed pending patent applications in the United States and internationally related to methods for building muscle mass and bone in patients and treating frailty, osteoporosis, cancer cachexia and other wasting diseases using Ostarine™ and other SARMs. As part of our collaboration with Merck, we have granted an exclusive license to Merck for these issued patents and pending patent applications that we have licensed from UTRF.

We also rely on trade secrets, technical know-how and continuing innovation to develop and maintain our competitive position. We seek to protect our proprietary information by requiring our employees, consultants, contractors, outside scientific collaborators and other advisors to execute non-disclosure and confidentiality agreements and our employees to execute assignment of invention agreements to the Company on commencement

of their employment. Agreements with our employees also prevent them from bringing any proprietary rights of third parties to us. We also require confidentiality or material transfer agreements from third parties that receive our confidential data or materials.

Government Regulation

New Drug Development and Approval Process

Numerous governmental authorities in the United States and other countries extensively regulate the testing, clinical development, manufacturing and marketing of pharmaceutical products and ongoing research and development activities. In the United States, the FDA rigorously reviews pharmaceutical products under the Federal Food, Drug, and Cosmetic Act and applicable regulations. Non-compliance with FDA regulations can result in administrative and judicial sanctions, including warning letters, clinical holds, fines, recall or seizure of products, injunctions, total or partial suspension of production, refusal of the government to approve marketing applications or allow entry into supply contracts, refusal to permit import or export of products, civil penalties, criminal prosecution and other actions affecting a company and its products. The FDA also has the authority to revoke previously granted marketing authorizations.

To secure FDA approval, an applicant must submit extensive preclinical and clinical data, as well as information about product manufacturing processes and facilities and other supporting information to the FDA for each indication to establish a product candidate's safety and efficacy. The development and approval process takes many years, requires the expenditure of substantial resources and may be subject to delays or limitations of approval or rejection of an applicant's new drug application. Even if the FDA approves a product, the approval is subject to post-marketing surveillance, adverse drug experience and other recordkeeping and reporting obligations, and may involve ongoing requirements for post-marketing studies. The FDA also recently obtained authority to place conditions on any approvals that could restrict the commercial applications, advertising, promotion or distribution of these products. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing.

Preclinical and Clinical Testing

Preclinical studies involve laboratory evaluation of product characteristics and animal studies to assess the biological activity and safety of the product. In some cases, long-term preclinical studies are conducted while clinical studies are ongoing. The FDA, under its Good Laboratory Practices regulations, regulates preclinical studies. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring these studies to be replicated. When the preclinical testing is considered adequate by the sponsor to demonstrate the safety and scientific rationale for initial human studies, the results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an Investigational New Drug application, or IND. The IND becomes effective, if not rejected by the FDA, within 30 days after the FDA receives the IND. The FDA may, either during the 30-day period after filing of an IND or at any future time, impose a clinical hold on proposed or ongoing clinical trials on various grounds, including that the study subjects are or would be exposed to an unreasonable and significant health risk. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization and then only under terms authorized by the FDA.

Clinical trials involve the administration of the investigational product candidates to humans under the supervision of a qualified principal investigator. Clinical trials must be conducted in accordance with Good Clinical Practices under protocols submitted to the FDA as part of the IND. In addition, each clinical trial must be approved and conducted under the auspices of an Investigational Review Board, or IRB, and with patient informed consent. The IRB typically considers, among other things, ethical factors and the safety of human subjects.

Clinical trials are conducted in three sequential phases, but the phases may overlap. Phase I clinical trials usually involve healthy human subjects. The goal of a Phase I clinical trial is to establish initial data about the safety, tolerability and pharmacokinetic properties of the product candidates in humans. In Phase II clinical trials, controlled studies are conducted on an expanded population of patients with the targeted disease. The primary purpose of these tests is to evaluate the effectiveness of the drug candidate on the patients to determine if there are

any side effects or other risks associated with the drug and to determine the optimal dose of the drug from the safety and efficacy profile developed from the clinical study. Phase III trials involve even larger patient populations, often with several hundred or even several thousand patients, depending on the use for which the drug is being studied. Phase III trials are intended to establish the overall risk-benefit ratio of the drug and provide, if appropriate, an adequate basis for product labeling. During all clinical trials, physicians monitor the patients to determine effectiveness and to observe and report any reactions or other safety risks that may result from use of the drug candidate.

Product Formulation and Manufacture

Concurrent with clinical trials and preclinical studies, companies must develop information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product. In addition, manufacturers, including contract manufacturers, are required to comply with current applicable FDA Good Manufacturing Practice regulations. The current Good Manufacturing Practice regulations include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. The manufacturing process must be capable of consistently producing quality batches of the product and the manufacturer must develop methods for testing the quality, purity and potency of the final drugs. Additionally, appropriate packaging must be selected and tested and chemistry stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf-life.

Compliance with current Good Manufacturing Practice regulations also is a condition of new drug application approval. The FDA must approve manufacturing facilities before they can be used in the commercial manufacture of drug products. In addition, manufacturing establishments are subject to pre-approval inspections and unannounced periodic inspections.

New Drug Application Process

After the completion of the clinical trial phases of development, if the sponsor concludes that there is substantial evidence that the drug candidate is safe and effective for its intended use, the sponsor may submit a NDA to the FDA. The application must contain all of the information on the drug candidate gathered to that date, including data from the clinical trials, and be accompanied by a user fee.

Under the Prescription Drug User Fee Act, or PDUFA, submission of a NDA with clinical data requires payment of a fee, with some exceptions. In return, the FDA assigns a goal of six or ten months from filing of the application to return of a first “complete response,” in which the FDA may approve the product or request additional information. There can be no assurance that an application will be approved within the performance goal timeframe established under PDUFA. The FDA initially determines whether a NDA as submitted is acceptable for filing. The FDA may refuse to file an application, in which case the FDA retains one-half of the user fees. If the submission is accepted for filing, the FDA begins an in-depth review of the application. As part of this review, the FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation. The FDA is not bound by the recommendation of an advisory committee.

If the FDA evaluations of the NDA and the manufacturing facilities are favorable, the FDA may issue an approval letter authorizing commercial marketing of the drug candidate for specified indications. The FDA could also issue an approvable letter, which usually contains a number of conditions that must be met in order to secure final approval of the NDA. When and if those conditions have been met to the FDA’s satisfaction, the FDA will issue an approval letter. On the other hand, if the FDA’s evaluation of the NDA submission or manufacturing facilities is not favorable, the FDA may refuse to approve the NDA or issue a non-approvable letter.

Marketing Approval and Post-Marketing Obligations

If the FDA approves an application, the drug becomes available for physicians to prescribe. Periodic reports must be submitted to the FDA, including descriptions of any adverse reactions reported. The FDA may require post-marketing studies, also known as Phase IV studies, as a condition of approval. In addition to studies required by the FDA after approval, trials and studies are often conducted to explore new indications for the drug. The purpose of these trials and studies and related publications is to develop data to support additional indications for the drug,

which must be approved by the FDA, and to increase its acceptance in the medical community. In addition, some post-marketing studies are done at the request of the FDA to develop additional information regarding the safety of a product.

In accordance with newly-gained authority pursuant to the Food and Drug Administration Amendments Act of 2007, the FDA may impose risk evaluation mitigation strategies, or REMs, on a product if the FDA believes there is a reason to monitor the safety of the drug in the marketplace. REMs are a new tool for the FDA, and it is unclear how the agency will implement this enforcement authority. However, REMs could add training requirements for healthcare professionals, safety communications efforts, and limits on channels of distribution, among other things. The sponsor would be required to evaluate and monitor the various REMs activities and adjust them if need be. The financial impact of REMs are uncertain at this time.

Any products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including record keeping requirements, reporting of adverse experiences with the drug, drug sampling and distribution requirements, notifying the FDA and gaining its approval of certain manufacturing or labeling changes, complying with certain electronic records and signature requirements, and complying with FDA promotion and advertising requirements. Drug manufacturers and their subcontractors are required to register their establishments and are subject to periodic unannounced inspections for compliance with Good Manufacturing Practice requirements. Also, newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, or even in some instances revocation or withdrawal of the product's approval.

Drug Price Competition and Patent Term Restoration Act of 1984

Under the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, a portion of a product's patent term that was lost during clinical development and application review by the FDA may be restored. The Hatch-Waxman Act also provides for a statutory protection, known as exclusivity, against the FDA's acceptance or approval of certain competitor applications. The Hatch-Waxman Act also provides the legal basis for the approval of abbreviated new drug applications, or ANDAs.

Patent term extension can compensate for time lost during product development and the regulatory review process by returning up to five years of patent life for a patent that covers a new product or its use. This period is generally one-half the time between the effective date of an IND and the submission date of a NDA, plus the time between the submission date of a NDA and the approval of that application. Patent term extensions, however, are subject to a maximum extension of five years, and the patent term extension cannot extend the remaining term of a patent beyond a total of 14 years. The application for patent term extension is subject to approval by the United States Patent and Trademark Office in conjunction with the FDA. It generally takes at least six months to obtain approval of the application for patent term extension.

The Hatch-Waxman Act also provides for a period of statutory protection for new drugs that receive NDA approval from the FDA. If a new drug receives NDA approval as a new chemical entity, meaning that the FDA has not previously approved any other new drug containing the same active entity, then the Hatch-Waxman Act prohibits an ANDA or a NDA submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetics Act, where the applicant does not own or have a legal right of reference to all of the data required for approval to be submitted by another company for a generic version of such drug (505(b)(2) NDA), with some exceptions, for a period of five years from the date of approval of the NDA. The statutory protection provided pursuant to the Hatch-Waxman Act will not prevent the filing or approval of a full NDA, as opposed to an ANDA or 505(b)(2) NDA, for any drug, including, for example, a drug with the same active ingredient, dosage form, route of administration, strength and conditions of use. In order to obtain a NDA, however, a competitor would be required to conduct its own clinical trials.

If NDA approval is received for a new drug containing an active ingredient that was previously approved by the FDA but the NDA is for a drug that includes an innovation over the previously approved drug, for example, a NDA approval for a new indication or formulation of the drug with the same active ingredient, and if such NDA approval was dependent upon the submission to the FDA of new clinical investigations, other than bioavailability studies, then the Hatch-Waxman Act prohibits the FDA from making effective the approval of an ANDA or 505(b)(2) NDA

for a generic version of such drug for a period of three years from the date of the NDA approval. This three year exclusivity, however, only covers the innovation associated with the NDA to which it attaches. Thus, the three year exclusivity does not prohibit the FDA, with limited exceptions, from approving ANDAs or 505(b)(2) NDAs for drugs containing the same active ingredient but without the new innovation.

While the Hatch-Waxman Act provides certain patent restoration and exclusivity protections to innovator drug manufacturers, it also permits the FDA to approve ANDAs for generic versions of their drugs. The ANDA process permits competitor companies to obtain marketing approval for a drug with the same active ingredient for the same uses but does not require the conduct and submission of clinical studies demonstrating safety and effectiveness for that product. Instead of safety and effectiveness data, an ANDA applicant needs only to submit data demonstrating that its product is bioequivalent to the innovator product as well as relevant chemistry, manufacturing and product data. The Hatch-Waxman Act also instituted a third type of drug application that requires the same information as a NDA, including full reports of clinical and preclinical studies, except that some of the information from the reports required for marketing approval comes from studies which the applicant does not own or have a legal right of reference. This type of application, a 505(b)(2) NDA, permits a manufacturer to obtain marketing approval for a drug without needing to conduct or obtain a right of reference for all of the required studies.

Finally, the Hatch-Waxman Act requires, in some circumstances, an applicant submitting an ANDA or 505(b)(2) NDA to notify the patent owner and the holder of the approved NDA of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed. Upon receipt of this notice, the patent owner and the NDA holder have 45 days to bring a patent infringement suit in federal district court and obtain a 30-month stay against the company seeking to reference the NDA. The NDA holder could still file a patent suit after the 45 days, but if they miss the 45-day deadline, they would not have the benefit of the 30-month stay. Alternatively, after this 45-day period, the applicant may file a declaratory judgment action, seeking a determination that the patent is invalid or will not be infringed. Depending on the circumstances, however, the applicant may not be able to demonstrate a controversy sufficient to confer jurisdiction on the court. The discovery, trial and appeals process in such suits can take several years. If such a suit is commenced, the Hatch-Waxman Act provides a 30-month stay on the approval of the competitor's ANDA or 505(b)(2) NDA. If the litigation is resolved in favor of the competitor or the challenged patent expires during the 30-month period, unless otherwise extended by court order, the stay is lifted and the FDA may approve the application. Under regulations recently issued by the FDA, and essentially codified under the recent Medicare prescription drug legislation, the patent owner and the NDA holder have the opportunity to trigger only a single 30-month stay per ANDA or 505(b)(2) NDA. Once the applicant of the ANDA or 505(b)(2) NDA has notified the patent owner and the NDA holder of the infringement, the applicant cannot be subjected to another 30-month stay, even if the applicant becomes aware of additional patents that may be infringed by its product.

Pharmaceutical Pricing and Reimbursement

In both domestic and foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare product candidates. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Our product candidates may not be considered cost-effective. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. The United States and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. Adoption of new legislation could further limit reimbursement for pharmaceuticals.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on managed care in the United States has and will continue to increase the pressure on pharmaceutical pricing. Currently, our only marketed product, FARESTON® for the treatment of metastatic breast cancer, is eligible for coverage and reimbursement by third-party payors.

Research and Development

Since our inception, we have been focused on drug discovery, preclinical development and clinical development programs. Our research and development expenses were $38.5 million for the year ended December 31, 2007, $33.9 million for the year ended December 31, 2006 and $30.9 million for the year ended December 31, 2005.

Employees

As of December 31, 2007, we had 111 employees, 30 of whom were M.D.s and/or Ph.D.s. None of our employees is subject to a collective bargaining agreement. We believe that we have good relations with our employees.

Available Information

We file reports with the Securities and Exchange Commission, or SEC, including annual reports on Form 10-K, quarterly reports on Form 10-Q, and other reports from time to time. The public may read and copy any materials filed with the SEC at the SEC's Public Reference Room at 100 F Street, NW, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. We are an electronic filer and the SEC maintains an Internet site at http://www.sec.gov that contains the reports, proxy and information statements, and other information filed electronically. Our website address is http://www.gtxinc.com. Please note that these website addresses are provided as inactive textual references only. We make available free of charge through our website our Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. The information provided on our website is not part of this report, and is therefore not incorporated by reference unless such information is otherwise specifically referenced elsewhere in this report.

Executive Officers of the Registrant

The following table sets forth information about our executive officers as of February 29, 2008.

Name	Age	Position(s)
Mitchell S. Steiner, M.D., F.A.C.S	47	Chief Executive Officer and Vice Chairman of the Board of Directors
Marc S. Hanover	45	President, Chief Operating Officer and Director
Ronald A. Morton, Jr., M.D., F.A.C.S	49	Vice President, Chief Medical Officer
Henry P. Doggrell	59	Vice President, General Counsel and Secretary
Mark E. Mosteller	45	Vice President, Chief Financial Officer and Treasurer
K. Gary Barnette, Ph.D	40	Vice President, Clinical Research and Development Strategy
James T. Dalton, Ph.D	45	Vice President, Preclinical Research and Development
Gregory A. Deener	46	Vice President, Sales and Marketing, Product Commercialization
Jeffrey G. Hesselberg	49	Vice President, Regulatory Affairs
Christopher K. West	41	Vice President, Sales

Mitchell S. Steiner, M.D., F.A.C.S., a co-founder of GTx, has served as our Chief Executive Officer and Vice Chairman of our Board of Directors since our inception in September 1997. From 1995 to 2003, Dr. Steiner held numerous academic appointments, including Chairman and Professor of Urology, Director of Urologic Oncology and Research and the Chair of Excellence in Urologic Oncology at the University of Tennessee. Since 2003, Dr.

Steiner has continued to serve on the faculty at the University of Tennessee. Dr. Steiner holds a B.A. in Molecular Biology from Vanderbilt University and an M.D. from the University of Tennessee, and performed his surgery and urologic training at The Johns Hopkins Hospital.

Marc S. Hanover, a co-founder of GTx, has served as our President and Chief Operating Officer and a director since our inception in September 1997. Prior to joining GTx, Mr. Hanover was a founder of Equity Partners International, Inc., a private equity firm in Memphis, Tennessee, and participated as a founder and investor in three healthcare companies. From 1985 to 1997, Mr. Hanover was a Senior Vice President and a member of the Executive Management Committee of National Bank of Commerce in Memphis, Tennessee. Mr. Hanover holds a B.S. in Biology from the University of Memphis and a MBA in Finance from the University of Memphis.

Ronald A. Morton, Jr., M.D., F.A.C.S., was appointed Vice President and Chief Medical Officer in April 2007. He joined GTx from the University of Medicine & Dentistry of New Jersey Robert Wood Johnson Medical School, where he served as Professor of Surgery, Chief of Urology and Director of Urologic Oncology for the Cancer Institute of New Jersey from January 2004 until April 2007. Dr. Morton also held the Conzen Chair for Clinical Research and was the Director of the New Jersey Center for Clinical and Translational Sciences. Prior to joining Robert Wood Johnson Medical School in 2004, Dr. Morton held a dual faculty appointment at the Baylor College of Medicine in the Scott Department of Urology and in the Department of Molecular and Cell Biology (May 1994 to December 2003), was Clinical Director of the Baylor Adult Urology Program (July 2000 to December 2003), Chief of Urology at the Houston Veterans Administration Medical Center (January 1999 to December 2003), and Director of the Baylor Prostate Cancer Center Research Laboratories (July 1996 to December 2003). He received his bachelor and medical degrees from the Johns Hopkins University and completed his urology training and postdoctoral fellowship and was an AFUD Scholar at the Johns Hopkins Brady Urological Institute.

Henry P. Doggrell has served as our General Counsel and Secretary since October 2001 and was appointed Vice President on January 20, 2005. From April 1998 to August 2001, Mr. Doggrell was Senior Vice President, Corporate Affairs at Buckeye Technologies, Inc., a specialty cellulose company, where he was responsible for matters including corporate finance, investor relations, mergers and acquisitions, intellectual property and licensing and strategic development. From 1996 to 1998, Mr. Doggrell served as General Counsel and Secretary of Buckeye Technologies. Prior to joining Buckeye Technologies, Mr. Doggrell was a partner of the Baker, Donelson, Bearman, Caldwell and Berkowitz law firm from 1988 to 1996, where he served as a member of the law firm management committee and Chair of the firm's Corporate Securities department. Mr. Doggrell holds a B.S. in Commerce from the University of Virginia and a JD from Vanderbilt University.

Mark E. Mosteller has served as our Chief Financial Officer since August 2001 and was appointed Vice President and Treasurer on January 20, 2005. From April 1997 to August 2001, Mr. Mosteller was an Executive Vice President of Union Planters Bank National Association, a subsidiary of Union Planters Corporation, a bank holding company, and Chief Operating Officer of Union Planters Mortgage, the mortgage division of Union Planters Bank National Association. From 1994 to 1997, Mr. Mosteller was the Chief Financial Officer of Boatmen's National Mortgage, Inc., the mortgage subsidiary of Boatmen's Bancshares, Inc. From 1984 to 1994, Mr. Mosteller was employed as an audit senior manager with Ernst & Young LLP. Mr. Mosteller is a Certified Public Accountant and holds a B.S. in Accounting from the University of Tennessee.

K. Gary Barnette, Ph.D., was appointed Vice President, Clinical Research and Development Strategy in November 2005, and prior to that he served as Vice President, Clinical Research and Development since January 20, 2005. He also served as our Director of Regulatory Affairs from December 2001 until April 2007. From May 1998 to December 2001, Dr. Barnette was Assistant Director and then Director, Regulatory Affairs at Solvay Pharmaceuticals, Inc., a specialty pharmaceutical company. From March 1995 to May 1998, Dr. Barnette was a Clinical Pharmacology and Biopharmaceutics Reviewer at the FDA, where he reviewed in the Divisions of Reproductive and Urologic Drug Products, Metabolic and Endocrine Drug Products and Gastrointestinal and Coagulation Drug Products. Dr. Barnette holds a B.S. in Biology from Salem College, and a Ph.D. in Basic Pharmaceutical Sciences from West Virginia University.

James T. Dalton, Ph.D., has served as Vice President, Preclinical Research and Development since January 2005. Dr. Dalton served as a scientific consultant to GTx from 1999 to 2005. Prior to joining GTx, Dr. Dalton held several academic appointments including Assistant and Associate Professor of Pharmaceutical Sciences in the

College of Pharmacy at the University of Tennessee, Memphis (1992-2000) and Professor in the Division of Pharmaceutics, College of Pharmacy at The Ohio State University (2000-2007). SARMs were first discovered in Dr. Dalton's research laboratories, and he is co-inventor on all SARM patents. Dr. Dalton holds a B.S. in Pharmacy from the University of Cincinnati and a Ph.D. in Pharmaceutics and Pharmaceutical Chemistry from The Ohio State University.

Gregory A. Deener was appointed Vice President, Sales and Marketing, Product Commercialization on January 20, 2005, and prior to that he served as our Director of Marketing and Sales since February 2004. Mr. Deener has over 20 years of experience in Marketing and Sales and has launched a urology medicine within the U.S. From 1996 to December 2003, Mr. Deener served as a Marketing Director for GlaxoSmithKline in various roles within the U.S. and Europe. Most recently Mr. Deener was responsible for the launch of Avodart, a urology medicine for BPH. From 1983 to 1996, Mr. Deener worked for Procter & Gamble in Brand Management and Sales. Mr. Deener holds a B.S. in Business Administration from the University of North Carolina at Chapel Hill.

Jeffrey G. Hesselberg was appointed Vice President, Regulatory Affairs in April 2007, and has over 19 years of experience in the biopharmaceutical industry, including 13 years of regulatory affairs drug development experience. From 1996 to April 2007, Mr. Hesselberg served as Manager, Associate Director, and then Director of Regulatory Affairs for ICOS Corporation. Most recently, Mr. Hesselberg worked on the successful development, launch and commercialization of Cialis® (tadalafil) for the treatment of erectile dysfunction. From 1984 to 1996, Mr. Hesselberg worked for Immunex Corporation and the Puget Sound Blood Center. Mr. Hesselberg holds a B.S. in Molecular Biology from the University of Wisconsin-Madison and a MBA from the University of Washington.

Christopher K. West was appointed Vice President, Sales on January 7, 2008. Mr. West has over 14 years of pharmaceuticals sales and marketing experience and joins us from Warner Chilcott, Limited where he served as Regional Sales Director (2006) and then as head of Sales and Marketing for the Dermatology division (2007). From 2002 through 2006, Mr. West worked for GlaxoSmithKline plc in marketing positions of increasing responsibility for the urology medicines Avodart®, Valtrex® and Advair®. From 1992 to 2000, Mr. West worked for Warner Lambert's Parke-Davis division in a variety of sales, sales training, and sales management positions. Mr. West is a graduate of the United States Military Academy at West Point and the Fuqua School of Business at Duke University.

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 December 31, 2007, we had an accumulated deficit of $270.1 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 $40.4 million for the year ended December 31, 2007, $35.5 million in 2006, and $36.8 million in 2005. We expect to continue to incur significant and increasing operating losses for the foreseeable future. These losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Because of the numerous risks and uncertainties associated with developing small molecule drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. We have primarily financed

our operations and internal growth through sales of common stock and preferred stock, including $30.0 million in proceeds from the sale of our common stock to Merck & Co., Inc., or Merck, pursuant to a stock purchase agreement we entered into with Merck in November 2007. In addition, we have received upfront license fees and payments pursuant to our collaborative arrangements with third parties, including $40.0 million in upfront license fees from Merck received in January 2008. FARESTON® is currently our only commercial product and, we expect, will account for all of our product revenue for the foreseeable future. For the year ended December 31, 2007, we recognized $1.1 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.

We estimate that our current cash resources, including the $40.0 million license fee we received from Merck in January 2008, interest on these funds and product revenue from the sale of FARESTON®, will be sufficient to meet our projected operating requirements through at least the first quarter of 2009. This estimate does not include funding from milestone payments that we may receive under our existing collaborations with Ipsen Limited, or Ipsen, and Merck, nor does it include any funding that we may receive under potential future collaboration arrangements with other pharmaceutical companies or potential future issuances and sales of our securities. Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our and/or our collaborators' clinical trials and other research and development activities;
- future clinical trial results;
- the achievement of certain milestone events under, and other matters related to, our collaborative arrangements with Merck and Ipsen;
- the terms and timing of any future collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- potential future licensing fees, milestone payments and royalty payments, including any milestone payments or royalty payments that we may receive under our collaborative arrangements with Merck and Ipsen;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we and/or our collaborators may develop;
- the effect of competing technological and market developments;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and

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

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

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

Risks Related to Development of Product Candidates

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

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

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

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

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

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

For some of the indications for which we intend to conduct or are currently conducting clinical trials for our product candidates, we do not have evidence from prior preclinical studies in animals or clinical trials in humans of

the potential effectiveness of such product candidates for such indications. In the absence of preclinical or clinical data, our beliefs regarding the potential effectiveness of our product candidates for these indications is generally based on pharmacokinetic data and analyses and pharmacological rationales. Our or our collaborators' preclinical or clinical trials may produce negative or inconclusive results that would not support our belief regarding the potential effectiveness of our product candidates.

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

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

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

We have relied on third party vendors for Ostarine™. We have executed agreements with third party contractors for the manufacture of Ostarine™ drug substance and the supply of Ostarine™ drug product for our Phase II clinical trial for the treatment of cancer cachexia. However, Merck has assumed primary manufacturing responsibilities for Ostarine™ and other SARM products developed under our exclusive license and collaboration agreement with Merck. If our current supply of Ostarine™ becomes unusable or if our Ostarine™ supply is not sufficient to complete our clinical trials and Merck does not manufacture and supply sufficient quantities of clinical trial materials to support our clinical trials, we could experience a delay in conducting clinical trials of Ostarine™ or other SARM product candidates. We may not be able to maintain or renew our existing or any other third-party manufacturing arrangements on acceptable terms, if at all. If we are unable to continue relationships with Orion for ACAPODENE®and Merck for Ostarine™ and other SARM product candidates, or to do so at an acceptable cost, or if these or other suppliers fail to meet our requirements for Ostarine™ or other SARM product candidates for any

reason, we would be required to obtain alternate suppliers. However, we may not be permitted to obtain alternate suppliers for ACAPODENE® under our license agreement with Orion if Orion terminates its supply of ACAPODENE® due to our uncured material breach or bankruptcy. Any inability to obtain alternate suppliers, including an inability to obtain approval from the FDA of an alternate supplier, would delay or prevent the clinical development and commercialization of these product candidates.

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

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

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

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

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

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

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

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

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

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

We may not receive any future milestone payments provided for under our collaborative arrangements with Ipsen and Merck if our agreements with them are terminated, if certain clinical development and regulatory milestones under our agreements with them are not achieved, with respect to our agreement with Ipsen, if Ipsen fails to develop and commercialize ACAPODENE® in the European Territory, or, with respect to our agreement with Merck, if we and Merck fail to develop and commercialize any of the SARMs included in or arising from our collaboration. In addition, even if required regulatory approvals are obtained, it is possible that neither Ipsen nor Merck will successfully market and sell ACAPODENE® or any SARM products, respectively, in which case we would not receive royalties to the extent that we currently anticipate. Furthermore, our royalty rates under our collaboration and license agreement with Ipsen are subject to a possible reduction if a generic version of toremifene achieves

specified sales levels in a major country within the European Territory, and each of Ipsen and Merck may be entitled to offset a portion of any royalties due to us if Ipsen or Merck licenses patent rights from a third party that would otherwise be infringed by Ipsen's or Merck's use, manufacture, sale or import of toremifene or SARM compounds, respectively.

Under our agreement with Ipsen, we and Ipsen have agreed that neither party will seek to commercialize, promote, market or sell certain products within the European Territory for an agreed period of time subsequent to the time of the first commercial launch of 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. However, we cannot assure you that we will be able to reach an agreement with Ipsen on reasonable terms, or at all, for any new SERM-based products.

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

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

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

Risks Related to Our Intellectual Property

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

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

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

development plans adversely affect these activities, any future modifications to our or Ipsen's plans imposed by Orion may limit our and Ipsen's ability to maximize the commercial potential of ACAPODENE®.

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

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

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

Our rights to certain patent applications relating to SARM compounds that we have licensed from the University of Tennessee Research Foundation, or UTRF, are subject to the terms of UTRF's inter-institutional agreements with The Ohio State University, or OSU, and our rights to future related improvements in some instances are subject to UTRF's exercise of exclusive options under its agreements with OSU for such improvements, which UTRF is required to do at our request. In addition, under the terms of our agreements with the diagnostic companies to which we provided clinical samples from our Phase IIb and Phase III clinical trials of ACAPODENE®, we will not obtain any intellectual property rights in any of their developments, including any test developed to detect high grade PIN or prostate cancer.

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

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

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

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

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

Even in the event that patents are issued from our pending method of use patent applications, after the expiration of the patent covering the composition of matter of toremifene in a particular country, competitors could market and sell toremifene products for uses for which FARESTON® has already been approved. Thus, physicians in such countries would be permitted to prescribe these other toremifene products for indications that are protected by our method of use patents or patents issuing from pending patent applications, even though these other toremifene products would not have been approved for those uses, and in most cases, the physician would not be liable for contributing to the infringement of our patents. Moreover, because Orion has licensed and could further license other parties to market, sell and distribute toremifene for breast cancer outside the United States, physicians in such countries could prescribe these products sold pursuant to another Orion license off-label. This further increases the

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

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

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

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

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

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

Risks Related to Regulatory Approval of Our Product Candidates

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

Our product candidates and the activities associated with their development and commercialization are subject to comprehensive regulation by the FDA, other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent us or our collaborators from commercializing the product candidate. We have not received regulatory approval to market any of our product candidates in any jurisdiction and have only limited experience in preparing and filing the applications necessary to gain regulatory approvals. In addition, we will not receive a substantial majority of the milestone payments provided under our collaboration and license agreement with Ipsen or any royalty payments if Ipsen is unable to obtain the

necessary regulatory approvals to commercialize ACAPODENE® within the European Territory. Likewise, we may not receive a majority of the milestone payments or any royalty payments provided for under our exclusive license and collaboration agreement with Merck if Merck is not able to obtain the necessary regulatory approvals to commercialize any SARM products, including Ostarine™, developed under the collaboration. The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved.

Changes in the regulatory approval policy during the development period, changes in or the enactment of additional regulations or statutes, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. For example, the Food and Drug Administration Amendments Act of 2007, or the FDA Amendments Act, which was enacted in September 2007, expands the FDA's authority to regulate drugs throughout the product life cycle, including enhanced authority to require post-approval studies and clinical trials. Other proposals have been made to impose additional requirements on drug approvals, further expand post-approval requirements and restrict sales and promotional activities. This new legislation, and the additional proposals if enacted, may make it more difficult or burdensome for us or our collaborators to obtain approval of our product candidates. Even if the FDA approves a product candidate, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product, and may impose ongoing requirements for post-approval studies, including additional research and development and clinical trials. The approval may also impose risk evaluation mitigation strategies, or REMS, on a product if the FDA believes there is a reason to monitor the safety of the drug in the market place. REMS may include requirements for additional training for health care professionals, safety communication efforts and limits on channels of distribution, among other things. The sponsor would be required to evaluate and monitor the various REMS activities and adjust them if need be. The FDA also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

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

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

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

Risks Related to Commercialization

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

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

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

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

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

- the loss of the availability of Orion's website to market FARESTON®, which is an important source of advertising;
- the loss of one or more of our three largest wholesale drug distributors, which together accounted for approximately 93% of our gross product sales of FARESTON® for the year ended December 31, 2007;
- the continued success of competing products, including aromatase inhibitors;
- the loss of coverage or reimbursement for FARESTON® from Medicare and Medicaid, private health insurers or other third-party payors;
- exposure to product liability claims related to the commercial sale of FARESTON®, which may exceed our product liability insurance;
- the failure of Orion to maintain regulatory filings or comply with applicable FDA requirements with respect to FARESTON®;
- the ability of third parties to market and sell generic toremifene products that will compete with FARESTON for the treatment of breast cancer after the composition of matter patents that we license from Orion expire in the United States in September 2009;

- the loss of Orion, upon which we rely as a single source, as our supplier of FARESTON®; and
- our inability to manufacture FARESTON® until Orion's patents with respect to the composition of matter of toremifene expire if Orion terminates our license and supply agreement due to our uncured material breach or bankruptcy.

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

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

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

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

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

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

Cost-control initiatives could decrease the price we might establish for products that we or our collaborators may develop or sell, which would result in lower product revenues or royalties payable to us.

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

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

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

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

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

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

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

Various products are currently marketed or used off-label for some of the diseases and conditions that we are targeting, and a number of companies are or may be developing new treatments. These product uses, as well as promotional efforts by competitors and/or clinical trial results of competitive products, could significantly diminish our or our collaborators' ability to market and sell any products that we and/or our collaborators may develop. For example, although there are no products that have been approved by the FDA to treat multiple side effects of androgen deprivation therapy, we are aware of a number of drugs marketed by Eli Lilly (Evista®), Merck (Fosamax®), Sanofi-Aventis and Procter & Gamble (Actonel®), Wyeth Pharmaceuticals (Effexor®), Boehringer Ingelheim (Catapres®), Novartis (Zometa®) and Bristol Myers Squibb (Megace®) that are prescribed to treat single side effects of androgen deprivation therapy; that external beam radiation and tamoxifen are used to treat breast pain

and enlargement, or gynecomastia; and that Amgen is developing a product candidate for the treatment of osteoporosis in prostate cancer patients. While we have the only pharmaceutical product in clinical development to prevent prostate cancer in high risk men with high grade PIN, GlaxoSmithKline is conducting a Phase III study for Avodart® on prostate cancer prevention in men with elevated prostate specific antigen. In addition, there are nutritional supplement studies (for example, selenium) investigating prostate cancer prevention in men with high grade PIN. Similarly, while there are no drugs that have been approved by the FDA for the treatment of muscle wasting from cancer, there are drugs marketed by Steris Laboratories and Savient Pharmaceuticals that are being prescribed off-label for the treatment of some types of muscle wasting from cancer. Testosterone and other anabolic agents are used to treat involuntary weight loss in patients who have acute muscle wasting. There are other SARM product candidates in development that may compete with our product candidates. Wyeth and Amgen have myostatin inhibitors in development which may compete for similar patients as Ostarine™. This could result in reduced sales and pricing pressure on our product candidates, if approved, which in turn would reduce our ability to generate revenue and have a negative impact on our results of operations.

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

Risks Related to Employees and Growth

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

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

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

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

Risks Related to Our Common Stock

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

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

- adverse results or delays in our clinical trials;

- the timing of achievement of our and our collaborators' clinical, regulatory and other milestones, such as the commencement of clinical development, the completion of a clinical trial or the receipt of regulatory approval;
- announcement of FDA approval or non-approval of our product candidates or delays in the FDA review process;
- actions taken by regulatory agencies with respect to our product candidates or products, our clinical trials or our sales and marketing activities;
- the commercial success of any product approved by the FDA or its foreign counterparts;
- developments with respect to our collaborations with Ipsen and Merck;
- the terms and timing of any collaborative, licensing or other arrangements that we may establish;
- regulatory developments in the United States and foreign countries;
- changes in the structure of health care payment systems;
- any intellectual property infringement lawsuit involving us;
- announcements of technological innovations or new products by us or our competitors;
- market conditions for the biotechnology or pharmaceutical industries in general;
- actual or anticipated fluctuations in our results of operations;
- changes in financial estimates or recommendations by securities analysts;
- sales of large blocks of our common stock;
- sales of our common stock by our executive officers, directors and significant stockholders;
- changes in accounting principles; and
- the loss of any of our key scientific or management personnel.

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

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

As of January 31, 2008, our officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 68.2% of our outstanding common stock and our officers and directors alone beneficially owned approximately 47.4% of our outstanding common stock. As a result, these stockholders, acting together, will be able to control all matters requiring approval by our stockholders, including the election of directors

and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders.

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

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

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

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

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

For the 12-month period ended December 31, 2007, the average daily trading volume of our common stock on the NASDAQ Global Market was approximately 160,000 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 December 31, 2007, we had 36,216,263 shares of common stock outstanding.

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We sublease approximately 53,000 square feet of laboratory and office space in Memphis, Tennessee, under an operating lease through December 31, 2008 with an option to extend for up to two additional years. This lease is terminable by either party on 90 days' notice. In December 2007, we entered into a sublease for approximately 31,000 square feet of additional office space in Memphis, Tennessee, under an operating lease through April 30, 2015. We have an option to cancel this sublease beginning December 31, 2010.

ITEM 3. LEGAL PROCEEDINGS

We are not currently involved in any material legal proceedings.

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

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market for Registrant's Common Equity

Our common stock began trading on The NASDAQ Global Market under the symbol "GTXI" on February 3, 2004. Prior to that date, there was no established public trading market for our common stock. The following table presents, for the periods indicated, the high and low closing sales prices per share of our common stock as reported on The NASDAQ Global Market.

	2007		2006	
	High	Low	High	Low
First Quarter	$22.95	$15.83	$12.08	$7.57
Second Quarter	23.38	16.19	11.57	8.11
Third Quarter	18.36	14.25	9.53	7.71
Fourth Quarter	18.19	13.67	18.30	9.26

On March 5, 2008 the closing price of our common stock as reported on The NASDAQ Global Market was $14.71 per share and there were approximately 68 holders of record of our common stock.

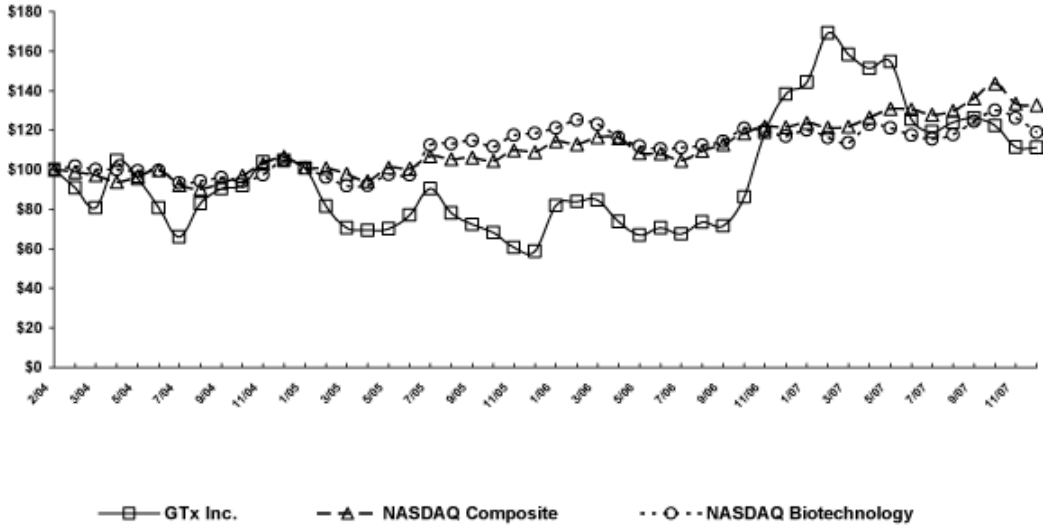
Performance Graph

The rules of the SEC require that we include in our annual report to shareholders a line-graph presentation comparing cumulative stockholder returns on our common stock with a broad equity market index that includes companies whose equity securities are traded on the NASDAQ and either a published industry or line-of-business standard index or an index of peer companies selected by us. We have elected to use the NASDAQ Composite Index (which tracks the aggregate price performance of equity securities of companies traded on NASDAQ) and the NASDAQ Biotechnology Index (consisting of a group of approximately 130 companies in the biotechnology sector, including us) for purposes of the performance comparison that appears below.

The following graph shows the cumulative total stockholder return assuming the investment of $100.00 at the closing prices on February 3, 2004, the first day of trading of the Company's common stock on the NASDAQ Global Market: (1) our common stock; (2) NASDAQ Composite Index and (3) NASDAQ Biotechnology Index. All values assume reinvestment of the full amounts of all dividends. No dividends have been declared on the Company's common stock. The closing sale price of our common stock on December 31, 2007 as reported on the NASDAQ Global Market was $14.35.

The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

COMPARISON OF 47 MONTH CUMULATIVE TOTAL RETURN*
Among GTx Inc., The NASDAQ Composite Index
And The NASDAQ Biotechnology Index



* $100 invested on 2/3/04 in stock or on 1/31/04 in index-including reinvestment of dividends. Fiscal year ending December 31.

The material in this section is not "soliciting material," is not deemed filed with the SEC and is not to be incorporated by reference in any filing of GTx, Inc. under the Securities Act of 1933 or the Exchange Act whether made before or after the date hereof and irrespective of any general incorporation language in such filing.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings to fund the development and expansion of our business, and therefore we do not anticipate paying cash dividends on our common stock in the foreseeable future. Any future determination to pay dividends will be at the discretion of our Board of Directors.

ITEM 6. SELECTED FINANCIAL DATA

You should read the selected financial data below in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the audited financial statements, notes thereto and other financial information included elsewhere in this Annual Report on Form 10-K. The statements of operations data for the years ended December 31, 2005, 2006 and 2007, and the balance sheet data at December 31, 2006 and 2007, are derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The statements of operations data for the years ended December 31, 2003 and 2004, and the consolidated balance sheet data at December 31, 2003, 2004 and 2005, are derived from our audited financial statements that are not included in this Annual Report on Form 10-K. Historical results are not indicative of the results to be expected in the future.

	Years Ended December 31,				
	2007	2006	2005	2004	2003
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenues:					
Product sales, net	$ 1,076	$ 1,357	$ 2,445	$ —	$ —
Total collaboration revenue	6,050	6,148	1,337	1,867	—
Total revenues	7,126	7,505	3,782	1,867	—
Operating expenses:					
Cost of product sales	621	773	1,573	—	—
Research and development expenses	38,508	33,897	30,923	17,950	10,778
General and administrative expenses	13,501	11,352	9,845	7,211	3,559
Loss from operations	(45,504)	(38,517)	(38,559)	(23,294)	(14,337)
Interest income	5,145	3,007	1,720	946	143
Net loss	(40,359)	(35,510)	(36,839)	(22,348)	(14,194)
Accrued preferred stock dividends	—	—	—	(455)	(3,436)
Adjustment to preferred stock redemption value	—	—	—	17,125	(77,844)
Net loss attributable to common stockholders	$ (40,359)	$ (35,510)	$ (36,839)	$ (5,678)	$ (95,474)
Net loss per share attributable to common stockholders:					
Basic	$ (1.16)	$ (1.14)	$ (1.42)	$ (0.25)	$ (12.34)
Diluted	$ (1.16)	$ (1.14)	$ (1.42)	$ (0.93)	$ (12.34)

	As of December 31,				
	2007	2006	2005	2004	2003
			(in thousands)		
Balance Sheet Data:					
Cash and cash equivalents	$ 100,178	$ 119,550	$ 74,014	$ 64,528	$ 14,769
Working capital	132,932	111,363	70,030	61,298	12,775
Total assets	159,730	129,255	82,811	73,082	17,310
Cumulative redeemable convertible preferred stock	—	—	—	—	165,292
Accumulated deficit	(270,138)	(229,779)	(194,269)	(157,430)	(151,752)
Total stockholders' equity (deficit)	78,917	97,049	73,579	63,909	(150,231)

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with our financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion may contain forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under Item 1A "Risk Factors" and elsewhere in this Annual Report on Form 10-K.

Overview

We are a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules that selectively target hormone pathways to treat cancer, osteoporosis and bone loss, muscle wasting and other serious medical conditions. We are developing ACAPODENE® (toremifene citrate), a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: first, a pivotal Phase III clinical trial for the treatment of multiple serious side effects of androgen deprivation therapy, or ADT, for advanced prostate cancer, and second, 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. In February 2008, we announced that the Phase III clinical trial results for ACAPODENE® 80 mg for the treatment of multiple serious side effects of ADT showed that ACAPODENE® 80 mg reduced new morphometric vertebral fractures and met other key endpoints of bone mineral density, or BMD, lipid profiles and gynecomastia. In March 2008, we announced that the results from this Phase III clinical trial also showed that ACAPODENE® 80 mg demonstrated a reduction in hot flashes in a subset analysis. We expect to file a New Drug Application, or NDA, for ACAPODENE® 80 mg for the treatment of multiple serious side effects of ADT with the U.S. Food and Drug Administration, or FDA, in 2008. We have licensed to Ipsen exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States, which we refer to collectively as the European Territory, to develop and commercialize ACAPODENE® and other products containing toremifene in all indications which we have licensed from Orion Corporation, or Orion, which include all indications in humans except the treatment and prevention of breast cancer outside of the United States. We have entered into an exclusive license and collaboration agreement with Merck and Co., Inc., or Merck, establishing a global strategic collaboration for the discovery, development and commercialization of selective androgen receptor modulators, or SARMs, including Ostarine™. We believe that Ostarine™ and other SARM candidates, including GTx-838, have the potential to treat a variety of indications associated with muscle wasting and bone loss, including frailty, muscle wasting associated with aging, also known as sarcopenia, muscle wasting in cancer patients, known as cancer cachexia, osteoporosis and chronic kidney disease muscle wasting. We are currently evaluating Ostarine™ in a Phase II clinical trial for the treatment of cancer cachexia.

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

We commenced a pivotal Phase III clinical trial of ACAPODENE® 80 mg under a Special Protocol Assessment, or SPA, with the FDA, for the treatment of multiple serious side effects of ADT in November 2003. The last patient completed the ADT clinical trial in November 2007. In February 2008, we announced that ACAPODENE® 80 mg reduced new morphometric vertebral fractures and met other key endpoints of BMD, lipid profiles and gynecomastia. Also, in March 2008, we announced that ACAPODENE® 80 mg demonstrated a reduction in hot flashes. We expect to file a NDA with the FDA in 2008.

In January 2005, we initiated a pivotal Phase III clinical trial of ACAPODENE® 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, which is being conducted under a SPA with the FDA. We will evaluate efficacy endpoints for the clinical trial at 36 months after completion of enrollment, and we anticipate

conducting a planned efficacy interim analysis after a certain number of cancer events have been recorded among study patients, which we currently expect to occur by the end of the first quarter of 2008. If the efficacy results from the planned interim analysis achieve the statistical outcome specified in the SPA (a £ 0.001), we plan to file a NDA with the FDA. If we are able to file a NDA based on the results of the efficacy interim analysis, we will continue to collect efficacy data and safety data during the review process to satisfy the FDA's safety requirements set forth in the SPA. If the efficacy results from the planned interim analysis do not satisfy the specified statistical requirements in the SPA, we plan to continue the clinical trial for the full 36 month period and then determine whether the trial results satisfy the efficacy endpoints required by the SPA.

In our third clinical program, Ostarine™, a SARM, is being developed to treat a variety of medical conditions relating to muscle wasting and/or bone loss. In December 2006, we announced that Ostarine™ met its primary endpoint in a Phase II proof of concept, double blind, randomized, placebo controlled clinical trial in 60 elderly men and 60 postmenopausal women. We initiated a Phase II randomized, double blind, placebo controlled clinical trial evaluating Ostarine™ for the treatment of cancer cachexia in 150 patients diagnosed with non-small cell lung cancer, colorectal cancer, non-Hodgkin's lymphoma, or chronic lymphocytic leukemia. The clinical trial is being conducted at approximately 50 clinical sites in the United States, Argentina and Canada and we expect to receive data from this trial during the summer of 2008. We and Merck, through our SARM collaboration, will determine the development strategy of Ostarine™, GTx-838 and other collaboration compounds.

In November 2007, we entered into a license and collaboration agreement with Merck which governs our and Merck's joint research, development and commercialization of SARM compounds and related SARM products, including SARMs currently being developed by us and Merck and those yet to be discovered, for all potential indications of interest. Under the agreement, we will conduct preclinical research of SARM compounds and products, and Merck will be primarily responsible for conducting and funding development and commercialization of products developed. We received an upfront licensing fee of $40.0 million in January 2008, of which $1.9 million was due to the University of Tennessee Research Foundation, or UTRF, as sublicense royalty. Merck also agreed to pay us $15.0 million in guaranteed cost reimbursements for research and development activities in equal annual installments over a three year period beginning on the first anniversary of the effective date of the agreement. We are also eligible to receive up to $422.0 million in future milestone payments associated with the development and regulatory approval of a lead product candidate, including Ostarine™, as defined in the agreement, if multiple indications are developed and receive required regulatory approvals, as well as additional milestone payments for the development and regulatory approval of other product candidates developed under the agreement, upon the achievement of such development and regulatory approval milestones and assuming the continued effectiveness of the agreement. Merck also has agreed to pay us tiered royalties on net sales of products that may be developed under the agreement. On the date the agreement became effective in December 2007, we issued to Merck 1,285,347 newly-issued shares of our common stock for an aggregate purchase price of approximately $30.0 million.

Our net loss for the year ended December 31, 2007 was $40.4 million. Our net loss included FARESTON® net product sales of $1.1 million and the recognition of collaboration revenue of $6.1 million. We have financed our operations and internal growth primarily through public offerings and private placements of our common stock and preferred stock, as well as proceeds from our collaborations. We expect to continue to incur net losses as we continue our clinical development and research and development activities, apply for regulatory approvals, expand our sales and marketing capabilities and grow our operations.

Sales and Marketing

We currently market FARESTON® (toremifene citrate 60 mg) tablets, which have been approved by the FDA for the treatment of metastatic breast cancer in postmenopausal women in the United States. In January 2005, we acquired from Orion the right to market FARESTON® tablets in the United States for the metastatic breast cancer indication. We also acquired from Orion a license to toremifene for all indications in humans worldwide, except breast cancer outside of the United States. The active pharmaceutical ingredient in FARESTON® is the same as in ACAPODENE®, but in a different dose. We plan to build a specialty sales and marketing infrastructure, which we expect to include 50 to 100 sales representatives, to market ACAPODENE® to the relatively small and concentrated community of urologists and medical oncologists in the United States and to market FARESTON® to targeted prescribers, principally medical oncologists and other key specialists in the United States. We have partnered with

Ipsen to commercialize ACAPODENE® in Europe. We are currently seeking partners to market ACAPODENE® in Asia and other markets outside of the United States and Europe.

Research and Development

Since our inception in 1997, we have been focused on drug discovery and development programs. Research and development expenses represented 74% of our total operating expenses for the year ended December 31, 2007. 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, quality assurance activities and license and royalty fees.

We expect that research and development expenditures will continue to increase in future years due to (1) obtaining regulatory approval of ACAPODENE® 80 mg for the treatment of multiple serious side effects of ADT for advanced prostate cancer, (2) the continuation of the pivotal Phase III clinical trial of ACAPODENE® 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, (3) the completion of the Phase II clinical trial evaluating Ostarine™ for the treatment of cancer cachexia, (4) the continued preclinical development of other product candidates, including GTx-758 and GTx-878 and (5) increases in research and development personnel.

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

Drug development in the United States is a process that includes several steps defined by the FDA. The FDA approval process for a new drug involves completion of preclinical studies and the submission of the results of these studies to the FDA, together with proposed clinical protocols, manufacturing information, analytical data and other information in an Investigational New Drug application which must become effective before human clinical trials may begin. Clinical development typically involves three phases of study: Phase I, II and III. The most significant costs associated with clinical development are the Phase III clinical trials as they tend to be the longest and largest studies conducted during the drug development process. After completion of clinical trials, a NDA may be submitted to the FDA. In responding to a NDA, the FDA may refuse to file the application, or if accepted for filing, the FDA may not grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval.

The successful development and commercialization of our product candidates is highly uncertain. We cannot reasonably estimate or know the nature, timing and estimated costs of the efforts necessary to complete the development and commercialization of, or the period in which material net cash inflows are expected to commence from, any of our product candidates, including the product candidates developed or commercialized through our collaborations with Merck and Ipsen, due to the numerous risks and uncertainties associated with developing and commercializing drugs, including the uncertainty of:

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

- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we and/or our collaborators may develop;
- the effect of competing technological and market developments; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Any failure to complete the development of our product candidates in a timely manner could have a material adverse effect on our operations, financial position and liquidity. A discussion of the risks and uncertainties associated with completing our projects on schedule, or at all, and some consequences of failing to do so, are set forth under Part I, Item 1A "Risk Factors" of this Annual Report on Form 10-K.

General and Administrative Expenses

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

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. 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 at the end of this Annual Report on Form 10-K, 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"), Statement of Financial Accounting Standards ("SFAS") No. 48, *Revenue Recognition When Right of Return Exists* ("SFAS No. 48"), Emerging Issues Task Force ("EITF") Issue No. 00-21, *Revenue Arrangements with Multiple Deliverable* ("EITF

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

We estimate the performance obligation period to be ten years for our collaboration agreement with Merck and five years for the development of 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 continually monitor these factors for indications of appropriate revisions

We recognize net product sales revenue from sales of FARESTON® less deductions for estimated sales discounts and sales returns. We recognize revenue from product sales when the goods are shipped and title and risk of loss pass to the customer and the other criteria of SAB No. 104 and SFAS No. 48 are satisfied. We account for rebates to certain governmental agencies as a reduction of product sales. We allow customers to return product within a specified time period prior to and subsequent to the product's labeled expiration date. As a result, we estimate an accrual for product returns, which is recorded as a reduction of product sales, based on factors which include historical product returns and estimated product in the distribution channel which is expected to exceed its expiration date. We retained substantially the same wholesale customers of, and the distribution channel that was used by, another pharmaceutical company that distributed FARESTON® for six years prior to our obtaining the rights to market FARESTON® in January 2005. We also obtained historical product return trend information that we continue to update with our own product return data. We estimate the amount of product in the distribution channel which is expected to exceed its expiration date and be returned by the customer by receiving information from our three largest wholesale customers about the levels of FARESTON® inventory held by these customers. These three largest wholesale customers accounted for 93% of our gross product sales of FARESTON® for the year ended December 31, 2007. Based on this information, and other factors, we estimate the number of months of product on hand. At December 31, 2007 and December 31, 2006, our accrual for product returns was $324,000 and $415,000, respectively. If actual future results are different than our estimates, we may need to adjust our estimated accrual for product returns, which could have a material effect on our financial results in the period of the adjustment.

Research and Development Expenses

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

Patent Costs

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

Share-Based Compensation

We have stock option plans that provide for the purchase of our common stock by certain of our employees and directors. Effective January 1, 2006, we adopted SFAS 123(R), *Share-Based Payment* ("SFAS 123R"), and began recognizing compensation expense for our share-based payments based on the fair value of the awards. Share-based payments include stock option grants under our stock option plans. 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, A*ccounting for Stock Issued to Employees* ("APB 25") and SFAS No.123, *Accounting for Share-based Compensation* ("SFAS 123"). Since we adopted SFAS 123R under the modified prospective and the prospective transition methods, results from prior periods have not been restated.

The determination of the fair value of share-based payment awards on the date of grant include the expected life of the award, the expected stock price volatility over the expected life of the awards, expected dividend yield, and risk-free interest rate. We estimate the expected life of options by calculating the average of the vesting term and contractual term of the options, as allowed by SAB 107. We estimate the expected stock price volatility based on the historical volatility of our common stock. Prior to 2007, we estimated the stock price volatility based on the average expected stock price volatility of other publicly traded biopharmaceutical companies as we believed that it was the best indicator of future volatility, since we had less than two years of our own historical stock price volatility. The risk-free interest rate is determined using U.S. Treasury rates where the term is consistent with the expected life of the stock options. Expected dividend yield is not considered as we have not made any dividend payments and have no plans of doing so in the foreseeable future. Forfeitures are estimated at the time of valuation and reduce expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate.

Total share-based compensation expense for the year ended December 31, 2007 was $2.2 million, of which $1.0 million and $1.2 million were recorded in the statements of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the years ended December 31, 2006 and 2005 was $1.4 million and $819,000, 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 $183,000, $140,000 and $180,000 for the years ended December 31, 2007, 2006 and 2005, respectively. On the date of adoption of SFAS 123R, the unamortized balance of deferred stock compensation of $1.7 million was reduced to zero with an offsetting adjustment to additional paid-in capital. At December 31, 2007, the total compensation cost related to non-vested awards not yet recognized was approximately $5.0 million with a weighted average expense recognition period of 2.08 years.

Income Taxes

We account for deferred taxes by recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. This valuation allowance is estimated by management based on our projected future taxable income. The estimate of future taxable income is highly subjective. We have incurred losses since inception and anticipate that we will incur continued losses for the foreseeable future. However, these assumptions may be inaccurate, and unanticipated events and circumstances may occur in the future. To the extent actual results differ from these estimates, our future results of operations may be affected. At December 31, 2007 and 2006, net of the valuation allowance, the net deferred tax assets were reduced to zero.

Intangible Assets

We account for our intangible assets in accordance with SFAS No. 142, *Goodwill and Other Intangible Assets*, which requires that purchased intangible assets with finite lives be amortized over their estimated economic lives. Our purchased intangible assets, license fees, represent license fees paid to Orion in connection with entering into an amended and restated license and supply agreement and to UTRF in connection with entering into amended and restated license agreements. The Orion license fee is being amortized on a straight-line basis over the term of the

agreement which we estimate to be 16 years. The UTRF license fees are being amortized on a straight-line basis over the term of the agreements which we estimate to be approximately 14 years and 11.5 years. In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets and for Long-Lived Assets to be Disposed of*, we review long-lived assets for impairment whenever events or changes in facts and circumstances, both internally and externally, may indicate that an impairment of long-lived assets held for use are present. An impairment loss would be recognized when estimated future cash flows is less than the carrying amount. The cash flow estimates would be based on management's best estimates, using appropriate and customary assumptions and projections at the time.

Recent Accounting Pronouncements

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

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ("SFAS 157"), which defines fair value, establishes a framework for measuring fair value under GAAP and expands disclosures about fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. The FASB has deferred the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis. We do not expect the adoption of SFAS 157 will have a material impact on our financial position or results of operations.

In June 2007, the Emerging Issues Task Force issued EITF Issue No. 07-03, *Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development* ("EITF 07-03"). EITF 07-03 concludes that nonrefundable advance payments for future research and development activities should be deferred and capitalized and recognized as expense as the related goods are delivered or the related services are performed. EITF 07-03 is effective for fiscal years beginning after December 15, 2007. We do not expect the adoption of EITF 07-03 will have a material impact on our financial position or results of operations.

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

Results of Operations

Comparison of Years Ended December 31, 2007 and December 31, 2006

Revenues. Revenues for the year ended December 31, 2007 were $7.1 million as compared to $7.5 million for the same period of 2006. Revenues for the year ended December 31, 2007 included net sales of FARESTON® marketed for the treatment of metastatic breast cancer and collaboration income from Ipsen and Merck. During the years ended December 31, 2007 and 2006, FARESTON® net sales were $1.1 million and $1.4 million, respectively, while costs of products sales were $621,000 and $773,000, respectively. The 21% decrease in net sales of FARESTON® for the year ended December 31, 2007, as compared to the same period of 2006, was due to a decrease in sales volume of 42%, which was offset by a 7% increase in sales price and a reduction in the provision for product returns. We expect FARESTON® sales will continue to decline in future periods, particularly as a result of aromatase inhibitors continuing to capture breast cancer market share from SERMs, including FARESTON®. Collaboration income was $6.1 million for the year ended December 31, 2007, of which $5.9 million and $198,000

was from Ipsen and Merck, respectively. For the year ended December 31, 2006, collaboration income was $6.1 million, of which $4.3 million and $1.8 million was from Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, and Ipsen, respectively. In December 2006, we reacquired full rights to develop and commercialize andarine and all backup compounds previously licensed to Ortho Biotech, and our joint collaboration and license agreement with Ortho Biotech was terminated by mutual agreement of the parties. In connection with the termination of this agreement, we recognized the associated $3.1 million balance of deferred revenue as additional collaboration revenue for the year ended December 31, 2006.

Research and Development Expenses. Research and development expenses increased 13.6% to $38.5 million for the year ended December 31, 2007 from $33.9 million for the year ended December 31, 2006. The following table identifies the research and development expenses for certain of our product candidates, as well as research and development expenses pertaining to our other research and development efforts for each of the periods presented. Included in "Other research and development" is a sublicense royalty of approximately $1.9 million due to UTRF as a result of our collaboration with Merck. Research and development spending for past periods is not indicative of spending in future periods.

Program	Product Candidate/ Indication	Years Ended December 31, 2007	2006	Increase (Decrease)
		(in thousands)		
SERM	**ACAPODENE®** **80 mg** Multiple serious side effects of ADT	$ 9,422	$ 8,446	$ 976
	ACAPODENE® **20 mg** Prevention of prostate cancer in high risk men with high grade PIN	8,694	10,737	(2,043)
SARM	**Ostarine™** Cancer cachexia	7,056	6,723	333
	GTx-838	1,747	—	1,747
Other research and development		11,589	7,991	3,598
Total research and development expenses		$ 38,508	$ 33,897	$ 4,611

General and Administrative Expenses. General and administrative expenses increased 18.4% to $13.5 million for the year ended December 31, 2007 from $11.4 million for the year ended December 31, 2006. The increase of approximately $2.1 million was primarily the result of increased personnel related expenses of approximately $1.0 million, an increase in marketing and promotional expenses of $757,000 and an increase in intellectual property and other legal expenses of $730,000.

Interest Income. Interest income increased to $5.1 million for the year ended December 31, 2007 from $3.0 million for the year ended December 31, 2006. The increase of approximately $2.1 million was attributable to higher average interest rates in addition to higher average cash and cash equivalents balances during the year ended December 31, 2007, as compared to the prior year.

Comparison of Years Ended December 31, 2006 and December 31, 2005

Revenues. Revenues for the year ended December 31, 2006 were $7.5 million as compared to $3.8 million for the same period of 2005. Revenues for the year ended December 31, 2006 included net sales of FARESTON® of $1.4 million while cost of product sales was $773,000. Collaboration income for the year ended December 31, 2006 was $6.1 million, which consisted of $4.3 million from Ortho Biotech and $1.8 million from Ipsen. During the year ended December 31, 2005, FARESTON® net sales were $2.4 million while cost of product sales was $1.6 million. Revenues for the year ended December 31, 2005 also included collaboration income of $1.3 million from Ortho Biotech.

Research and Development Expenses. Research and development expenses increased 9.7% to $33.9 million for the year ended December 31, 2006 from $30.9 million for the year ended December 31, 2005. The following table identifies the research and development expenses for certain of our product candidates, as well as research and development expenses pertaining to our other research and development efforts for each of the periods presented.

Program	Product Candidate/ Indication	Year Ended December 31, 2006	Year Ended December 31, 2005	Increase (Decrease)
		(in thousands)		
SERM	**ACAPODENE®** **80 mg** Multiple serious side effects of ADT	$ 8,446	$ 11,720	$ (3,274)
	ACAPODENE® **20 mg** Prevention of prostate cancer in high risk men with high grade PIN	10,737	7,615	3,122
SARM	**Ostarine™** Cancer cachexia	6,723	4,750	1,973
Other research and development		7,991	6,838	1,153
Total research and development expenses		$ 33,897	$ 30,923	$ 2,974

General and Administrative Expenses. General and administrative expenses increased 16% to $11.4 million for the year ended December 31, 2006 from $9.8 million for the year ended December 31, 2005. The increase of approximately $1.6 million was primarily due to an increase in personnel related expenses, share-based compensation expense as a result of the adoption of SFAS No. 123R effective January 1, 2006 and foreign currency transactions losses related to our Ipsen collaboration.

Interest Income. Interest income increased to approximately $3.0 million for the year ended December 31, 2006 from $1.7 million for the year ended December 31, 2005. The increase was the result of higher average interest rates in addition to higher average cash and cash equivalents balances during the year ended December 31, 2006, as compared to the prior year.

Liquidity and Capital Resources

Through December 31, 2007, we financed our operations and internal growth through private placements of preferred stock and common stock, the proceeds of our public offerings of our common stock, and proceeds from our collaborations. We have incurred significant losses since our inception in 1997 as we have devoted substantially all of our resources to research and development, including our clinical trials. As of December 31, 2007, we had an accumulated deficit of $270.1 million, of which $96.3 million related to non-cash dividends and adjustments to the preferred stock redemption value. Our accumulated deficit resulted primarily from:

- Our research and development activities associated with:
  - ACAPODENE® 80 mg for the treatment of multiple serious side effects of ADT, including two Phase II clinical trials and a pivotal Phase III clinical trial;
  - ACAPODENE® 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, including our Phase IIb clinical trial and an ongoing pivotal Phase III clinical trial;
  - Preclinical and clinical development of Ostarine™, GTx-838, and our other SARM compounds, which are being developed for the treatment of muscle wasting and/or bone loss;
- General and administrative expenses; and
- Non-cash dividends and adjustments to the preferred stock redemption value of $96.3 million related to our cumulative redeemable convertible preferred 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, expand our sales and marketing capabilities and grow our operations.

At December 31, 2007, we had cash, cash equivalents and short-term investments of $110.0 million, compared to $119.6 million at December 31, 2006 and $74.0 million at December 31, 2005. On October 17, 2005, we completed an underwritten public offering of 6,325,000 shares of common stock at an offering price to the public of $7.80 per share resulting in net proceeds of approximately $45.7 million. On December 18, 2006, we completed a public offering of 3,799,600 shares of common stock at an offering price to the public of $16.00 per share resulting in net proceeds of approximately $57.4 million. On December 18, 2007, we completed a private placement of 1,285,347 shares of common stock to Merck and received proceeds of approximately $30.0 million.

Net cash used in operating activities was $37.6 million, $11.5 million and $34.8 million for the years ended December 31, 2007, 2006 and 2005, respectively. The use of cash in all periods resulted primarily from funding our net losses. Net cash used in operating activities for the year ended December 31, 2006 was reduced by the receipt of approximately $27.1 million in connection with our collaboration with Ipsen. Cash requirements for operating activities are expected to increase in future periods, due in part to costs related to the continuation of two pivotal Phase III clinical trials for ACAPODENE® as well as the clinical and preclinical development of Ostarine™ and our other product candidates.

Net cash used in investing activities for the year ended December 31, 2007 was $1.7 million and was primarily for the purchase of research and development equipment, office equipment, computer equipment and software and the purchase of intangible assets (license fees) of $513,000. Net cash used in investing activities for 2006 was $578,000 and was primarily for the purchase of research and development equipment, computer equipment and software. Net cash used in investing activities in 2005 was $1.4 million and was primarily for the purchase of research and development equipment, leasehold improvements, office and computer equipment, software and furniture and fixtures. We currently expect to make expenditures for property and equipment of up to $3.3 million for the year ended December 31, 2008.

Net cash provided by financing activities was $20.0 million, $57.6 million and $45.7 million for the years ended December 31, 2007, 2006 and 2005, respectively. Net cash provided by financing activities for the year ended December 31, 2007 reflected the proceeds from our private placement of 1,285,347 shares of common stock to Merck on December 18, 2007 and proceeds of $826,000 from the exercise of employee stock options. Net cash provided by financing activities for the year ended December 31, 2006 reflected net proceeds from our follow-on

public offering, which closed on December 18, 2006. Net cash provided by financing activities for the year ended December 31, 2005 reflected net proceeds from our follow-on offering which closed October 17, 2005.

We estimate that our current cash resources, including the $40.0 million license fee we received from Merck in January 2008, interest on these funds and product revenue from the sale of FARESTON®, will be sufficient to meet our projected operating requirements through at least the first quarter of 2009. This estimate does not include funding from milestone payments that we may receive under our existing collaborations with Ipsen and Merck, nor does it include any funding that we may receive under potential future collaboration arrangements with other pharmaceutical companies or potential future issuances and sales of our securities.

Our forecast of the period of time through which our financial resources will be adequate to support our projected operating requirements is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed under Item 1A “Risk Factors” section of this annual report on Form 10-K. 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 and commercialization 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, other research and development activities and commercialization. Our future funding requirements will depend on many factors, including:

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

Until we can generate a sufficient amount of product revenue, we expect to finance future cash needs through public or private equity offerings, debt financings or collaboration and licensing arrangements, such as our arrangements with Merck and Ipsen, as well as through interest income earned on cash balances and short-term investments and revenues from the sale of FARESTON®. With the exception of payments that we may receive under our collaborations with Merck and Ipsen, we do not currently have any commitments for future external funding. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through

collaboration and licensing arrangements, such as our arrangements with Merck and Ipsen, it may be necessary to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or to obtain funds through collaborations with others that are on unfavorable terms or that may require us to relinquish rights to some of our technologies or product candidates that we would otherwise seek to develop on our own.

We have no long-term debt. At December 31, 2007, we had contractual obligations as follows:

	Payment Due by Period (in thousands)				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Capital lease obligations	$ 10	$ 5	$ 5	$ —	$ —
Operating lease obligations	2,198	1,141	1,057	—	—
Purchase obligations	280	280	—	—	—
Total	$ 2,488	$ 1,426	$ 1,062	$ —	$ —

Our long-term commitments under the operating leases shown above consist of payments relating to a lease for laboratory and office space at 3 North Dunlap Street, Memphis, Tennessee and a lease for office space at 50 South Third Street, Memphis, Tennessee. Our lease agreement for the premises located at 3 North Dunlap Street expires on December 31, 2008, unless we exercise options to extend the lease for an additional two years. Our lease agreement for the premises located at 50 South Third Street expires on April 30, 2015, but we have the ability to cancel the lease beginning on December 31, 2010. The table above excludes contingent payments under the license agreements to which we are a party.

ITEM 7A. 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 ten percent in the average yield earned on our cash equivalents and short-term investments would have resulted in a decrease in our interest income of approximately $500,000 for the year ended December 31, 2007.

Our exposure to credit risk relates to our investment in money market funds and in Bank of America Corporation's Columbia Strategic Cash Portfolio (the "Fund"). In December 2007, Columbia Management Group, LLC, the Fund's manager, determined that the assets of the Fund had declined in fair value and the Fund would no longer seek to maintain a net asset value ("NAV") of one dollar per share. As a result, the Fund's NAV began to fluctuate based on changes in the market values of the assets owned by the Fund. The Fund ceased accepting orders for new shares and began an orderly liquidation of Fund assets for distribution to its shareholders. At December 31, 2007, the Fund's NAV was $0.9874 per share. For the year ended December 31, 2007, we recognized a loss on our investment in the Fund of approximately $137,000. If the current credit environment continues to deteriorate, our investments in money market funds could become impaired and our investment in the Columbia Strategic Cash Portfolio could suffer additional losses, which would adversely impact our financial results.

We operate primarily in the United States. However, some of our clinical trial sites are located in 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 our collaboration and license agreement with Ipsen, Ipsen is required to pay us €1.0 million as additional license fees over the next two years. We are also entitled to receive from Ipsen up to €39.0 million in milestone payments subject to 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 if and to the extent we are able to commercialize ACAPODENE® 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 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our financial statements and the reports of our independent registered public accounting firm are included in this Annual Report on Form 10-K beginning on page F-1. The index to these reports and our financial statements is included in Part IV, Item 15 below.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

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

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

Management's Report on Internal Control over Financial Reporting

We, as management of GTx, Inc., are responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Securities Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with United States generally accepted accounting principles. Any system of internal control, no matter how well designed, has inherent limitations, including the possibility that a control can be circumvented or overridden and misstatements due to error or fraud may occur and not be detected. Also, because of changes in conditions, internal control effectiveness may vary over time. Accordingly, even an effective system of internal control will provide only reasonable assurance that the objectives of the internal control system are met.

Under the supervision and with the participation of management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2007 using the criteria for effective internal control over financial reporting as described in "Internal Control — Integrated Framework," issued by the Committee of Sponsoring Organization of the Treadway Commission. Based on this evaluation, we concluded that, as of December 31, 2007, our internal control over financial reporting was effective. The effectiveness of our internal control over financial reporting has been audited by Ernst & Young LLP, an independent registered public accounting firm.

Attestation Report of the Independent Registered Public Accounting Firm

Ernst & Young LLP, an independent registered public accounting firm, has issued an audit report on the effectiveness of our internal control over financial reporting, which report is included elsewhere herein.

Changes in Internal Control over Financial Reporting

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

ITEM 9B. OTHER INFORMATION

On December 17, 2007, we entered into a sublease agreement (the "Sublease") with ESS SUSA Holdings, LLC ("Landlord") for the lease of premises containing approximately 30,748 square feet of office space (the "Leased Space") located at 50 South Third Street, Memphis, Tennessee (the "Premises"). The term of the Sublease will continue through April 30, 2015, subject to our option to cancel the Sublease beginning December 31, 2010 upon six months prior written notice and subject to the early cancellation payments as indicated in the table below:

Sublease Cancellation Date	Early Cancellation Payment
12/31/2010	$150,000
12/31/2011	$ 75,000
12/31/2012	$ 50,000
12/31/2013	$ 50,000

Rent payments under the Sublease commenced on January 1, 2008. The monthly base rent during the term of the Sublease (the "Base Rent") is as follows:

Period	Base Rent[1]
1/1/2008-6/30/2008	$17,936 per month
7/1/2008-12/31/2008	$35,873 per month
1/1/2009-12/31/2009	$37,154 per month
1/1/2010-12/31/2010	$38,435 per month
1/1/2011-12/31/2011	$40,997 per month
1/1/2012-12/31/2012	$43,560 per month
1/1/2013-12/31/2013	$44,841 per month
1/1/2014-4/30/2015	$46,122 per month

1 Base Rent under the Sublease is subject to certain upward operating expense adjustments allocable to the Leased Space.

Under the terms of the Sublease, the Landlord granted to us a right of first refusal to lease additional office space in the Premises. The Sublease also contains customary operating lease provisions and is subject to certain terms of the lease agreement between the lessor of the Premises and Landlord, as tenant thereunder. The foregoing is only a brief description of the material terms of the Sublease, does not purport to be a complete statement of the rights and obligations of the parties under the Sublease, and is qualified in its entirety by reference to the Sublease that is filed as Exhibit 10.46 this Annual Report on Form 10-K.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because we will file our definitive proxy statement for our 2008 Annual Meeting of Stockholders with the U.S. Securities and Exchange Commission pursuant to Regulation 14A (the "2008 Proxy Statement") not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information included in the 2008 Proxy Statement is incorporated herein by reference.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

(1) The information required by this Item concerning our directors and nominees for director, including information with respect to our audit committee and audit committee financial experts, may be found under the section entitled "Proposal No. 1 — Election of Directors" and "Additional Information About the Board of Directors" appearing in the 2008 Proxy Statement. Such information is incorporated herein by reference.

(2) The information required by this Item concerning compliance with Section 16(a) of the Securities Exchange Act of 1934 may be found in the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" appearing in the 2008 Proxy Statement. Such information is incorporated herein by reference.

(3) The information required by this Item concerning our executive officers is set forth in the section entitled "Executive Officers of Registrant" in Part I, Item 1 of this Form 10-K and is incorporated herein by reference.

(4) Our Board has adopted a Code of Business Conduct and Ethics applicable to all officers, directors and employees as well as Guidelines on Governance Issues. These documents are available on our website (www.gtxinc.com) under "About GTx" at "Corporate Governance." We will provide a copy of these documents to any person, without charge, upon request, by writing to us at GTx, Inc. Director, Corporate Communications and Financial Analysis, 3 North Dunlap Street, Memphis, Tennessee 38163. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of the Code of Business Conduct and Ethics by posting such information on our website at the address and the locations specified above.

ITEM 11. EXECUTIVE COMPENSATION

(1) The information required by this Item concerning director and executive compensation is incorporated herein by reference to the information from the 2008 Proxy Statement under the sections entitled "Compensation Discussion and Analysis," "Executive Compensation" and "Director Compensation."

(2) The information required by this Item concerning Compensation Committee interlocks and insider participation is incorporated herein by reference to the information from the 2008 Proxy Statement under the section entitled "Compensation Committee Interlocks and Insider Participation."

(3) The information required by this Item concerning our Compensation Committee's review and discussion of our Compensation Discussion and Analysis is incorporated herein by reference to the information from the 2008 Proxy Statement under the section entitled "Compensation Committee Report."

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

(1) The information required by this Item with respect to security ownership of certain beneficial owners and management is incorporated herein by reference to the information from the 2008 Proxy Statement under the section entitled "Security Ownership of Certain Beneficial Owners and Management."

(2) The information required by this Item with respect to securities authorized for issuance under our equity compensation plans is incorporated herein by reference to the information from the 2008 Proxy Statement under the section entitled "Equity Compensation Plan Information."

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

(1) The information required by this Item concerning related party transactions is incorporated herein by reference to the information from the 2008 Proxy Statement under the section entitled "Certain Relationships and Related Party Transactions."

(2) The information required by this Item concerning director independence is incorporated herein by reference to the information from the 2008 Proxy Statement under the section entitled "Additional Information about the Board of Directors — Director Independence."

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated herein by reference to the information from the 2008 Proxy Statement under the section entitled "Proposal No. 2 — Ratification of Appointment of Independent Registered Public Accounting Firm."

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Index to Financial Statements

(a)(2) Financial statement schedules are omitted as they are not applicable.

(a)(3) See 15(b) below.

(b) Exhibits

Number	Description
3.1	Restated Certificate of Incorporation of GTx, Inc. (1)
3.2	Amended and Restated Bylaws of GTx, Inc.(2)
4.1	Reference is made to Exhibits 3.1 and 3.2
4.2	Specimen of Common Stock Certificate(3)
4.3	Amended and Restated Registration Rights Agreement between Registrant and Oracle Partners, L.P. dated August 7, 2003(3)
4.4*	Amended and Restated Registration Rights Agreement between Registrant and J. R. Hyde, III dated August 7, 2003(3)
4.5	Consent, Waiver and Amendment between the Registrant and Oracle Partners, L.P., Oracle Investment Management, Inc. and Oracle Institutional Partners, L.P. dated November 29, 2007(4)
4.6	Consent, Waiver and Amendment between Registrant and J. R. Hyde, III and Pittco Associates, L.P. dated December 3, 2007(4)
4.7	Registration Rights Agreement between Registrant and Merck & Co., Inc. dated December 18, 2007(5)
10.1*	Genotherapeutics, Inc. 1999 Stock Option Plan(3)
10.2*	GTx, Inc. 2000 Stock Option Plan(3)
10.3*	GTx, Inc. 2001 Stock Option Plan(3)
10.4*	GTx, Inc. 2002 Stock Option Plan(3)
10.5*	2004 Equity Incentive Plan and Form of Stock Option Agreement(3)
10.6	Reserved
10.7*	Directors' Deferred Compensation Plan(6)
10.8*	Employment Agreement dated October 1, 2003, between Registrant and Mitchell S. Steiner, M.D.(3)
10.9*	Employment Agreement dated October 1, 2003, between Registrant and Marc S. Hanover(3)
10.10*	Employment Agreement dated October 1, 2003, between Registrant and Mark E. Mosteller(3)
10.11*	Employment Agreement dated October 1, 2003, between Registrant and Henry P. Doggrell(3)
10.12*	Form of Indemnification Agreement(3)
10.13	Lease Agreement, dated March 7, 2001, between The University of Tennessee and TriStar Enterprises, Inc.(3)
10.14	Sublease Agreement dated October 1, 2000, as amended, between Registrant and TriStar Enterprises, Inc.(3)

Number	Description
10.15†	Amended and Restated License and Supply Agreement dated October 22, 2001, between Registrant and Orion Corporation(7)
10.16†	Amendment No. 1 to the License and Supply Agreement dated March 5, 2003, between Registrant and Orion Corporation(3)
10.20	Reserved
10.21	Reserved
10.22	Reserved
10.23†	Amendment No. 2 to the License and Supply Agreement dated December 29, 2003, between Registrant and Orion Corporation(3)
10.24††	Purchase Agreement dated December 13, 2004, between Registrant and Orion Corporation(8)
10.25††	Amended and Restated License and Supply Agreement effective January 1, 2005, between Registrant and Orion Corporation(9)
10.26	Sublease Agreement dated April 1, 2005, as amended, between Registrant and TriStar Enterprises, Inc.(10)
10.27*	Employment Agreement dated April 12, 2007, between Registrant and James T. Dalton(11)
10.28*	2007 Compensation Information for Registrant's Executive Officers(12)
10.29*	Employment Agreement dated August 26, 2005, between Registrant and K. Gary Barnette(13)
10.30*	Employment Agreement dated August 26, 2005, between Registrant and Gregory A. Deener(14)
10.31*	Amended and Restated 2004 Non-Employee Directors' Stock Option Plan(15)
10.32††	Amendment dated May 23, 2006 to the Amended and Restated License and Supply Agreement effective January 1, 2005, between Registrant and Orion Corporation(16)
10.33††	Amendment dated June 30, 2006 to the Amended and Restated License and Supply Agreement effective January 1, 2005, between Registrant and Orion Corporation(17)
10.34*	Form of Stock Option Agreement under the Amended and Restated 2004 Non-Employee Directors' Stock Option Plan(18)
10.35††	Partial Assignment Agreement among Registrant, Orion Corporation and Ipsen Limited dated September 7, 2006(19)
10.36†	Collaboration and License Agreement between Registrant and Ipsen Limited dated September 7, 2006(20)
10.37*	Executive Bonus Compensation Plan (21)
10.38*	Employment Agreement dated April 12, 2007, between Registrant and Ronald A. Morton, Jr., M.D. (11)
10.39*	Employment Agreement dated May 15, 2007, between Registrant and Jeff G. Hesselberg(11)
10.40†	Consolidated, Amended, and Restated License Agreement dated July 24, 2007, between Registrant and University of Tennessee Research Foundation(6)
10.41†	Amended and Restated License Agreement dated September 24, 2007, between Registrant and University of Tennessee Research Foundation(6)
10.42	Stock Purchase Agreement, dated November 5, 2007, between the Registrant and Merck & Co., Inc. (22)
10.43†††	Exclusive License and Collaboration Agreement between the Registrant and Merck & Co., Inc. dated November 5, 2007
10.44*	2008 Compensation Information for Registrant's Executive Officers
10.45*	Non-Employee Director Compensation Arrangements
10.46	Sublease Agreement, dated December 17, 2007 by and between the Registrant and ESS SUSA Holdings, LLC
12.1	Statement of Computation of Deficiency of Earnings Available to Cover Fixed Charges
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (included on the signature pages hereto)
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)(23)
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)(23)

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

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

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

* Indicates a management contract or compensation plan or arrangement.

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

(2) Filed as the like numbered Exhibit to the Registrant's Current Report on Form 8-K (File No. 000-50549), filed with the SEC on July 26, 2007, as amended, and incorporated herein by reference.

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

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

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

(6) Filed as the like numbered Exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on November 9, 2007, and incorporated herein by reference.

(7) Filed as the like numbered Exhibit to the Registrant's Annual Report on Form 10-K (File No. 000-50549), filed with the SEC on March 9, 2007, and incorporated herein by reference.

(8) Filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K/A (File No. 000-50549), filed with the SEC on March 7, 2005, and incorporated herein by reference.

(9) Filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K/A (File No. 000-50549), filed with the SEC on March 7, 2005, and incorporated herein by reference.

(10) Filed as Exhibit 10.27 to the Registrant's Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on July 27, 2005, and incorporated herein by reference.

(11) Filed as the like numbered Exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on August 1, 2007, and incorporated herein by reference.

(12) Filed as Exhibit 10.28 to the Registrant's Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on May 7, 2007, and incorporated herein by reference.

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

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

(15) Filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 000-50549), filed with the SEC on April 27, 2006, and incorporated herein by reference.

(16) Filed as Exhibit 10.33 to the Registrant's Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on August 9, 2006, and incorporated herein by reference.

(17) Filed as Exhibit 10.34 to the Registrant's Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on August 9, 2006, and incorporated herein by reference.

(18) Filed as Exhibit 10.35 to the Registrant's Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on August 9, 2006, and incorporated herein by reference.

(19) Filed as Exhibit 10.36 to the Registrant's Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on November 3, 2006, and incorporated herein by reference.

(20) Filed as Exhibit 10.37 to the Registrant's Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on November 3, 2006, and incorporated herein by reference.

(21) Filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 000-50549), filed with the SEC on November 3, 2006, and incorporated herein by reference.

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

(23) This certification accompanies the Form 10-K 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-K), irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

By /s/ Mitchell S. Steiner
Mitchell S. Steiner, M.D., F.A.C.S.
Chief Executive Officer, Vice Chairman and Director
Date: March 11, 2008

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENT, that each person whose signature appears below constitutes and appoints Mitchell S. Steiner and Mark E. Mosteller, and each of them, acting individually, as his attorney-in-fact, each with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

		Date
/s/ J. R. Hyde, III J. R. Hyde, III	Chairman of the Board of Directors	March 11, 2008
/s/ Mitchell S. Steiner Mitchell S. Steiner, M.D., F.A.C.S.	Chief Executive Officer, Vice Chairman and Director	March 11, 2008
/s/ Mark E. Mosteller Mark E. Mosteller, CPA	Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 11, 2008
/s/ Marc S. Hanover Marc S. Hanover	President, Chief Operating Officer and Director	March 11, 2008
/s/ Andrew M. Clarkson Andrew M. Clarkson	Director	March 11, 2008
/s/ J. Kenneth Glass J. Kenneth Glass	Director	March 11, 2008
/s/ Robert W. Karr Robert W. Karr, M.D.	Director	March 11, 2008
/s/ Rosemary Mazanet Rosemary Mazanet, M.D., Ph.D.	Director	March 11, 2008

/s/ John H. Pontius John H. Pontius	Director	March 11, 2008
/s/ Timothy R. G. Sear Timothy R. G. Sear	Director	March 11, 2008
/s/ Michael G. Carter Michael G. Carter, M. D.	Director	March 11, 2008

GTx, Inc.

INDEX TO FINANCIAL STATEMENTS

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

We, as management of GTx, Inc., are responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Securities Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with United States generally accepted accounting principles. Any system of internal control, no matter how well designed, has inherent limitations, including the possibility that a control can be circumvented or overridden and misstatements due to error or fraud may occur and not be detected. Also, because of changes in conditions, internal control effectiveness may vary over time. Accordingly, even an effective system of internal control will provide only reasonable assurance that the objectives of the internal control system are met.

Under the supervision and with the participation of management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2007 using the criteria for effective internal control over financial reporting as described in "Internal Control – Integrated Framework," issued by the Committee of Sponsoring Organization of the Treadway Commission. Based on this evaluation, we concluded that, as of December 31, 2007, our internal control over financial reporting was effective. The effectiveness of our internal control over financial reporting has been audited by Ernst & Young LLP, an independent registered public accounting firm.

/s/ Mitchell S. Steiner
Mitchell S. Steiner, M.D., F.A.C.S.
Vice Chairman and
Chief Executive Officer

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

Memphis, Tennessee
March 6, 2008

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of GTx, Inc.

We have audited GTx, Inc.'s internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). GTx Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, GTx, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on the COSO criteria**.**

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the accompanying balance sheets as of December 31, 2007 and 2006, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2007 of GTx, Inc. and our report dated March 6, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Memphis, Tennessee
March 6, 2008

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of GTx, Inc.

We have audited the accompanying balance sheets of GTx, Inc. as of December 31, 2007 and 2006, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of GTx, Inc. at December 31, 2007 and 2006, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the financial statements, effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123R, *Share-Based Payment*, to account for stock based compensation.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of GTx, Inc.'s internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 6, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Memphis, Tennessee
March 6, 2008

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

	December 31, 2007	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 100,178	$ 119,550
Short-term investments	9,810	—
Accounts receivable, net	117	61
Inventory	78	207
Receivable from collaboration partners	40,719	660
Prepaid expenses and other current assets	1,362	1,222
Total current assets	152,264	121,700
Property and equipment, net	2,308	1,936
Intangible assets, net	4,430	4,226
Other assets	728	1,393
Total assets	$ 159,730	$ 129,255
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,614	$ 1,336
Accrued expenses	6,784	3,149
Deferred revenue – current portion	10,934	5,852
Total current liabilities	19,332	10,337
Deferred revenue, less current portion	61,245	21,554
Capital lease obligation	10	15
Other long-term liability	226	300
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value: 60,000,000 shares authorized; 36,216,263 shares issued and outstanding at December 31, 2007 and 34,822,362 shares issued and outstanding at December 31, 2006	36	35
Additional paid-in capital	349,019	326,793
Accumulated deficit	(270,138)	(229,779)
Total stockholders' equity	78,917	97,049
Total liabilities and stockholders' equity	$ 159,730	$ 129,255

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

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

	Years Ended December 31,		
	2007	2006	2005
Revenues:			
Product sales, net	$ 1,076	$ 1,357	$ 2,445
Collaboration revenue	6,050	6,148	1,337
Total revenues	7,126	7,505	3,782
Costs and expenses:			
Cost of product sales	621	773	1,573
Research and development expenses	38,508	33,897	30,923
General and administrative expenses	13,501	11,352	9,845
Total costs and expenses	52,630	46,022	42,341
Loss from operations	(45,504)	(38,517)	(38,559)
Interest income	5,145	3,007	1,720
Net loss	$ (40,359)	$ (35,510)	$ (36,839)
Net loss per share:			
Basic and diluted	$ (1.16)	$ (1.14)	$ (1.42)
Weighted average shares used in computing net loss per share:			
Basic and diluted	34,940,151	31,150,035	25,982,478

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

GTx, Inc.
STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years Ended December 31, 2007, 2006 and 2005
(in thousands, except share and per share data)

	Stockholders' Equity					
	Common Stock		Deferred Stock Compensation	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at January 1, 2005	24,664,716	$ 25	$ (2,701)	$ 224,015	$ (157,430)	$ 63,909
Issuance of common stock	6,325,000	6	—	45,657	—	45,663
Amortization of stock-based compensation	—	—	487	—	—	487
Exercise of employee stock options	4,251	—	—	27	—	27
Forfeitures of stock-based compensation	—	—	489	(489)	—	—
Directors' deferred compensation	—	—	—	180	—	180
Share-based compensation related to the modification of employee stock options	—	—	—	152	—	152
Net loss and comprehensive loss		—	—		(36,839)	(36,839)
Balances at December 31, 2005	30,993,967	31	(1,725)	269,542	(194,269)	73,579
Issuance of common stock	3,799,600	4	—	57,422	—	57,426
Exercise of employee stock options	28,795	—	—	153	—	153
Directors' deferred compensation	—	—	—	140	—	140
Share-based compensation	—	—	—	1,261	—	1,261
Reversal of deferred stock compensation	—	—	1,725	(1,725)	—	—
Net loss and comprehensive loss	—	—	—	—	(35,510)	(35,510)
Balances at December 31, 2006	34,822,362	35	—	326,793	(229,779)	97,049
Issuance of common stock	1,285,347	1	—	19,176	—	19,177
Exercise of employee stock options	108,554	—	—	826	—	826
Directors' deferred compensation	—	—	—	183	—	183
Share-based compensation	—	—	—	2,041	—	2,041
Net loss and comprehensive loss	—	—	—	—	(40,359)	(40,359)
Balances at December 31, 2007	36,216,263	$ 36	$ —	$ 349,019	$ (270,138)	$ 78,917

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

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

	Years Ended December 31,		
	2007	2006	2005
Cash flows from operating activities:			
Net loss	$ (40,359)	$ (35,510)	$ (36,839)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,150	1,140	1,038
Share-based compensation	2,041	1,261	639
Directors' deferred compensation	183	140	180
Deferred revenue amortization	(6,050)	(6,148)	(1,337)
Foreign currency transaction (gain) loss	(140)	237	—
Loss on retirement of property and equipment	9	—	33
Changes in assets and liabilities:			
Short-term investments	(9,810)	—	—
Accounts receivable, net	(56)	92	(153)
Inventory	129	(72)	313
Receivable from collaboration partners	(39,372)	(2,146)	—
Prepaid expenses and other assets	(21)	419	(93)
Accounts payable	278	(71)	507
Accrued expenses and other long-term liability	3,561	(61)	893
Deferred revenue	50,823	29,259	—
Net cash used in operating activities	(37,634)	(11,460)	(34,819)
Cash flows from investing activities:			
Purchase of property and equipment	(1,223)	(578)	(1,381)
Purchase of intangible assets	(513)	—	—
Net cash used in investing activities	(1,736)	(578)	(1,381)
Cash flows from financing activities:			
Proceeds from issuance of common stock	19,177	57,426	45,663
Proceeds from exercise of employee stock options	826	153	27
Payments on capital lease obligation	(5)	(5)	(4)
Net cash provided by financing activities	19,998	57,574	45,686
Net increase (decrease) in cash and cash equivalents	(19,372)	45,536	9,486
Cash and cash equivalents, beginning of year	119,550	74,014	64,528
Cash and cash equivalents, end of year	$ 100,178	$ 119,550	$ 74,014

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

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

1. Business and Basis of Presentation

Business

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

GTx is developing ACAPODENE® (toremifene citrate), a selective estrogen receptor modulator ("SERM") in two separate clinical programs in men: first, a pivotal Phase III clinical trial for the treatment of multiple serious side effects of androgen deprivation therapy ("ADT") for advanced prostate cancer and second, a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia ("high grade PIN"). GTx has licensed to Ipsen Limited ("Ipsen") exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein, and the Commonwealth of Independent States (collectively, the "European Territory") to develop and commercialize ACAPODENE® and other products containing toremifene for all indications which we have licensed from Orion Corporation ("Orion"). The Company has entered into an exclusive license and collaboration agreement with Merck & Co., Inc. ("Merck") establishing a global strategic collaboration for the discovery, development and commercialization of selective androgen receptor modulators ("SARMs"), including Ostarine™. GTx is currently evaluating Ostarine™ in a Phase II clinical trial for the treatment of muscle loss in patients with cancer, which is known as cancer cachexia.

2. Significant Accounting Policies

Use of Estimates

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

Cash and Cash Equivalents

The Company considers highly liquid investments with initial maturities of three months or less to be cash equivalents.

Short-term Investments

Short-term investments consist of an investment in Bank of America Corporation's Columbia Strategic Cash Portfolio (the "Fund"). In December 2007, Columbia Management Group, LLC, the Fund's manager, determined that the assets of the Fund had declined in fair value and the Fund would no longer seek to maintain a net asset value ("NAV") of one dollar per share. As a result, the Fund's NAV began to fluctuate based on changes in the market values of the assets owned by the Fund. The Fund ceased accepting orders for new shares and began an orderly liquidation of Fund assets for distribution to its shareholders. The Company, therefore, reclassified this investment to short-term investments from cash equivalents. At December 31, 2007, the Fund's NAV was $0.9874 per share. For the year ended December 31, 2007, the Company recognized a loss on its investment in the Fund of approximately $137.

The Company has classified this investment as trading, in accordance with Statement of Financial Accounting Standards ("SFAS") No. 115, *Accounting for Certain Investments in Debt and Equity Securities.* Accordingly, this investment is carried at fair value and all unrealized gains and losses are included in the statement of operations.

GTx, Inc.
NOTES TO FINANCIAL STATEMENTS
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Inventory

Inventory consists of FARESTON® tablets that are manufactured by Orion and delivered to the Company as finished goods. Inventory is stated at the lower of cost (first-in, first-out method) or market.

Property and Equipment

Property and equipment is stated at cost. Amortization of leasehold improvements is recognized over the shorter of the estimated useful life of the leasehold improvement or the lease term. Depreciation is computed using the straight-line method over the estimated useful lives as follows:

Laboratory and office equipment	3 to 5 years
Leasehold improvements	3 to 6 years
Furniture and fixtures	5 years
Computer equipment and software	3 years

Intangible Assets

The Company accounts for its intangible assets in accordance with SFAS No.142, *Goodwill and Other Intangible Assets*, which requires that purchased intangible assets with finite lives be amortized over their estimated economic lives. The Company's intangible assets consist of license fees and represent the value of each license acquired by the Company pursuant to the agreements described in Note 6. The license fees are being amortized on a straight-line basis over the respective terms of the agreements.

Impairment of Long-Lived Assets

In accordance with SFAS No.144, *Accounting for the Impairment or Disposal of Long-Lived Assets and for Long-Lived Assets to be Disposed of*, the Company reviews long-lived assets for impairment whenever events or changes in facts and circumstances, both internally and externally, may indicate that an impairment of long-lived assets held for use are present. An impairment loss would be recognized when estimated future cash flows is less than the carrying amount. The cash flow estimates would be based on management's best estimates, using appropriate and customary assumptions and projections at the time.

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, which include cash, cash equivalents, short-term investments, accounts receivable and accounts payable approximate their fair values.

Concentration of Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents, short-term investments and accounts receivable. The Company has established guidelines relating to diversification and maturities of its cash equivalents and short-term investments which are designed to manage risk. The Company's cash equivalents consist of bank deposits, certificates of deposit and money market funds. Bank deposits may at times be in excess of FDIC insurance limits. The Company's short-term investments consist of an investment in Bank of America Corporation's Columbia Strategic Cash Portfolio as discussed in *Short-term Investments* in Note 2.

GTx, Inc.
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Three wholesale drug distributors individually comprised 51%, 35% and 8%, respectively, of the Company's accounts receivable as of December 31, 2007. These three distributors represented 33%, 38% and 22%, respectively, of the Company's gross product sales for the year ended December 31, 2007.

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 SFAS No. 48, *Revenue Recognition When Right of Return Exists*, are satisfied. The Company accounts for rebates to certain governmental agencies as a reduction of product sales. The Company allows customers to return product within a specified time period prior to and subsequent to the product's labeled expiration date. The Company estimates an accrual for product returns, which is recorded as a reduction of product sales, based on factors which include historical product returns and estimated product in the distribution channel which is expected to exceed its expiration date. At December 31, 2007 and 2006, the Company's accrual for product returns was $324 and $415, respectively. If actual future results are different than the Company's estimates, the Company may need to adjust its estimated accrual for product returns, which could have a material effect on results of operations in the period of the adjustment.

Collaboration revenue consists of non-refundable upfront payments and license fees associated with the Company's collaboration and license agreements discussed in Note 8. The Company recognizes this revenue in accordance with SAB No. 104, Emerging Issues Task Force ("EITF") Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* ("EITF 00-21") and EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent* ("EITF 99-19"). Accordingly, revenues from licensing agreements are recognized based on the performance requirements of the agreement. The Company analyzes agreements with multiple element arrangements to determine whether the deliverables under the agreement, including license and performance obligations such as joint steering committee participation and research and development activities, can be separated or whether all of the deliverables must be accounted for as a single unit of accounting in accordance with EITF 00-21. For these arrangements, the Company generally is not able to identify evidence of fair value for the undelivered elements and therefore recognizes any consideration for a single unit of accounting in the same manner as revenue is recognized for the final deliverable, which is generally ratable over the performance period. The performance period is estimated at the inception of the agreement and is reevaluated at each reporting period. Cost reimbursements for research and development activities are recognized as collaboration revenue if the provisions of EITF 99-19 are met, the amounts are determinable and collection of the related receivable is reasonably assured. Revenues from milestone payments for which the Company has no continuing performance obligations are recognized upon achievement of the performance milestone, as defined in the related agreement, provided the milestone is substantive and a culmination of the earnings process has occurred. Performance obligations typically consist of significant milestones in the development life cycle of the related products and technology, such as initiation of clinical trials, filing for approval with regulatory agencies and approvals by regulatory agencies.

Research and Development Costs

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

Patent Costs

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

GTx, Inc.
NOTES TO FINANCIAL STATEMENTS
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Income Taxes

The Company accounts for deferred taxes by recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. Accordingly, at December 31, 2007 and 2006, net of the valuation allowance, the net deferred tax assets were reduced to zero.

Stock Options

The Company has stock option plans that provide for the purchase of the Company's common stock by certain of its employees and directors. Effective January 1, 2006, the Company adopted SFAS No. 123(R), *Share-Based Payment* ("SFAS 123R") and began recognizing compensation expense for its share-based payments based on the fair value of the awards. See Note 3 for further discussion.

Deferred Stock Compensation

In anticipation of the Company's initial public offering on February 6, 2004, the Company determined that, for financial reporting purposes, the estimated value of its common stock was in excess of the exercise price for stock options issued to employees from June 30, 2003 to December 31, 2003. Accordingly, the Company recorded non-cash deferred stock-based compensation of $4,055, and amortized the related expense on a straight-line basis over the estimated service period, which was generally five years. The Company recorded amortization of deferred stock compensation of $487 for year ended December 31, 2005. At December 31, 2005, the Company had approximately $1,725 of deferred stock-based compensation to be amortized over the remaining vesting periods of the related stock options. At January 1, 2006, upon adoption of SFAS 123R, the unamortized balance was reduced to zero with an offsetting adjustment to additional paid-in capital.

Basic and Diluted Net Loss Per Share

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

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

GTx, Inc.
NOTES TO FINANCIAL STATEMENTS
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The following table sets forth the computation of the Company's basic and diluted net loss per share for the years ended December 31, 2007, 2006 and 2005:

	Years Ended December 31,		
	2007	2006	2005
Basic and diluted net loss per share			
Numerator:			
Net loss	$ (40,359)	$ (35,510)	$ (36,839)
Denominator:			
Common stock outstanding at beginning of period	34,822,362	30,993,967	24,664,716
Issuance of common stock on a weighted average basis	49,301	145,738	1,316,986
Exercise of employee stock options on a weighted average basis	68,488	10,330	776
Weighted average shares used in computing basic and diluted net loss per share	34,940,151(1)	31,150,035(2)	25,982,478(3)
Basic and diluted net loss per share	$ (1.16)	$ (1.14)	$ (1.42)

(1) The weighted average shares used in computing basic and diluted net loss per share for the year ended December 31, 2007 included 49,301 shares, which represents the weighted average effect during the period of the Company's issuance of 1,285,347 shares of common stock to Merck on December 18, 2007. At December 31, 2007, the Company had outstanding 36,216,263 shares of common stock.

(2) The weighted average shares used in computing basic and diluted net loss per share for the year ended December 31, 2006 included 145,738 shares, which represents the weighted average effect during the period of the Company's issuance of 3,799,600 shares of common stock on December 18, 2006.

(3) The weighted average shares used in computing basic and diluted net loss per share for the year ended December 31, 2005 included 1,316,986 shares, which represents the weighted average effect during the period of the Company's issuance of 6,325,000 shares of common stock on October 17, 2005.

Weighted average options outstanding to purchase shares of common stock of 1,835,743, 1,462,842, and 1,244,232 were excluded from the calculation of diluted net loss per share for the years ended December 31, 2007, 2006 and 2005, respectively, as inclusion of the options would have an anti-dilutive effect on the net loss per share for the periods.

Comprehensive Loss

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

Reclassification

The prior period computer software balance of $488 has been reclassified from intangible assets to property and equipment in order to conform to the current period presentation. In addition, the 2006 and 2005 computer software purchases of $240 and $446, respectively, as reported in the statements of cash flows for the respective periods, have been reclassified from purchase of intangible assets to purchase of property and equipment.

GTx, Inc.
NOTES TO FINANCIAL STATEMENTS
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Recent Accounting Pronouncements

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

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ("SFAS 157"), which defines fair value, establishes a framework for measuring fair value under GAAP and expands disclosures about fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. The FASB has deferred the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis. The Company does not expect the adoption of SFAS 157 will have a material impact on its financial position or results of operations.

In June 2007, the Emerging Issues Task Force issued EITF Issue No. 07-03, *Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development* ("EITF 07-03"). EITF 07-03 concludes that nonrefundable advance payments for future research and development activities should be deferred and capitalized and recognized as expense as the related goods are delivered or the related services are performed. EITF 07-03 is effective for fiscal years beginning after December 15, 2007. The Company does not expect the adoption of EITF 07-03 will have a material impact on its financial position or results of operations.

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

3. Share-Based Compensation

Effective January 1, 2006, the Company adopted SFAS 123R and began recognizing compensation expense for its share-based payments based on the fair value of the awards. Share-based payments include stock option grants under the Company's stock option plans. Prior to January 1, 2006, the Company accounted for share-based compensation expense using the intrinsic value recognition method prescribed by Accounting Principles Board Opinion ("APB") No. 25, A*ccounting for Stock Issued to Employees* ("APB 25") and SFAS No.123, *Accounting for Share-based Compensation* ("SFAS 123").

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

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Total share-based compensation expense for the year ended December 31, 2007 was $2,224, of which $1,047 and $1,177 were recorded in the statement of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the year ended December 31, 2006 was $1,401, of which $540 and $861 were recorded in the statement of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the year ended December 31, 2005 was $819. Share-based compensation expense for the years ended December 31, 2007, 2006 and 2005 included share-based compensation expense related to deferred compensation arrangements for the Company's directors of $183, $140 and $180, respectively.

Since the Company adopted SFAS 123R under the modified prospective and the prospective transition methods, results from periods prior to 2006 have not been restated. On the date of adoption of SFAS 123R, the unamortized balance of deferred stock compensation of $1,725 was reduced to zero with an offsetting adjustment to additional paid-in capital (see Note 2). SFAS 123R 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 123R. The impact of adopting SFAS 123R 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 following table illustrates the effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of SFAS No.123 to options granted under the Company's stock option plans in 2005.

	Year Ended December 31, 2005
Net loss as reported	$ (36,839)
Add: Share-based compensation expense included in reported net loss	819
Deduct: Share-based compensation expense determined under the fair value based method	(2,034)
Pro forma net loss	$ (38,054)
Net loss per share:	
Basic – as reported	$ (1.42)
Basic – pro forma	$ (1.46)
Diluted – as reported	$ (1.42)
Diluted – pro forma	$ (1.46)

For the years ended December 31, 2007, 2006 and 2005, the weighted average grant date fair value per share of options granted was $10.41, $5.67 and $6.23, respectively. The weighted average for key assumptions used in determining the fair value of options granted in 2007, 2006 and 2005 and a summary of the methodology applied to develop each assumption are as follows:

	Years Ended December 31,		
	2007	2006	2005
Expected price volatility	50.6%	70.3%	61.6%
Risk-free interest rate	4.6%	4.6%	4.0%
Weighted average expected life in years	6.9 years	6.0 years	5.7 years
Dividend yield	0%	0%	0%
Forfeiture rate	12.0%	14.0%	n/a

GTx, Inc.
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Expected Price Volatility — This is a measure of the amount by which a price has fluctuated or is expected to fluctuate. During 2007, the Company based its determination of expected volatility on its historical stock price volatility. Prior to 2007, the Company used an average expected price volatility of other publicly traded biopharmaceutical companies because the Company believed that it was the best indicator of future volatility, since the Company had less than two years of its own historical stock price volatility. This change in estimate did not have a material effect on the Company's results from operations for the year ended December 31, 2007. An increase in the expected price volatility will increase compensation expense.

Risk-Free Interest Rate — This is the U.S. Treasury rate for the week of 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 determined by calculating the average of the vesting term and the contractual term of the options, as allowed by SAB 107. The Company has utilized this method due to the lack of historical option exercise information related to the Company's stock option plans. Options granted have a maximum term of ten years. An increase in the expected life will increase compensation expense.

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. The forfeiture rate is estimated at the time of valuation and reduces 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.

The following is a summary of stock option transactions for all of the Company's stock option plans for the three year period ended December 31, 2007:

	Number of Shares	Weighted Average Exercise Price Per Share
Options outstanding at January 1, 2005	1,143,207	$ 7.66
Options granted	236,000	10.71
Options forfeited	(73,206)	6.83
Options exercised	(4,251)	8.87
Options outstanding at December 31, 2005	1,301,750	8.27
Options granted	225,834	8.50
Options forfeited	(40,500)	9.42
Options exercised	(28,795)	5.32
Options outstanding at December 31, 2006	1,458,289	8.33
Options granted	566,417	18.23
Options forfeited	(36,500)	12.70
Options exercised	(108,554)	7.61
Options outstanding at December 31, 2007	1,879,652	11.27

GTx, Inc.
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The following table summarizes information about stock options outstanding at December 31, 2007:

	Options Outstanding			Options Exercisable	
Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$2.24	17,775	2.89	$ 2.24	17,775	$ 2.24
$2.25 - $7.85	761,044	5.54	6.64	492,110	6.49
$7.86 - $20.45	1,100,833	8.14	14.61	169,549	11.75
	1,879,652	7.04	11.27	679,434	7.69

At December 31, 2007, the aggregate intrinsic value of all outstanding options was $7,967 with a weighted average remaining contractual term of 7.04 years, of which 679,434 of the outstanding options are currently exercisable with an aggregate intrinsic value of $4,530, a weighted average exercise price of $7.69 and a weighted average remaining contractual term of 5.25 years. There were 108,554 options exercised during the year ended December 31, 2007. The total intrinsic value of options exercised during the years ended December 31, 2007, 2006 and 2005 was $1,191, $204, and $11, respectively. At December 31, 2007, the total compensation cost related to non-vested awards not yet recognized was $5,047 with a weighted average expense recognition period of 2.08 years. Options available for future issuance under the Company's stock option plans were 1,774,536 at December 31, 2007. On January 1, 2008, options available for future issuance increased to 2,830,203 in accordance with the provisions of the Company's stock option plans.

4. Property and Equipment, Net

Property and equipment consist of the following:

	December 31,	
	2007	2006
Laboratory and office equipment	$ 3,080	$ 2,633
Leasehold improvements	669	669
Furniture and fixtures	328	312
Computer equipment and software	1,581	1,209
In process equipment and software	491	136
	6,149	4,959
Less: accumulated depreciation	(3,841)	(3,023)
	$ 2,308	$ 1,936

Depreciation and amortization expense for the years ended December 31, 2007, 2006 and 2005 was $841, $842 and $736, respectively. Of these amounts, $388, $403 and $468, respectively, were included in research and development expenses in the statements of operations.

GTx, Inc.
NOTES TO FINANCIAL STATEMENTS
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5. Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2007	December 31, 2006
Research and development	$ 3,314	$ 627
Clinical trial	1,502	1,117
Other	1,475	924
Professional fees	493	481
	$ 6,784	$ 3,149

6. Intangible Assets

Intangible assets consist of the following:

	December 31, 2007	December 31, 2006
License fees	$ 5,339	$ 4,826
Less: accumulated amortization	(909)	(600)
	$ 4,430	$ 4,226

In accordance with the terms of the Amended and Restated License and Supply Agreement that the Company entered into with Orion in December 2004 (“Orion License and Supply Agreement”), the Company was required to pay a license fee of $4,826. This license fee is being amortized on a straight-line basis over the term of the Orion License and Supply Agreement which the Company estimates to be 16 years. In accordance with the terms of the Consolidated, Amended, and Restated License Agreement (“SARM License”) and the Amended and Restated License Agreement (“SERM License”) that the Company entered into with the University of Tennessee Research Foundation (“UTRF”) in July 2007 and September 2007, respectively, the Company paid a one-time up-front fee of $290 per license. The license fees under the SARM License and SERM License are being amortized on a straight-line basis over the respective terms of the agreements, which the Company estimates to be approximately 14 years and 11.5 years, respectively. Amortization expense for the years ended December 31, 2007, 2006 and 2005 was $309, $298 and $302, respectively. See Note 8 for additional information on intangible assets. See also Note 2 for additional information on the reclassification of the prior period computer software balance from intangible assets to property and equipment.

Estimated future amortization expense for purchased intangible assets at December 31, 2007 is as follows:

Years Ending December 31,	
2008	$ 332
2009	332
2010	332
2011	332
2012	332
Thereafter	2,770
Total	$ 4,430

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7. Common and Preferred Stock

The Company's certificate of incorporation authorizes the Company to issue 60,000,000 shares of common stock with $0.001 par value per share and 5,000,000 shares of preferred stock, par value $0.001.

On October 17, 2005, the Company completed an underwritten public offering of 6,325,000 shares of common stock including the exercise of the over-allotment option by the underwriters, at a price to the public of $7.80 per share. Net cash proceeds from this offering were $45,663 after deducting underwriting discounts and other offering expenses.

On December 18, 2006, the Company completed a public offering of 3,799,600 shares of common stock at a price to the public of $16.00 per share. Net cash proceeds from this offering were $57,426 after deducting placement agent fees and other offering expenses.

On December 18, 2007, the Company completed a private placement of 1,285,347 shares of common stock to Merck at a per share price of $23.34 (see Note 8).

8. Collaboration and License Agreements

Merck & Co., Inc.

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

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

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

The Company and Merck also entered into a Stock Purchase Agreement on November 5, 2007 pursuant to which the Company agreed to sell and Merck agreed to purchase at the closing on December 18, 2007, 1,285,347

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newly-issued shares of the Company's common stock for an aggregate purchase price of approximately $30,000, or $23.34 per share. The per share price of $23.34 represents 140% of the average of the last reported sales prices of the Company's common stock for the 30 consecutive trading days ended November 2, 2007.

The Company deferred the recognition of the upfront licensing fee of $40,000 and the $10,800 in equity premium received that represents the difference between the purchase price and the closing price of the Company's common stock on the date the stock was purchased by Merck. These payments are being recognized as revenue over the period of the Company's performance obligation, which the Company estimates to be ten years. The Company recognized as collaboration revenue $198 for the year ended December 31, 2007 from the amortization of the Merck deferred revenue. Cost reimbursements for research and development activities will begin to be recognized as collaboration revenue when the amounts are determinable and collection of the related receivable is reasonably assured.

Ipsen Collaboration and License Agreement

In September 2006, the Company entered into a collaboration and license agreement with Ipsen pursuant to which the Company granted Ipsen exclusive rights in the European Territory to develop and commercialize ACAPODENE® and other products containing toremifene in all indications which the Company has licensed from Orion, which include all indications in humans except the treatment and prevention of breast cancer outside of the United States. In accordance with the terms of the license agreement, Ipsen has agreed to pay the Company €23,000 as a license fee and expense reimbursement, of which €1,500 is to be paid in equal installments over a three year period from the date of the agreement. In October 2006, the Company received €21,500 (approximately $27,100) from Ipsen as the initial payment for the license fee and expense reimbursement. In September 2007, the Company received €500 (approximately $688) from Ipsen as the first annual installment payment. Pursuant to the agreement, 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 UTRF for the PIN indication and to Orion only for the ADT indication. Ipsen will purchase the bulk drug product supply directly from Orion and is responsible for the packaging and labeling of the final product.

The Company recorded deferred revenue of $29,259 related to the Ipsen upfront license fee and expense reimbursement which is expected to be amortized into revenue on a straight-line basis over the estimated five year development period for ACAPODENE® in the European Territory. The Company recognized as collaboration revenue $5,852 and $1,853 for the years ended December 31, 2007and 2006, respectively, from the amortization of the Ipsen deferred revenue.

University of Tennessee Research Foundation License Agreements

On July 24, 2007, the Company and UTRF entered into the SARM License to consolidate and replace the Company's two previously existing SARM license agreements with UTRF and to modify and expand certain rights and obligations of each of the parties under both license agreements. Pursuant to the SARM License, the Company was granted exclusive worldwide rights in all existing SARM technologies owned or controlled by UTRF, including all improvements thereto, and exclusive rights to future SARM technology that may be developed by certain scientists at the University of Tennessee or subsequently licensed to UTRF under certain existing inter-institutional agreements with The Ohio State University.

On September 24, 2007, the Company and UTRF entered into the SERM License to replace the Company's previously existing exclusive worldwide license agreement for ACAPODENE®. Pursuant to the SERM License, the

GTx, Inc.
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Company was granted exclusive worldwide rights to UTRF's method of use patents relating to SERMs, including ACAPODENE® for chemoprevention of prostate cancer as well as future related SERM technologies that may be developed by certain scientists at the University of Tennessee.

Under both the SARM License and the SERM License, the Company agreed to pay to UTRF a one-time, upfront fee of $290 per license. The Company is also obligated to pay UTRF annual license maintenance fees and royalties on sublicense revenues and net sales of products.

Orion Corporation License and Supply Agreement

On December 29, 2004, the Company entered into the Orion License and Supply Agreement granting the Company exclusive rights to Orion's compound, toremifene, for all products for human uses, including the Company's product candidate, ACAPODENE®, excluding, however, products for breast cancer sold outside of the United States. The Orion License and Supply Agreement, which has an effective date of January 1, 2005, replaces an earlier agreement entered into with Orion in 2000, and subsequently amended in 2001 and 2003 ("Original Orion License"). Under the Orion License and Supply Agreement, the Company was required to pay a license fee of $4,826. The term of the Orion License and Supply Agreement will survive for the term of the Company's patents, including the Company's patents to treat complications arising from ADT and the patents it licenses from UTRF for the treatment and/or prevention of PIN and prostate cancer. The term of the Company's method of use patents extend from 2019 to 2023.

Under the Original Orion License, the Company paid Orion $400, which it is allowed to offset along with clinical trial expenses against licensing fees and milestone payments it will pay to Orion if the Company sublicenses rights to its patents to third parties. The Orion License and Supply Agreement retains these provisions and obligates the Company to make future royalty payments of varying amounts for toremifene based products for breast cancer in the United States and to treat or prevent PIN or prostate cancer or to treat complications arising from ADT.

The Company has agreed to achieve specified minimum sales requirements of ACAPODENE® in the United States after commercialization of the product or it must pay Orion royalties based on the amount of the shortfall. In addition, the Company is required to pay up to $1,000 if the Company is acquired before receiving marketing approval for the use of ACAPODENE® for the prevention or treatment of PIN or prostate cancer or to treat complications arising from ADT. Orion may terminate the Orion License and Supply Agreement if marketing approval for ACAPODENE® is not granted in the United States by December 31, 2009.

Ortho Biotech Collaboration and License Agreement

In March 2004, the Company entered into a joint collaboration and license agreement with Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson ("Ortho Biotech"), for andarine and specified backup SARM compounds. Under the terms of the agreement, the Company received in April 2004 an upfront licensing fee and expense reimbursement totaling $6,687. The upfront licensing fee and expense reimbursement were deferred and amortized into revenue on a straight-line basis over the estimated five year andarine development period. In December 2006, the Company reacquired full rights to develop and commercialize andarine and all backup compounds previously licensed to Ortho Biotech, and the joint collaboration and license agreement was terminated by mutual agreement of the parties. In connection with the termination of the Ortho Biotech agreement, the Company recognized the associated $3,100 balance of deferred revenue as additional collaboration revenue. The Company recognized revenue of $4,295 and $1,337 for the years ended December 31, 2006 and 2005, respectively, from the amortization of the upfront license fee and expense reimbursement.

9. Income Taxes

We have incurred net losses since inception and, consequently, have not recorded any U.S. federal and state income taxes. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

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The principal components of the Company's net deferred income tax assets consist of the following:

	December 31, 2007	December 31, 2006
Deferred income tax assets:		
Net federal and state operating loss carryforwards	$ 57,252	$ 38,921
Research and development credits	6,200	4,614
Cash basis method	—	641
Deferred stock compensation	2,010	1,185
Deferred revenue	7,511	10,319
Total deferred tax assets	72,973	55,680
Deferred income tax liabilities:		
Depreciation and amortization	66	84
Other	284	—
Total deferred tax liabilities	350	84
Net deferred income tax assets	72,623	55,596
Valuation allowance	(72,623)	(55,596)
	$ —	$ —

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $17,027, $14,690 and $15,047 in 2007, 2006 and 2005, respectively.

At December 31, 2007, the Company had net federal operating loss carryforwards of approximately $150,000, which expire from 2018 to 2027 if not utilized. The Company had state operating loss carryforwards of approximately $112,718, which expire from 2013 to 2022 if not utilized. The Company also had research and development credits of $6,200, which expire from 2018 to 2027 if not utilized.

Utilization of the net operating loss and tax credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations provided by the Internal Revenue Code of 1986, as amended and similar state provisions. The annual limitations may result in the expiration of net operating loss carryforwards before utilization.

10. Directors' Deferred Compensation Plan

Since June 30, 2004, non-employee directors have had the opportunity to defer all or a portion of their fees under the Company's Directors' Deferred Compensation Plan until termination of their status as directors. Deferrals can be made into a cash account, a stock unit account, or a combination of both. Stock unit accounts will be paid out in the form of Company common stock, except that any fractional shares will be paid out in cash valued at the then current market price of the Company's common stock. Cash accounts and stock unit accounts under the Directors' Deferred Compensation Plan are credited with interest or the value of any cash and stock dividends, as applicable. Non-employee directors are fully vested in any amounts that they elect to defer under the Directors' Deferred Compensation Plan.

For the years ended December 31, 2007, 2006 and 2005, the Company incurred board of director fee expense of $207, $163 and $192, respectively, of which $183, $140 and $180 was deferred and will be paid in common stock. At December 31, 2007, 43,367 stock units had been credited to individual director stock unit accounts.

GTx, Inc.
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11. 401(k) Plan

The Company sponsors a 401(k) retirement savings plan that is available to all eligible employees. The plan is intended to qualify under Section 401(k) of the Internal Revenue Code of 1986, as amended. The plan provides that each participant may contribute up to a statutory limit of their pre-tax compensation which was $15.5 for employees under age 50 and $20 for employees 50 and older in calendar year 2007. Employee contributions are held in the employees' name and invested by the plan's trustee. The plan also permits the Company to make matching contributions, subject to established limits. The Company elected to match a portion of employee's contributions to the plan in the amount of $210 and $89 in 2007 and 2006, respectively.

12. Commitments and Contingencies

Operating Lease Commitments

The Company leases laboratory facilities and office space pursuant to a lease, which is accounted for as an operating lease. The lease expires December 31, 2008, with an option to extend for up to two additional years and is terminable by either party upon 90 days' notice. In addition, in December 2007, the Company entered into a sublease for additional office space. This new office space sublease will be accounted for as an operating lease and has a term from January 1, 2008 through April 15, 2015. The Company has an option to cancel this sublease beginning December 31, 2010. Rent expense was approximately $765, $712 and $599 for the years ended December 31, 2007, 2006 and 2005, respectively.

As of December 31, 2007, minimum payments under operating lease arrangements were as follows:

2008	$ 323
2009	446
2010	611
Total	$ 1,380

Purchase Commitments

The Company had outstanding contractual purchase obligations of $280 and $19 at December 31, 2007 and 2006, respectively. These outstanding contractual purchase obligations are not recorded in the accompanying financial statements as the amounts represent future obligations, not liabilities, at December 31, 2007 and 2006 respectively.

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

13. Quarterly Financial Data (Unaudited)

The following is a summary of the quarterly results of operations for the years ended December 31, 2007 and 2006.

	Fiscal 2007 Quarters Ended			
	March 31	June 30	September 30	December 31
Revenues:				
Product sales, net	$ 192	$ 360	$ 268	$ 256
Collaboration revenue	1,463	1,463	1,463	1,661
Total revenues	1,655	1,823	1,731	1,917
Costs and expenses:				
Cost of product sales	109	206	148	158
Research and development expenses	8,007	8,575	9,881	12,045
General and administrative expenses	3,117	3,609	3,182	3,593
Total costs and expenses	11,233	12,390	13,211	15,796
Loss from operations	(9,578)	(10,567)	(11,480)	(13,879)
Interest income	1,454	1,364	1,238	1,089
Net loss	$ (8,124)	$ (9,203)	$ (10,242)	$ (12,790)
Net loss per share:				
Basic	$ (0.23)	$ (0.26)	$ (0.29)	$ (0.36)
Diluted	$ (0.23)	$ (0.26)	$ (0.29)	$ (0.36)

	Fiscal 2006 Quarters Ended			
	March 31	June 30	September 30	December 31
Revenues:				
Product sales, net	$ 876	$ 288	$ 348	$ (155)(a)
Collaboration revenue	334	335	724	4,755 (b)
Total revenues	1,210	623	1,072	4,600
Costs and expenses:				
Cost of product sales	467	170	118	18
Research and development expenses	8,441	8,444	9,614	7,398
General and administrative expenses	2,950	2,692	2,867	2,843
Total costs and expenses	11,858	11,306	12,599	10,259
Loss from operations	(10,648)	(10,683)	(11,527)	(5,659)
Interest income	724	699	638	946
Net loss	$ (9,924)	$ (9,984)	$ (10,889)	$ (4,713)
Net loss per share:				
Basic	$ (0.32)	$ (0.32)	$ (0.35)	$ (0.15)
Diluted	$ (0.32)	$ (0.32)	$ (0.35)	$ (0.15)

(a) Decrease in net product sales reflects the increase during the quarter to the Company's reserve for FARESTON® product returns. See Note 2, Revenue Recognition.

(b) Increase reflects amortization of Ipsen deferred revenue for the entire quarter and recognition of the remaining balance of Ortho Biotech deferred revenue in connection with the termination of the Ortho Biotech agreement. See Note 8, Collaboration and License Agreements.

[*] = 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 10.43

EXCLUSIVE LICENSE AND COLLABORATION AGREEMENT

by and between

Merck & Co., Inc.

and

GTx, Inc.

EXCLUSIVE LICENSE AND COLLABORATION AGREEMENT

This Exclusive License and Collaboration Agreement (this **"Agreement"**) is made and entered into effective as of the Closing Date (defined below) and is entered into by and between Merck & Co., Inc., a corporation organized and existing under the laws of New Jersey (**"Merck"**), and GTx, Inc., a corporation organized and existing under the laws of Delaware (**"GTx"**).

RECITALS:

WHEREAS, GTx and Merck have each engaged in research and development activities relating to selective androgen receptor modulators;

WHEREAS, Merck and GTx desire to enter into a collaboration to research, develop and commercialize Compounds and Products (as hereinafter defined) upon the terms and conditions set forth herein; and

WHEREAS, Merck and GTx each desires to obtain the licenses under the patent rights and know-how controlled by the other Party that are needed to conduct such a collaboration, upon the terms and conditions set forth herein;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the receipt and sufficiency which are hereby acknowledged, Merck and GTx hereby agree as follows:

ARTICLE 1 DEFINITIONS.

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below.

1.1 **"Act"** shall mean, as applicable, the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq., and/or the Public Health Service Act, 42 U.S.C. §§ 262 et seq., as such may be amended from time to time.

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

1.3 **"Affiliate"** of a particular Party shall mean any corporation or other business entity that controls, is controlled by, or is in common control with such Party, where for the purposes of this definition the term "control" (with correlative meanings for the terms "controlled by" and "in common control with") shall mean that (a) fifty percent (50%) or more (or the maximum ownership interest permitted by law) of the securities or other ownership interests representing the voting stock or general partnership interest of the applicable Party are owned, controlled or held, directly or indirectly, by the subject entity.

1.4 **"Agreement"** shall have the meaning given such term in the preamble to this document.

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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.

1.5 **"Calendar Quarter"** shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.6 **"Calendar Year"** shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.

1.7 **"Cancer Trial"** shall have the meaning set forth in Section 4.3.2.

1.8 **"Change of Control"** shall mean with respect to a Party: (1) the sale of all or substantially all of such Party's assets or business relating to the subject matter of this Agreement; (2) a merger, reorganization or consolidation involving such Party in which the voting securities of such Party outstanding immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (3) a person or entity, or group of persons or entities, acting in concert acquire more than fifty percent (50%) of the voting equity securities or management control of such Party.

1.9 **"Clinical Trial"** shall mean a Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, and/or Post-approval Clinical Trial.

1.10 **"Closing Conditions"** shall have the meaning provided in Section 13.3.

1.11 **"Closing Date"** shall mean the date when the Closing Conditions have been met.

1.12 **"Collaboration Compound"** shall mean a Compound that is initially synthesized during the R&D Collaboration Term as a result of the Collaboration and is determined to be a SARM by the JRC. For avoidance of doubt, "**Collaboration Compound**" does not include any GTx Compound or Merck Compound, including any prodrug, salt, base, acid, solvate, or any polymorph, racemate, isomer or metabolite thereof.

1.13 **"Collaboration"** shall mean the Research Program activities, Development Program activities and commercialization activities undertaken by the Parties and their respective Affiliates in the Field as set forth in ARTICLE 3, ARTICLE 4, and ARTICLE 5.

1.14 **"Combination Product"** shall mean either (a) any pharmaceutical product that consists of a Compound and at least one other Active Ingredient that is not a Compound, or (b) any combination of a Compound and another pharmaceutical product that contains at least one other Active Ingredient that is not a Compound where such products are not formulated together but are sold together as a single product and invoiced as one product. All references to Product in this Agreement shall be deemed to include Combination Product.

1.15 **"Commercialization Committee"** shall have the meaning set forth in 5.1.

1.16 **"Commercially Reasonable Efforts"** shall mean, with respect to the efforts to be expended by a Party and its Affiliates with respect to any objective for the Collaboration, the reasonable, diligent, good faith efforts to accomplish such objective as such Party and its Affiliates would normally use to accomplish a similar objective under similar circumstances. It is understood and agreed that with respect to the research, development and sale of Product by either Party, such efforts shall be substantially equivalent to those efforts and resources commonly used by such Party and its Affiliates for pharmaceutical products owned by it or to which it has rights, which

product is at a similar stage in its development or product life and is of similar market potential taking into account efficacy, safety, approved labeling, the competitiveness of alternative products in the marketplace, the patent and other proprietary position of the product, the likelihood of regulatory approval given the Regulatory Authority involved, the profitability of the product including the amounts payable to licensors of patent or other intellectual property rights, alternative products and other relevant factors. The Parties agree that Commercially Reasonable Efforts shall be determined on a market-by-market and Indication-by-Indication basis for a particular Product. It is acknowledged that the level of efforts expended by a particular Party under the Collaboration may be different for different markets, and may change over time, reflecting changes in the status of the Product and the market(s) involved. Notwithstanding the foregoing, the obligation of a Party to engage in Commercially Reasonable Efforts with respect to any Product is expressly conditioned upon the continuing absence of any adverse condition or event relating to the safety or efficacy of the Product, and the obligation of either Party to develop or market any such Product shall be delayed or suspended so long as in such Party's good faith opinion any such condition or event exists. If a Party decides that it will suspend its efforts in developing or marketing a Product on account of an adverse condition or event relating to the safety or efficacy of the Product, it shall so notify the JSC, which will determine how long such efforts shall be suspended.

1.17 **"Competing Pharma Change of Control"** shall mean a Change of Control in which a pharmaceutical or biotechnology company (or group of pharmaceutical or biotechnology companies acting in concert) (a) for whom collective worldwide sales of human pharmaceutical products in the Calendar Year that preceded the Change of Control were **[*]** or more, or (b) have a research, development or commercialization program for a **[*]**, is the acquirer (by asset purchase, merger, consolidation, reorganization or otherwise) as part of such Change of Control.

1.18 **"Compound"** shall mean a SARM or a prodrug, salt, base, acid, solvate, or any polymorph, racemate, isomer or metabolite thereof that is Controlled by Merck and/or GTx.

1.19 **"Control"**, **"Controls"** or **"Controlled by"** shall mean with respect to any material, item of Information, or intellectual property right under GTx Patent Rights or GTx SARM Know-How or Merck SARM Know-How or Merck Patent Rights, that the applicable Party (or its Affiliate) owns or has a license under such material, item of Information or intellectual property or right and has the ability to grant to the other Party access to and a license or sublicense (as applicable) under such material, item or right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be required hereunder to grant the other Party such access or license or sublicense.

1.20 **"Development Candidate"** shall mean a preparation containing a Compound which the JRC has identified for commencement of dosing of the first animal in a study under conditions meeting Good Laboratory Practices, where the JRC has determined that such study is intended to support the filing of an IND.

1.21 **"Development Program"** shall have the meaning set forth in Section 4.1.

1.22 **"Early Development Committee"** or **"EDC"** shall have the meaning set forth in Section 4.1.

1.23 **"Early-Stage Development"** shall mean (i) the activities to be conducted regarding the planning and execution, of pre-clinical and clinical development of a particular Product, beginning upon identification of a Compound as Development Candidate, and ending with the completion of

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Phase IIB Clinical Studies, including the conduct of GLP toxicology studies conducted for the purpose of obtaining an IND, the design of Clinical Trials and determination of which Products should be developed for particular Indications; and (ii) any interactions with any Regulatory Authority regarding such activities.

1.24 "**Exclusivity Period**" shall mean the period commencing with the Closing Date, and continuing until the expiration of the R&D Collaboration Term; *provided*, *however* that such Exclusivity Period shall expire **[*]**.

1.25 **"Execution Date"** shall mean the date that this Agreement is last executed by both Parties.

1.26 **"Field"** shall mean the use of Compound and Products for any and all purposes.

1.27 **"Filing"** of an NDA shall mean the acceptance by the applicable Regulatory Authority of an NDA for filing (which shall mean the date of filing if the applicable regulatory jurisdiction does not have an "acceptance" process or requirement).

1.28 **"First Commercial Sale"** shall mean, with respect to any particular Product, the first sale for end use or consumption of such Product in the applicable country, excluding, however, any sale or other distribution for use in a Clinical Trial.

1.29 **"Follow-up Compounds"** shall mean any Compound other than a Lead Compound that is Controlled by either Party; *provided*, *however*, that **[*]**.

1.30 **"GLP"** or **"Good Laboratory Practice"** shall mean the applicable then-current standards for laboratory activities for pharmaceuticals or biologicals, as set forth in the Act and any regulations or guidance documents promulgated thereunder, as amended from time to time, together with any similar standards of good laboratory practice as are required by any Regulatory Authority in the Territory.

1.31 **"GTx"** shall have the meaning given such term in the preamble to this Agreement.

1.32 **"GTX Background Patent Rights"** shall mean GTx Patent Rights which exist as of the Execution Date, including, but not limited to, those listed on Schedule 1.32.

1.33 **"GTX Background SARM Know-How"** shall mean SARM Know-How Controlled by GTx which exists as of the Execution Date.

1.34 **"GTx Compound"** shall mean (i) Ostarine, (ii) the other identified GTx Compounds listed in Schedule 1.34 hereto and (iii) any other Compound that is Controlled by GTx as of the Execution Date or during the R&D Collaboration Term, but not including any Collaboration Compound.

1.35 **"GTx Information and Inventions"** shall mean all protocols, formulas, data, Inventions, know-how and trade secrets, patentable or otherwise, resulting from the performance of the Collaboration solely by employee(s) of GTx and/or its Affiliate(s), or other persons not employed by Merck or GTx and/or their Affiliate(s), who are acting on behalf of GTx and/or its Affiliate(s).

1.36 **"GTx Patent Rights"** shall mean Patent Rights which during the Term are Controlled by GTx or its Affiliate (including, but not limited to, GTX Background Patent Rights) which: (i) claim or cover the Compound(s) and/or Product(s), including but not limited to any improvements,

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methods of use or methods of manufacture thereof; or (ii) claim or cover GTx Information and Inventions or Joint Information and Inventions.

1.37 **"GTx Program Patent Rights"** shall mean GTx Patent Rights that claim or cover GTx Information and Inventions.

1.38 **"GTx SARM Know-How"** shall mean SARM Know-How which during the Term is Controlled by GTx, (including without limitation GTx Background SARM Know-How, GTx Information and Inventions and GTx's rights in Joint Information and Inventions).

1.39 **"GTx SARM Program Scientists"** shall mean GTx's key clinical and scientific SARMs experts in medicinal chemistry, molecular modeling, pharmacology, screening, preclinical modeling and clinical development.

1.40 **"GTx Trademarks"** shall mean those trademarks set forth in Schedule 1.40, including Ostarine™.

1.41 **"HSR Act"** shall mean the Hart-Scott-Rodino Antitrust Improvements Act of 1974, as amended, 15 U.S.C. §18A.

1.42 **"HSR Clearance Date"** means the earliest date on which both Parties have actual knowledge that the following conditions, collectively, have been achieved: (a) the waiting period under the HSR Act shall have expired or earlier been terminated; (b) no injunction (whether temporary, preliminary or permanent) prohibiting consummation of the transactions contemplated by this Agreement or any material portion hereof shall be in effect; and (c) no requirements or conditions shall have been imposed by the United States Department of Justice or Federal Trade Commission (as applicable) in connection with the filings by the Parties under the HSR Act, other than requirements or conditions that are satisfactory to the Party on whom such requirements or conditions are imposed.

1.43 **"IND"** shall mean an Investigational New Drug application, Clinical Study Application, Clinical Trial Exemption, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

1.44 **"Indication"** shall mean the prevention, treatment and/or modulation of a loss of muscle mass, muscle strength/ function and/or bone mass (or other indications agreed by the Parties (e.g., **[*]**)) as a result of a separate and distinct disease or medical condition in humans for which a Product that is in Clinical Trials is intended to treat, prevent and/or modulate and/or for which a Product has received Marketing Authorization. For clarity, the following identified indications (**"Identified Indications"**) shall each be considered separate Indications: **[*]**.

1.44.1 **[*]**

1.44.2 **[*]**

1.44.3 **[*]**

1.44.4 **[*]**

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1.44.5 **[*]**

1.44.6 **[*]**

1.45 **"Information"** shall mean any and all information, results and data, including without limitation all discoveries, improvements, processes, formulations, methods, protocols, formulas, techniques, inventions, know-how and trade secrets, patentable or otherwise, and all other scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial and commercial information or data.

1.46 **"Initiates"**, **"Initiated"** or **"Initiation"** shall mean, with respect to a Clinical Trial, the first administration of a dose to a subject or patient in such Clinical Trial.

1.47 **"Invention"** shall mean any Information, composition of matter, or article of manufacture, that is developed, generated, made, conceived and/or reduced to practice by or on behalf of a Party (or its Affiliate) through the performance of activities conducted as a result of the Collaboration. Inventorship of such Invention shall be determined in accordance with United States patent laws, and ownership of such Invention shall be determined according to this Agreement.

1.48 **"Joint Information and Inventions"** shall mean protocols, formulas, data, Inventions, know-how and trade secrets, patentable or otherwise, resulting from the performance of the Collaboration, which are developed or invented jointly by employee(s) of Merck and/or its Affiliate(s) and/or a Third Party acting on behalf of Merck and/or its Affiliate(s), on the one hand, and GTx and/or its Affiliate(s) and/or a Third Party acting on behalf of GTx and/or its Affiliate(s), on the other hand.

1.49 **"Joint Patent Rights"** shall mean Patent Rights that claim or cover (i) Joint Information and Inventions; and/or (ii) Collaboration Compounds, including but not limited to any improvements, method of use or methods of manufacture thereof.

1.50 **"Joint Research Committee"** or **"JRC"** shall have the meaning set forth in Section 3.1.

1.51 **"Joint Steering Committee"** or **"JSC"** shall have the meaning set forth in Section 2.2.

1.52 **"Late Development Committee"** or **"LDC"** shall have the meaning set forth in Section 4.1.

1.53 **"Late-Stage Development"** shall mean activities to be conducted regarding (i) Phase III Clinical Studies, beginning with the decision to commence Phase III Clinical Studies for such Product for a particular Indication or Indications, including clinical trial designs for Phase III Clinical Studies and the determination of which Products will be developed for which Indications; (ii) any Post-approval Clinical Trials for a particular Product; and (iii) any interactions with any Regulatory Authority regarding such activities.

1.54 **"Lead Compound"** shall mean any of (i) Ostarine; (ii) **[*]**; or (iii) **[*]**.

1.55 **"Major Market"** shall mean any one of the following countries: United States, Japan, the United Kingdom, France, Germany, Italy or Spain.

1.56 **"Marketing Authorization"** shall mean all approvals from the relevant Regulatory Authority necessary to market and sell a Product in a particular country (including, without limitation all

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applicable pricing and governmental reimbursement approvals even if not legally required to sell Product in a country); provided that if the foregoing approvals have not all yet been achieved in a particular country as of the First Commercial Sale in such country, Marketing Authorization shall be deemed to have occurred as of the date of such First Commercial Sale in such country.

1.57 **"Material Patent Document"** shall mean, with respect to any Joint Patent Rights or Patent Rights of a particular Party being prosecuted: any restriction requirement, office action, notice of allowability, notice of allowance, notice of issuance, certificate of correction, and any other received document that is material to the prosecution of the applicable application, and all to the extent received from a United States or foreign patent office on or after the Execution Date.

1.58 **"Material Patent Draft"** shall mean, with respect to any Joint Patent Rights or Patent Rights of a particular Party being prosecuted: any draft of a patent application, amendment to a patent application, response to restriction requirement, response to an office action, request for certificate of correction, and any other patent prosecution document that is material to the prosecution of the applicable application including assignments and information disclosure statements, prepared by or on behalf of GTx or Merck or an Affiliate of either Party, in close to final form and prior to filing with the applicable patent office.

1.59 **"Merck Background Patent Rights"** shall mean Merck Patent Rights which exist as of the Execution Date, including, but not limited to those listed on Schedule 1.59.

1.60 **"Merck Background SARM Know-How"** shall mean Merck SARM Know-How which exists as of the Execution Date.

1.61 **"Merck Compound"** shall mean (i) the Compounds **[*]**; and (ii) any other Compound that is Controlled by Merck as of the Execution Date or during the R&D Collaboration Term, but not including any Collaboration Compound.

1.62 **"Merck Information and Inventions"** shall mean all protocols, formulas, data, Inventions, know-how and trade secrets, patentable or otherwise, resulting from the performance of the Collaboration solely by employee(s) of Merck and/or its Affiliate(s), or other persons not employed by Merck and/or its Affiliate(s) who are acting on behalf of Merck and/or its Affiliate(s).

1.63 **"Merck Patent Rights"** shall mean Patent Rights which during the Term are Controlled by Merck or its Affiliate, including, but not limited to, the Merck Background Patent Rights which: (i) claim or cover Compound(s) and/or Product(s) including without limitation any improvements, method of use or methods of manufacture thereof; or (ii) claim or cover Merck Information and Inventions or Joint Information and Inventions

1.64 **"Merck Program Patent Rights"** shall mean Merck Patent Rights that claim or cover Merck Information and Inventions.

1.65 **"Merck SARM Know-How"** shall mean SARM Know-How which during the Term is Controlled by Merck or its Affiliate, (including without limitation Merck's Background SARM Know-How, Merck Information and Inventions and Merck's rights in Joint Information and Inventions).

1.66 **"Merck"** shall have the meaning given such term in the preamble to this Agreement.

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1.67 **"NDA"** shall mean a New Drug Application, Biologics License Application, Worldwide Marketing Application, Marketing Application Authorization, filing pursuant to Section 510(k) of the Act, or similar application or submission for Marketing Authorization of a Product filed with a Regulatory Authority to obtain marketing approval for a biological, pharmaceutical or diagnostic product in that country or in that group of countries.

1.68 **"Net Sales"** shall mean the gross invoice price (not including value added taxes, sales taxes, or similar taxes) of Product sold by Merck or its Related Parties to the first Third Party after deducting, if not previously deducted, from the amount invoiced or received:

(a) trade and quantity discounts (other than early payment cash discounts) off of the invoice price, to the extent actually incurred or allowed;

(b) amounts actually credited, rebated or allowed for rejections or returns of Product;

(c) retroactive price reductions that are actually allowed or granted;

(d) sales commissions paid to non-Affiliated Third Party distributors and/or selling agents who are not employees of Merck, its Affiliates or sublicensees;

(e) an amount equal to **[*]** percent (**[*]**%) of the amount invoiced to cover early payment cash discounts, bad debt, transportation expenses related to the sale of Product and custom duties imposed and with reference to the sale of Product; and

(f) if applicable as to the Product sold, Merck's standard inventory cost, using Merck's standard internal system for determining such costs across all its products consistently applied, of a Product Delivery Device (as defined below) that is sold with the Product. A "Product Delivery Device" shall mean a device or delivery system that is used for administering or delivering a Product (such as a syringe, inhaler or specialized drug delivery system) and is sold accompanying such Product, such as in a sterile kit, but will not include packaging items such as bottles used to hold Product in tablet form;

Gross invoice price of Product sold and the deductions allowed in Sections 1.67(a)-(f) shall be calculated in accordance with Merck's internal accounting procedures, consistently applied.

[*]

1.69 **"Ostarine"** shall mean **[*]** .

1.70 **"Party"** shall mean Merck or GTx, individually, and "Parties" shall mean Merck and GTx, collectively.

1.71 **"Patent Rights"** shall mean any and all patents and patent applications in the Territory (which for the purpose of this Agreement shall be deemed to include certificates of invention and applications for certificates of invention), including any and all divisionals, continuations, continuations-in-part, reissues, renewals, substitutions, registrations, re-examinations, revalidations, extensions, supplementary protection certificates, pediatric exclusivity periods and the like of any such patents and patent applications, and foreign equivalents of the foregoing.

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1.72 **"Phase I Clinical Study"** shall mean a controlled human clinical study that would satisfy the requirements of 21 CFR 312.21(a), designed to provide evidence of safety and tolerability, metabolism, and pharmacological activity, the adverse experiences associated with increasing doses, and, possibly, early evidence of efficacy of a Compound. Any clinical study in healthy volunteers is a Phase I Clinical Study.

1.73 **"Phase II Clinical Study"** shall mean a controlled human clinical study that would satisfy the requirements of 21 CFR 312.21(b), conducted to study the effectiveness and establish the dose range of a Product for a particular Indication in patients with the disease or condition under study, including a Phase IIA Clinical Study or Phase IIB Clinical Study.

1.74 **"Phase IIA Clinical Study"** shall mean a relatively small Phase II Clinical Study designed to study the effectiveness of a particular Product against placebo or other positive controls for a particular Indication in patients with the disease or condition under study, including narrowing the optimal dose, the potential utility, and common short-term side effects of the Product.

1.75 **"Phase IIB Clinical Study"** shall mean a relatively longer and larger Phase II Clinical Study designed to study the effectiveness of different doses of a particular Product against placebo or other positive controls for a particular Indication in patients with the disease or condition under study, which is determined by the PDC to be a Phase IIB Clinical Study.

1.76 **"Phase III Clinical Study"** shall mean a large, controlled or uncontrolled Clinical Study that would satisfy the requirements of 21 CFR 312.21(c), intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling.

1.77 **"Post-approval Clinical Trial"** shall mean a human clinical trial in any country that is conducted after Marketing Authorization has been obtained, and is not conducted for the purpose of obtaining Marketing Authorization for a Product; *provided*, *however*, that if a Regulatory Authority requires the subsequent conduct of a Clinical Trial as a condition of obtaining a Marketing Authorization, such Clinical Trial will nevertheless be deemed to be a Post-approval Clinical Trial.

1.78 **"Product(s)"** shall mean any pharmaceutical preparation in finished dosage form containing a Compound either (i) for sale by prescription, over-the-counter or any other method; or (ii) for administration to human subjects or patients in a Clinical Trial, for any and all uses in the Field, including without limitation any Combination Product.

1.79 **"Product Development Committee"** or **"PDC"** shall have the meaning set forth in Section 4.1.

1.80 **"Program Patent Rights"** shall mean GTx Program Patent Rights, Joint Program Patent Rights and Merck Program Patent Rights.

1.81 **"R&D Collaboration Term"** shall mean the period during the Term that either Party is engaged in any activities under the Research Program or Development Program.

1.82 **"Registration Rights Agreement"** shall have the meaning ascribed to it in Section 1.1 of the Stock Purchase Agreement.

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1.83 **"Regulatory Authority"** shall mean any applicable government regulatory authority involved in granting approvals for the manufacturing, marketing, reimbursement and/or pricing of a Product in the Territory, including, in the United States, the United States Food and Drug Administration and any successor governmental authority having substantially the same function.

1.84 **"Related Party"** shall mean each of Merck, its Affiliates, and their respective sublicensees (which term does not include distributors), as applicable.

1.85 **"Research Program"** shall have the meaning set forth in Section 3.1.

1.86 "**Safety**" shall mean 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.

1.87 **"SARM Know-How"** shall mean any information and materials, including but not limited to, discoveries, improvements, processes, methods, protocols, formulas, data, inventions know-how and trade secrets, patentable or otherwise, which during the Term, (i) are Controlled by either Party, (ii) are not generally known, (iii) relate to SARMs and (iv) are necessary or useful to the other Party in the exercise and performance of its rights and obligations under this Agreement.

1.88 **"SARM"** shall mean a tissue-selective small molecule ligand whose primary pharmacologic effect at any concentration or dose observed *in vitro* or *in vivo* is mediated by the androgen receptor, **[*]**.

1.89 **"Shares"** shall have meaning ascribed to it in Section 1.1 of the Stock Purchase Agreement.

1.90 **"Shelf Registration Statement"** shall have meaning ascribed to it in Section 2.01(a) of the Registration Rights Agreement.

1.91 **"Stock Purchase Agreement"** shall mean the Stock Purchase Agreement executed by the Parties on even date with the Execution Date.

1.92 **"Term"** shall have the meaning set forth in Section 14.1.

1.93 **"Territory"** shall mean all of the countries in the world, and their territories and possessions.

1.94 **"Third Party"** shall mean an entity other than Merck and its Related Parties, and GTx and its Affiliates.

1.95 "**UT**" shall mean the University of Tennessee.

1.96 **"UTRF"** shall mean the University of Tennessee Research Foundation.

1.97 **"UTRF SARM License"** shall mean the Consolidated, Amended and Restated License Agreement dated July 24, 2007, by and between GTx and UTRF pertaining to GTX Background Patent Rights and GTX Background SARM Know-How.

1.98 **"Valid Patent Claim"** shall mean a claim of an issued and unexpired patent, including those with an extended term under patent term adjustment, patent term extension or pediatric exclusivity

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which are included within the Joint Patent Rights, GTx Patent Rights or Merck Patent Rights claiming the composition of matter of a Compound or use of Compound which would be infringed by the unauthorized sale or use of the Compound or Product in the country of sale, which claim has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction (which decision is no longer appealable), and which claim has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise (including such claim during the term of any statutory or regulatory exclusivity periods that relate back to or apply to that claim).

ARTICLE 2 COLLABORATION

2.1 **General.** Merck and GTx shall engage in a worldwide Collaboration regarding the research, development and commercialization of Compounds in the Field, pursuant to the terms and conditions of this Agreement. The Collaboration will be conducted under the oversight of the Joint Steering Committee or "JSC" (described in Section 2.2). The JSC shall oversee and resolve disputes regarding (i) the Research Program (described in Section 3.1), which shall be managed by the Joint Research Committee or "JRC" (described in Section 3.3); (ii) the Development Program (described in Section 4.1), which shall be managed by the Product Development Committee or "PDC" (described in Section 4.6); and manufacture, marketing and sale of Product(s), which shall be managed by the Commercialization Committee or "CC" (described in Section 5.1).

2.2 **Joint Steering Committee.** The Collaboration shall be overseen by the Joint Steering Committee (**"JSC"**). The JSC shall focus primarily on strategic issues relating to the research and development of Compounds and Products in the Field and aim to solve any issues referred to it by the JRC, PDC, or CC. Such oversight shall include providing guidance on the types of Indications to pursue for Compounds, new formulations that may be beneficial for Compound delivery, and the types of Compounds that the Parties should develop for new Indications.

2.2.1 **Conduct of the JSC.** The JSC will be comprised of an equal number of senior management members not to exceed three per Party, from each of Merck and GTx, or its respective Affiliates, including one co-chairman appointed by each Party or its respective Affiliates. The members will each have appropriate qualifications to participate on behalf of the Parties relating to Products, considering the stage of development and commercialization of the Products. Either Party may replace any of its representatives at any time, and from time to time, by giving written notice to the other Party. Each Party shall promptly fill any vacancy to the JSC caused by the resignation or removal of any of its representatives. The initial members of the JSC shall be appointed by each of the Parties within thirty (30) calendar days following the Execution Date. At any time commencing ten (10) years from the Closing Date, GTx may elect to relinquish its membership in the JSC, and if and when GTx shall make such an election, the JSC shall be composed of such Merck employees as Merck shall determine.

2.2.2 **Meetings.** The JSC shall meet in accordance with a schedule established by mutual agreement of the co-chairmen, but no less frequently than once per Calendar Quarter, with the location for such meetings alternating between GTx and Merck facilities (or such other location that may be determined by the co-chairmen). Alternatively, the JSC may meet by means of teleconference, videoconference or other similar communications equipment. Special meetings of the JSC may be called on at least

fifteen (15) calendar days notice by agreement of the co-chairmen. The decisions of the JSC shall at all times be decided by unanimous agreement of its members. Each Party shall keep the other Party regularly and fully apprised through the meetings of the JSC and quarterly written reports of the plans, results and developments in their respective research and development of Compounds and Products. Each Party's representatives on the JSC shall disclose to the other Party's representatives on the JSC, within a reasonable period of time, all Information and documentation in their respective Control relating to the research of Compounds that is reasonably necessary, in each Party's opinion, for each Party's representatives to participate in the proceedings of the JSC.

2.2.3 **Disputes.** The JSC shall resolve any disputes that may arise in the administration of the Research Program, Development Program, or Commercialization Program. In the event that the JSC fails to reach agreement on an issue within its area of oversight, the matter will be referred by both co-chairmen of the JSC to the President of Merck Research Laboratories (in the event of a dispute regarding research or development activities) or Merck's President of Global Human Health (in the event of a dispute regarding commercialization activities) and the Chief Executive Officer of GTx for resolution. The final resolution of matters (i) relating to Research Program matters referred to the JSC by the JRC shall be as set forth in Section 3.3.3; (ii) relating to Development Program matters referred to the JSC by the PDC shall be as set forth in 4.6.3; and (iii) relating to matters regarding commercialization of a Product referred to the JSC by the CC shall be as set forth in Section 5.2.3. For clarity, the JSC cannot modify or amend any terms of this Agreement.

2.3 **General Rules Regarding the Conduct of Committee Meetings Under the Collaboration.**

2.3.1 **Additional Representatives; Subcommittees for JSC, JRC, PDC or CC.** Additional representative(s) or consultant(s) may from time to time, by mutual consent of the Parties, be invited to attend JSC, JRC, PDC and CC meetings, subject to such representative's or consultant's written agreement to comply with the requirements of Section 7.1. The relevant committee may delegate such of its oversight and responsibilities to one or more of its members or to a sub-committee or sub-committees (to be equally represented by the Parties). The decisions of any sub-committee shall be reported to the relevant committee and subject to the approval of such committee.

2.3.2 **Exchange of Information.** Prior to the JSC, JRC, PDC or CC meetings, the Parties shall exchange written summaries of the matters to be presented to the Committee, which shall include a description of its activities and progress under the relevant portion of the Collaboration, including details of any GTx Information and Inventions, Merck Information and Inventions, and Joint Information and Inventions, and such other information that may reasonably be useful for the other Party to follow the progress of its activities and progress (including details of any problems, delays or extraordinary incidents) and any proposals it they may have with regard to the further activities and progress under the Collaboration. The Parties may establish a secure electronic database for the purpose of sharing such information. At committee meetings, the Parties, will share Information arising from the performance of such activities of the Collaboration being managed or overseen by such committee,

and any Information exchanged at such committee meetings shall be appropriately documented in the minutes.

2.4 **Exclusivity.** During the Exclusivity Period, neither Party nor their respective Affiliates shall, directly or indirectly through Third Parties working at the direction of or in collaboration with such Party or its Affiliates, engage in discovery, research, development, manufacturing or commercialization activities regarding SARMs, except pursuant to this Agreement. Any SARMs that are purchased, in-licensed or otherwise acquired by either Party from any Third Party during the Exclusivity Period shall be deemed to be Compounds Controlled by such Party and subject to the terms and conditions of this Agreement. Subject to the provisions of Section 15.2.3 in the event of a GTx Change of Control, the foregoing shall not in any way prohibit an entity that is the acquiring party in effecting a Change of Control of a Party from continuing to carry out and progress forward, outside and independent of this Agreement and without restriction under this Section 2.4, a program relating to SARMs that was ongoing at the time of such Change of Control.

2.5 **Services of Third Parties.** Merck and GTx shall each be entitled to utilize the services of Third Parties to perform its Collaboration activities as approved by the relevant committee, provided that such services are conducted in a manner that is consistent with this Agreement (including but not limited to Section 7.2.2) and preserves the rights of the Parties under this Agreement. Each Party shall remain at all times fully liable for its respective responsibilities under the Collaboration and the activities of any Third Parties utilized in connection therewith.

2.6 **Records and Reports.**

2.6.1 **Records.** Each Party and its Affiliates shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work done and results achieved in the performance of the Research Program and/or Development Program by such Party and its Affiliates.

2.6.2 **Copies and Inspection of Records.** Upon request, in furtherance of a patent or regulatory filing being performed by a Party or its designee, each Party shall provide to the other in a timely manner copies of records referred to in Section 2.6.1. The Party to whom such information is disclosed shall maintain all such records and the information disclosed therein in confidence in accordance with Section 7.1.

2.6.3 **Consultations.** Each Party, in fulfilling its rights and obligations under the Research Program and/or Development Program, shall have the right to arrange for its employee(s) and/or consultant(s) involved in Research Program and/or Development Program activities to visit the offices and laboratories of the other Party and any of its Third Party contractors as permitted under Section 2.5 during normal business hours and upon reasonable notice, and to discuss the Collaboration work and its results in detail with the technical personnel and consultant(s) of the other Party, and to review and copy the records described in Section 2.6.1.

2.7 **Alliance Managers.** Merck and GTx each shall appoint a person (an **"Alliance Manager"**) to coordinate its part of the Collaboration. The Alliance Managers shall be the primary contact between the Parties with respect to the Collaboration. Each Party shall notify the other within thirty (30) days of the Closing Date of the appointment of its Alliance Manager and shall notify the other Party as soon as practicable upon changing this appointment.

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2.8 **GTx SARM Program Scientists**. In the event that any of the personnel comprising GTx SARM Program Scientists (including GTx's Chief Scientific Officer, Chief Medical Officer, Vice President, Preclinical Research & Development and Director of Medicinal Chemistry) shall no longer work as a GTx SARM Program Scientist, or should any of these persons no longer be GTx employees, GTx will promptly notify Merck of such event, and GTx will use Commercially Reasonable Efforts to replace the vacant position(s) with demonstrably equal or better qualified individual(s) to support GTx's research activities described in Section 3.1.

2.9 **Compliance.** GTx and Merck each shall conduct the Collaboration in compliance with all applicable laws, rules and regulations, including, without limitation, current Good Manufacturing Practices and Good Laboratory Practice and all applicable aspects of Federal Policy (as such term is defined in Section 2.3 of the UTRF SARM License). In addition, if animals are used in research hereunder, both Parties will comply with the Animal Welfare Act or any other applicable local, state, national and international laws and regulations relating to the care and use of laboratory animals. Both Parties are encouraged to use the highest standards, such as those set forth in the Guide for the Care and Use of Laboratory Animals (NRC, 1996), for the humane handling, care and treatment of such research animals. Any animals which are used in the course of the Collaboration or products derived from those animals, such as eggs or milk, will not be used for food purposes, nor will these animals be used for commercial breeding purposes. Each Party shall notify the other Party in writing of any deviations from applicable regulatory or legal requirements. Each Party hereby certifies that it has not employed or otherwise used in any capacity and will not employ or otherwise use in any capacity, the services of any person debarred under United States law, including but not limited to Section 21 USC 335a, in performing any portion of the Collaboration.

2.10 **Use of Human Materials.** If any human cell lines, tissue, human clinical isolates or similar human-derived materials (**"Human Materials"**) have been or are to be collected and/or used in the Collaboration, the Party collecting such Human Materials (**"Collecting Party"**) shall assure (i) that it has complied, or shall comply, with all applicable laws, guidelines and regulations relating to the collection and/or use of the Human Materials and (ii) that it has obtained, or shall obtain, all necessary approvals and appropriate informed consents, in writing, for the collection and/or use of such Human Materials. The Party collecting such Human Materials shall provide documentation of such approvals and consents upon the other Party's request. The Collecting Party shall further assure that such Human Materials may be used as contemplated in this Agreement without any obligations to the individuals or entities (**"Providers"**) who contributed the Human Materials, including, without limitation, any obligations of compensation to such Providers or any other Third Party for the intellectual property associated with, or commercial use of, the Human Materials for any purpose unless otherwise previously approved by the JSC.

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2.11 **Information and Inventions.** The entire right, title and interest in:

2.11.1 Subject to Section 2.11.4, GTx Information and Inventions shall be owned solely by or exclusively licensed to GTx;

2.11.2 Subject to Section 2.11.4, Merck Information and Inventions shall be owned solely by Merck;

2.11.3 Joint Information and Inventions shall be owned jointly by GTx (or owned by UTRF and exclusively licensed to GTx) and Merck; and

2.11.4 Information and Inventions regarding Collaboration Compounds, including but not limited to any improvements, methods of use or methods of manufacture thereof, shall be owned jointly by GTx and Merck.

Each Party shall promptly disclose to the other Party in writing the development, making, conception or reduction to practice of Merck Information and Inventions, GTx Information and Inventions and Joint Information and Inventions, as applicable. Subject to the terms and conditions of this Agreement, each Party shall have the non-exclusive right to use and to grant licenses under its interest in Joint Information and Inventions outside the Field as it deems appropriate without the consent of or any obligation to the other Party as long as any such grant does not conflict with or otherwise violate any term of this Agreement.

ARTICLE 3 RESEARCH PROGRAM; TECHNOLOGY TRANSFER

3.1 **Conduct of Research Program.** GTx and Merck each shall exercise Commercially Reasonable Efforts, under the direction of the Joint Research Committee (**"JRC"**) to engage in basic research and medicinal chemistry activities for the purpose of identifying Development Candidates (the **"Research Program"**). The Parties shall work together to further develop the necessary assays and models to further characterize the Lead Compounds and the Follow-up Compounds, and to develop a robust platform for identifying Compounds for pre-clinical and clinical development. Within thirty (30) days after the Closing Date, the JRC shall commence good faith discussions regarding the establishment of a work plan for the Research Program, including expected Product profiles for one or more Indications, and the timelines and procedures the JRC will be following in reviewing the basic research and medicinal chemistry activities of the Parties to identify Development Candidates. Any work plan approved by the JRC shall be reviewed and updated as appropriate from time to time, but no less frequently than once per Calendar Year.

It is the intention of the Parties that GTx will be primarily responsible for conducting research activities to (and shall use Commercially Reasonable Efforts to) identify, synthesize and biologically characterize a sufficient number of SARMs, utilizing its SARM expertise and personnel, to provide sufficient information to the JRC for the JRC to identify at least **[*]** Collaboration Compounds that the JRC determines meet the criteria for a Development Candidate during the **[*]** period following the Closing Date. GTx shall undertake Commercially Reasonable Efforts, at its expense (subject only to Merck's funding obligations pursuant to Section 8.1) to provide sufficient basic research resources, including research scientists and technicians, to identify, screen and characterize sufficient SARMs to meet this goal, based on one or more Product profiles agreed upon by the JRC.

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Merck shall provide GTx with additional research resources (for example providing GTx with high throughput screening and molecular profiling), as agreed upon by the Parties in a work plan approved by the JRC from time to time As set forth in Section 3.2.1, the Parties shall exchange information promptly after the Closing Date, including making available to those scientists designated by each of the Parties to conduct activities under the Research Program their respective SARM structures, related data and material to effectively pool their collective resources and expertise for the benefit of the Collaboration.

3.2 **Exchange of SARM Know-How; Materials.**

3.2.1 **SARM Know-How.** Promptly after the Closing Date, both Parties shall commence collaborating on the Research Program through the exchange of personnel, materials, reagents and technology, including providing information regarding all work regarding identified Compounds, and other potential Compounds identified by GTx.

(a) GTx shall disclose to Merck in English and in writing or in an electronic format all GTx SARM Know-How not previously disclosed. GTx shall also promptly provide Merck with Information in its possession relative to the manufacturing, formulation, and packaging of Ostarine and any and all Compounds. Further GTx shall provide (at GTx's expense) the personnel and appropriate tech transfer for Merck to assume manufacturing of all Lead Compounds

(b) Merck shall disclose to GTx in English and in writing or in an electronic format all Merck SARM Know-How not previously disclosed. During the R&D Collaboration Term, the Parties shall continue to exchange SARM Know-How pursuant to procedures established by the JRC.

3.2.2 **Materials.** Except for Compounds that are subject to the Development Program, Materials exchanged pursuant to the Research Program are not to be used in humans, nor shall any such materials, or any derivatives, salts, isomers, analogs, modifications or components thereof be transferred, delivered or disclosed to any Third Party without the prior written approval of the originating Party. Any unused materials and any derivatives, analogs, modifications or components thereof shall be, at the originating Party's option, either returned to the originating Party, or destroyed in accordance with instructions by the originating Party.

3.3 **Joint Research Committee.** The Parties hereby establish the JRC to facilitate the Research Program as follows:

3.3.1 **Conduct of JRC.** The Research Program shall be conducted under the direction of the JRC comprised of three representatives of Merck and three representatives of GTx. Each Party may change its representatives to the JRC from time to time in its sole discretion, effective upon notice to the other Party of such change. These representatives shall have appropriate technical credentials, experience and knowledge, and ongoing familiarity with the Research Program. The JRC shall be chaired by a representative of Merck. Decisions of the JRC shall be made unanimously by the representatives of the Parties on the JRC. In the event that the JRC cannot or does not, after good faith efforts, reach agreement on an issue, the resolution and/or course of conduct shall be referred to the JSC for resolution. At any time commencing the earlier of (i) ten (10) years from the Closing Date or (ii) at

such time as there is a final determination by the JSC that no other or further efforts will be expended by either Party under the Research Program, GTx may elect to relinquish its membership in the JRC, and if and when GTx shall make such an election, the JRC shall be composed of such Merck employees as Merck shall determine.

3.3.2 **Meetings.** For so long as the Parties are engaged in Research Program activities, the JRC shall meet in accordance with a schedule established by mutual written agreement of the Parties, but no less frequently than once per Calendar Quarter, with the location for such meetings alternating between GTx and Merck facilities (or such other location that may be determined by the JRC). Alternatively, the JRC may meet by means of teleconference, videoconference or other similar communications equipment. The JRC shall confer regarding the status of the Research Program, review relevant data, consider and advise on any technical issues that arise, consider issues of priority, and review and advise on any expenses relating to the Research Program to the extent that funding for such expenses is shared between the Parties. The JSC may determine to suspend JRC meetings during any period where Research Program activities are suspended.

3.3.3 **Disputes.** If the JRC refers a dispute regarding the Research Program (such as a desired product profile or identification of a Development Candidate) to the JSC and an impasse develops at the JSC regarding such dispute which cannot be resolved by agreement of the two chairpersons of the JSC, then **[*]**.

3.4 **Opt-out of Differentiated Compound from Collaboration; Opt-In; Licenses.**

3.4.1 **Opt-Out.** If **[*]** the development of a new Compound for a new Indication, the JRC may determine that (i) the Compound **[*]**, and (ii) development of such Compound **[*]** (each such Compound a **"Differentiated Compound"**). If the JRC designates a Compound to be a Differentiated Compound, either Party may exercise its option (the **"Opt-Out"**) to develop such Differentiated Compound independently of the Collaboration for such **[*]** Indication, subject to the remaining provisions of this Section 3.4; *provided*, *however*, that GTx shall **[*]** and Merck shall **[*]**.

3.4.2 **Procedure.** Either Party may exercise the Opt-Out for a Differentiated Compound effective upon ninety (90) days written notice to the other Party. A Party may only exercise an Opt-Out with regard to a Compound that the JRC has determined meets the criteria of a Differentiated Compound pursuant to Section 3.4.1. **[*]**, and such Differentiated Compound shall be developed only for the Indication that has been approved by the JRC. Upon exercise of the Opt-Out for a Differentiated Compound, the Party exercising the Opt-out shall be free to conduct (and shall be responsible for conducting) Clinical Trials and commercialization of such Differentiated Compound for such Indication approved by the JRC, subject to option rights of the other Party pursuant to Section 3.4.3 (in the case of an Opt-Out by GTx) or Section 3.4.4 (in the case of an Opt-Out by Merck). Any Opt-Out by either Party shall be documented by the JRC, noting the particular Compound and Indication that have been approved for the Opt-Out.

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3.4.3 **Merck Opt-In.** In the event that GTx exercises the Opt-Out for a Differentiated Compound, then promptly upon **[*]** for such Differentiated Compound and reasonably in advance of a scheduled meeting of the PDC (as defined in Section 4.1), GTx shall provide to Merck's chairman of the PDC or his or her representative as designated in writing, all relevant data regarding such **[*]** (including but not limited to all relevant clinical and pre-clinical data and all costs incurred by GTx for which it would seek reimbursement from Merck in the event of a Merck Opt-In) (**"Merck Opt-In Package"**). GTx shall make qualified personnel of GTx available to discuss all such relevant data in the Merck Opt-In Package at the next PDC meeting that occurs with reasonable advance notice after disclosure of all relevant data to Merck. Merck shall have the option to have such Differentiated Compound become part of the Collaboration (the **"Merck Opt-In"**) by (i) providing written notice to GTx within ninety (90) days after review of the Merck Opt-in Package at such PDC meeting of Merck's desire to have such Differentiated Compound become part of the Collaboration; and (ii) within 30 days after providing such notice, paying GTx an amount equal to **[*]** (and as documented in the Merck Opt-In Package), and (iii) within 30 days after providing such notice, paying **[*]**. Upon meeting such conditions, such Differentiated Compound shall again be treated as a Compound subject to the Collaboration and all of the provisions of this Agreement. If Merck shall not exercise its Merck Opt-In, then GTx shall have the exclusive license rights defined in Section 6.4.1.

3.4.4 **GTx Opt-In.** In the event that Merck exercises the Opt-Out for a Differentiated Compound, then promptly upon **[*]** for such Differentiated Compound and reasonably in advance of a scheduled PDC meeting, Merck shall provide to GTx's chairman of the PDC or his or her representative as designated in writing, all relevant data regarding such **[*]** (including but not limited to all relevant clinical and pre-clinical data and all costs incurred by Merck for which it would seek reimbursement from GTx in the event of a GTx Opt-In) (**"GTx Opt-In Package"**). Merck shall make qualified personnel of Merck available to discuss all such relevant data in the GTx Opt-In Package at the next PDC meeting that occurs with reasonable advance notice after disclosure of all relevant data to GTx. GTx shall have the option to have such Differentiated Compound become part of the Collaboration (the **"GTx Opt-In"**) by (i) providing written notice to Merck within ninety (90) days after review of the GTx Opt-in Package at such PDC meeting of GTx's desire to have such Differentiated Compound become part of the Collaboration; and (ii) within 30 days after providing such notice, paying Merck an amount equal to **[*]** (and as documented in the GTx Opt-In Package). Upon meeting such conditions, such Differentiated Compound shall again be treated as a Compound subject to the Collaboration and all of the provisions of this Agreement. If GTx shall not exercise its GTx Opt-In, then Merck shall have the exclusive license rights defined in Section 6.4.2.

ARTICLE 4 DEVELOPMENT PROGRAM

4.1 **Conduct of Development Program.** GTx and Merck each shall exercise Commercially Reasonable Efforts, under the direction of the Product Development Committee (**"PDC"**) to engage in the pre-clinical and clinical development of one or more Products for one or more Indications (the **"Development Program"**). The Parties will endeavor to coordinate activities of Early-Stage Development and Late-Stage Development into one integrated program for all

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Products and Indications, managed by the PDC. In the event that multiple Products enter development, the PDC may create an Early Development Committee (**"EDC"**), responsible for managing Early-Stage Development, and a Late Development Committee (**"LDC"**), responsible for managing Late-Stage Development.

4.2 **Supply of Bulk Drug Substance for Clinical Trials.** After the Closing Date and upon receipt of the written request of Merck, GTx shall promptly provide Merck with such amount of GTx's existing inventory of intermediate SARM material or Clinical Trial material for Ostarine as Merck shall request, stored and handled in accordance with current good manufacturing practices, subject to GTx retaining a reasonably sufficient supply of Ostarine and/or intermediate to conduct its research activities under Section 3.1 and the development activities it already has initiated or currently plans to initiate, including initiating and supplying the Cancer Trial.

4.3 **Early-Stage Development.** Immediately after the Closing Date, the PDC will commence good faith discussions regarding a path forward for pre-clinical and clinical development of one or more Products for one or more Indications, including establishing pre-clinical and clinical milestones, timelines, procedures and protocols.

4.3.1 Except as set forth in Section 4.3.2 regarding the Cancer Trial, Merck shall be responsible, subject to Section 4.6.3, for managing and diligently pursuing a development plan for each Compound and Indication approved by the PDC pursuant to a protocol and timetable established by the PDC. If **[*]** and the PDC **[*]**, subject to Section 4.6.3 and ARTICLE 9; provided that the PDC may determine not to pursue or continue a clinical study that it determines should be discontinued due to concerns with safety and/or efficacy issues.

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4.3.2 As a part of the Collaboration, (i) GTx shall conduct its existing Clinical Study studying Ostarine for muscle wasting associated with non-small cell lung cancer, colorectal cancer, non-Hodgkin's lymphoma or chronic lymphocytic leukemia (the **"Cancer Trial"**) pursuant to the Cancer Trial clinical protocol attached as Schedule 4.3.2, subject to Section 4.6.3 and ARTICLE 9.

4.3.3 GTx shall work with Merck to coordinate the entry into the Merck-managed clinical study tracking database of the results of the Cancer Trial, and any other clinical study delegated to GTx pursuant to Section 4.3.1.

4.4 **Late-Stage Development.** Merck will take the lead in managing Phase III Clinical Studies and any Post-approval Clinical Trials, under the management of the PDC.

4.5 **Funding of Development Program.** Merck shall fund all clinical development activities for all Products for all Indications, all GLP toxicology studies for a Compound, and all other pre-clinical development activities that are conducted after the identification of a Development Candidate, including all related product development and manufacturing activities, which are (a) required by the applicable Regulatory Authority for a particular clinical study, (b) reasonably necessary or appropriate to conduct additional clinical studies, or (c) reasonably necessary or useful to support the filing of an NDA or comparable application for Marketing Authorization for the Product which is the subject of the clinical development activity, except that GTx shall be fully responsible for funding all clinical development activities for the Cancer Trial, with no reimbursement from Merck. In the event that GTx engages in activities in support of the Development Program as requested by the PDC, GTx shall submit a budget of the expenses that it expects to incur as a result of such activities to the PDC, and such expenses shall be reviewed and agreed upon by the PDC prior to GTx engaging in any such activities. Upon completion of such activities and submission of an invoice by GTx, Merck shall reimburse GTx for such previously approved expenses. Reimbursement of such previously approved expenses shall occur within thirty (30) days after receipt by Merck of such invoice.

4.6 **Product Development Committee.** The Parties hereby establish the PDC to facilitate the Development Program as follows:

4.6.1 **Conduct of PDC.** The Development Program shall be conducted under the direction of the PDC comprised of three representatives of Merck and three representatives of GTx. Each Party may change its representatives to the PDC from time to time in its sole discretion, effective upon notice to the other Party of such change. These representatives shall have appropriate technical credentials, experience and knowledge, and ongoing familiarity with the Development Program. The PDC shall be chaired by a representative of Merck. Decisions of the PDC shall be made unanimously by the representatives of the Parties on the PDC. In the event that the PDC cannot or does not, after good faith efforts, reach agreement on an issue, the resolution and/or course of conduct shall be referred to the JSC for resolution. At any time, GTx may elect to relinquish its membership in the PDC, and if and when GTx shall make such an election, the PDC shall be composed of such Merck employees as Merck shall determine.

4.6.2 **Meetings.** For so long as the Parties are engaged in Development Program activities, the PDC shall meet in accordance with a schedule established by mutual written agreement of the Parties, but no less frequently than once per Calendar Quarter, with

the location for such meetings alternating between GTx and Merck facilities (or such other location may be determined by the PDC). Alternatively, the PDC may meet by means of teleconference, videoconference or other similar communications equipment. The PDC shall confer regarding the status of the Development Program, review relevant data, consider and advise on any technical issues that arise, consider issues of priority, and review and advise on any expenses relating to the Research Program to the extent that funding for such expenses is shared between the Parties. The JSC may determine to suspend PDC meetings during any period where Development Program activities are suspended.

4.6.3 **Disputes.** If the PDC refers a dispute regarding the Development Program to the JSC and an impasse develops at the JSC regarding the dispute which cannot be resolved by agreement of the two chairpersons of the JSC, then the final resolution of such dispute (other than the decision to commence the Cancer Trial in accordance with the protocol heretofore approved by the Parties,) will be decided by **[*]**.

ARTICLE 5 COMMERCIALIZATION

5.1 **Commercialization Activities.** Merck shall engage in Commercially Reasonable Efforts to commercialize Products, and shall take the lead on the marketing and sale of Products throughout the Territory, and have the sole right and responsibility regarding the manufacture and supply of Product. Merck and GTx will participate through the Commercialization Committee regarding the development of strategies for marketing of Products. Under the direction of the Commercialization Committee, GTx shall have the right to participate in conducting thought leader meetings and maintaining relationships with thought leaders, and Merck shall reimburse GTx's reasonable costs associated with any such activities, provided that GTx shall have obtained the approval of the Commercialization Committee for such costs before incurring any such costs. Additionally, GTx shall have the right to request the Commercialization Committee for approval for GTx to co-promote Products in the United States, which co-promotion activities, if approved by the Commercialization Committee in its discretion, would be pursuant to a written agreement entered into between the Parties regarding the terms and conditions of such co-promotion. Similarly, GTx may participate in such other commercialization activities for Products, as requested by GTx and approved by the Commercialization Committee.

5.2 **Commercialization Committee.** The Parties hereby agree to establish the Commercialization Committee (**"CC"**) upon the completion of Phase IIB Clinical Studies (or any other Clinical Trial that immediately proceeds a Phase III Clinical Study) for the first Product.

5.2.1 **Conduct of Commercialization Committee.** The CC shall be comprised of three representatives of Merck and three representatives of GTx. Each Party may change its representatives to the CC from time to time in its sole discretion, effective upon notice to the other Party of such change. These representatives shall have appropriate technical credentials, experience and knowledge, and ongoing familiarity with issues regarding the manufacture, marketing and sale of Products. The CC shall be chaired by a representative of Merck. Decisions of the CC shall be made unanimously by the representatives. In the event that the CC cannot or does not, after good faith efforts, reach agreement on an issue, the resolution and/or course of conduct shall be referred to the JSC for resolution. At any time, GTx may elect to relinquish its membership in the CC, and if and when GTx shall make such an election, the CC shall be composed of such Merck employees as Merck shall determine.

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5.2.2 **Meetings.** CC meetings shall not be required until completion of Phase IIB Clinical Studies (or any other Clinical Trial that immediately proceeds a Phase III Clinical Study) for the first Product, and shall be held thereafter on a regular basis consistent with the need to inform GTx of commercialization activities and obtain input from GTx regarding commercialization issues regarding Products that are being marketed or in Late-Stage Development. The location for such meetings will alternate between GTx and Merck facilities (or such other location may be determined by the CC). Alternatively, the CC may meet by means of teleconference, videoconference or other similar communications equipment. The CC shall confer regarding the status of the commercialization activities and to review relevant data, and consider and advise on any technical issues that may arise in the manufacture, packaging, distribution, marketing and sale of a Product.

5.2.3 **Disputes.** If the CC refers a dispute regarding commercialization to the JSC and an impasse develops at the JSC regarding the dispute which cannot be resolved by agreement of the two chairpersons of the JSC, then the final resolution of such dispute will be decided by **[*]**.

ARTICLE 6 LICENSE; EXCHANGE OF INFORMATION

6.1 **GTx License Grant; Retained Rights.**

6.1.1 Subject to the terms and conditions of this Agreement, including the provisions of Sections 6.8 hereof, GTx hereby grants to Merck an exclusive license (even as to GTx, but subject to Sections 6.1.2 and 6.4.1) under the GTx Patent Rights and GTx SARM Know-How (i) to make, have made, use, offer to sell, sell and/or import Compound(s) and Product(s) in the Field in the Territory, and (ii) to carry out the Collaboration and other activities specifically as set forth in this Agreement. Merck shall be entitled to grant and authorize sublicenses under the GTx Patent Rights and GTx SARM Know-How, subject to Section 6.5.

6.1.2 Notwithstanding the rights granted in Section 6.1.1 and 6.6, GTx hereby retains the rights necessary solely in connection with performing its activities under ARTICLE 2, ARTICLE 3 and ARTICLE 4 of this Agreement to research, develop, make, have made, and use in the Territory all Compound(s), Product(s), and methods of use of Compounds and Products.

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6.2 **Merck License Grant, Retained Rights.**

6.2.1 Merck hereby grants to GTx a co-exclusive license (co-exclusive with Merck and its Affiliates, but subject to Section 6.2.2) under the Merck Patent Rights, Merck SARM Know-How, and such other intellectual property (as reasonably determined by Merck) Controlled by Merck as needed by GTx in the Field in the Territory, to carry out its activities under ARTICLE 2, ARTICLE 3 and ARTICLE 4 of this Agreement, subject, however, to Section 6.4.1. GTx may grant sublicenses under such rights to Third Parties as may be necessary or useful for each such Third Party to provide services for Collaboration activities as contemplated by Section 2.5 hereof.

6.2.2 Merck shall retain rights under the Merck Patent Rights and Merck SARM Know-How to make, have made, use, sell, offer to sell and import Compound(s) and Product(s) in the Field in the Territory, and to practice any Invention claimed in or covered by Merck Patent Rights (**"Merck Retained Rights"**) but only in accordance with the provisions of this Agreement. Merck shall be entitled to grant and authorize sublicenses to such Merck Retained Rights, subject to Section 6.5.1.

6.3 **Non-Exclusive License Grant.** In the event that the making, having made, use, offer for sale, sale or import by Merck, or Merck's Related Parties, of Compound(s) or Product(s) would infringe during the Term a claim under and Patent Rights Controlled by GTx and which Patent Rights are not covered by the grant in Section 6.1, GTx hereby grants to Merck, to the extent GTx is legally able to do so, a non-exclusive license in the Field in the Territory under such issued Patent Rights for Merck and its Related Parties to develop, make, have made, use, sell, offer for sale or import Compound(s) and Product(s) in the Territory, subject, however, to Section 6.4.1. Merck shall be entitled to grant and authorize sublicenses under such Patent Rights, subject to Section 6.5.1.

6.4 **Licenses in the event of an Opt-Out by either Party.**

6.4.1 **Opt-Out by GTx.** In the event that GTx exercises its Opt-Out rights pursuant to Section 3.4.1, Merck hereby grants to GTx an exclusive license (even as to Merck, but subject to the Merck Opt-In set forth in Section 3.4.3) under the Merck Patent Rights and Merck SARM Know-How, and GTx shall retain the exclusive rights under GTx Patent Rights and GTx SARM Know-How, in each case solely (i) to make, have made, use, offer to sell, sell and/or import Differentiated Compound(s) and any product that contains a Differentiated Compound for the Indication approved by the JRC pursuant to Section 3.4.1 in the Territory. GTx shall be entitled to grant and authorize sublicenses under the rights set forth in this Section 6.4.1, subject to Section 6.5.2.

6.4.2 **Opt-Out by Merck.** In the event that Merck exercises its Opt-Out rights pursuant to Section 3.4.1, GTx hereby grants to Merck an exclusive license (even as to GTx, but subject to the GTx Opt-In set forth in Section 3.4.4) under the GTx Patent Rights and GTx SARM Know-How, and Merck shall retain the exclusive rights under Merck Patent Rights and Merck SARM Know-How, in each case solely (i) to make, have made, use, offer to sell, sell and/or import Differentiated Compound(s) and any product that contains a Differentiated Compound for the Indication approved by the JRC pursuant to Section 3.4.1 in the Territory. Merck shall be entitled to grant and authorize sublicenses under the rights set forth in this Section 6.4.2, subject to Section 6.5.1.

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6.5 **Sublicenses.**

6.5.1 **By Merck.** Merck shall be entitled to grant and authorize sublicenses under the licenses granted to it under Sections 6.1.1, 6.3 and 6.4.2, and under the Merck Retained Rights retained pursuant to Section 6.2.2; *provided* that upon any such sublicense to a Third Party, Merck will notify GTx and provide GTx with a copy of such sublicense agreement. Merck shall only grant such sublicenses pursuant to a written agreement that notifies such sublicensees of the relevant obligations contained in this Agreement and the UTRF SARM License.

6.5.2 **By GTx.** GTx shall be entitled to grant and authorize sublicenses under the licenses granted to it under Section 6.4.1, and under the GTx Retained Rights retained pursuant to Section 6.2.2. GTx shall only grant such sublicenses pursuant to a written agreement that notifies such sublicensees of the relevant obligations contained in this Agreement.

6.6 **Trademark License.** GTx hereby grants to Merck a fully paid-up, non-exclusive license in the Field in the Territory to use the GTx Trademark, and such other GTx trademarks and/or trade names as the Parties may agree, in connection with use, sale, offer to sell and import of Product; *provided, however*, that in the event that the parties agree that any GTx Trademark shall be used in connection with the marketing and/or sale of a Product, such license shall becoume a fully-paid up, exclusive (even as to GTx, but subject to Section 6.1.2) license to use such GTx Trademark for any and all uses. The Parties agree that, upon written request of either Party, the Parties shall execute a trademark license containing the standard terms and conditions of such a trademark license for the use by Merck, its Affiliates and/or their sublicensee(s) of one or more GTx Trademarks and/or trade names in furtherance of and conformity with this Section 6.6 as requested by Merck in its sole discretion. Any such transfer to Merck of one or more GTx Trademarks shall require Merck to keep in force and to use Commercially Reasonable Efforts not to abandon or otherwise terminate the GTx Trademark without first obtaining the prior written approval of GTx, which approval shall not be unreasonably withheld. Notwithstanding the foregoing, it is understood and agreed that Merck, its Affiliates and their respective sublicensees shall have no obligation to use the GTx Trademark, or any other GTx trademark and/or trade name; Merck, its Affiliates and their respective sublicensees may develop one or more trademarks and/or trade names for use in connection with Product and all rights to such trademark(s) and/or trade name(s) are retained by Merck, its Affiliates and their respective sublicensees, except as set forth in Sections 14.2.2(vi) or 14.3.2(b)(iii).

6.7 **No Implied Licenses.** Except as set forth in Sections 6.1 through 6.6, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, in any Information disclosed to it under this Agreement or under any trademarks, patents or patent applications owned or controlled by the other Party or its Affiliates.

6.8 **UTRF SARM License**. Merck acknowledges that certain GTx Patent Rights are licensed to GTx pursuant to the UTRF SARM License ("**UTRF Licensed Patents**"). The Parties agree that the provisions of this Section 6.8 shall apply as it relates to the UTRF SARM License and the licenses granted to Merck pursuant to Article 6. For avoidance of doubt, any capitalized terms

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contained in this Section 6.8 that are not otherwise defined in this Agreement shall have the meaning provided in the UTRF SARM License.

6.8.1 Notwithstanding Section 2.5 of the UTRF SARM License, Merck shall not be required to notify UTRF of any sublicense that it is permitted to grant pursuant to Article 6 of this Agreement, or to enter into written agreements with Merck Affiliates granting a sublicense that it is permitted to grant pursuant to Article 6 of this Agreement.

6.8.2 Notwithstanding Sections 2.6 of the UTRF SARM License, GTx acknowledges that this Agreement complies with the sublicense requirements set forth in Section 2.6 of the UTRF SARM License;

6.8.3 Notwithstanding Sections 2.6 and 12.3 of the UTRF SARM License, GTx hereby covenants that (i) it shall comply in all material respects with, and shall not default under, the UTRF SARM License (including but not limited to Section 6.5 thereof), and (ii) GTx shall promptly notify Merck of any communication with UT or UTRF, whether oral or in writing, regarding any potential default by GTx under the UTRF SARM License, and shall promptly confer with Merck regarding appropriate steps to cure any such default or potential default by GTx;

6.8.4 **[*]**

6.8.5 Notwithstanding Section 4.2 of the UTRF SARM License, GTx acknowledges that Merck's sole withholding obligations regarding payments made to GTx pursuant to this Agreement are as set forth in Section 8.9 of this Agreement.

6.8.6 Notwithstanding Sections 4.4, 5.2 and 5.3 of the UTRF SARM License, GTx acknowledges that Merck's sole obligations regarding (i) payment of milestone payments are as set forth in Section 8.4.7 of this Agreement, and (ii) payment and reporting of royalties shall be as set forth in Section 8.6 of this Agreement.

6.8.7 Notwithstanding Sections 2.6 and 5.1 of the UTRF SARM License, GTx acknowledges that Merck's sole obligation regarding audit rights are as set forth in Section 8.7 of this Agreement.

6.8.8 (a) GTx acknowledges that Merck Patent Rights under this Agreement are not **[*]**.

(b) To the extent that any Merck Information and Inventions or Joint Information and Inventions are conceived or reduced to practice as a result of Merck practicing under the UTRF Licensed Patents, Merck hereby grants to UTRF, UT, OSU or OSURF a non-exclusive royalty free license to practice such inventions for non-commercial, educational, research and academic purposes only (such right excluding the practice of UTRF Licensed Patents for any fee-for-services arrangement or for sponsored research on behalf of any commercial entity).

6.8.9 Without limiting GTx's obligations under Article 12 of this Agreement, GTx shall not fail to file, and shall not abandon, a patent application claiming an "Existing Invention", "Improvement Invention" or "New Invention" in any "Major Countries"

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(as such terms are defined in the UTRF SARM License) without first consulting with Merck pursuant to Article 12 of this Agreement.

6.8.10 Merck's obligations under Section 6.9 of the UTRF SARM License shall be limited to those required by applicable law.

6.8.11 Merck acknowledges that its right to enforce UTRF Licensed Patents is limited by the provisions of Sections 7.2, 7.3, 7.4 and 7.5 of the UTRF SARM License.

6.8.12 Merck acknowledges the limitations of liability set forth in Section 8.3 of the UTRF SARM License, and the provisions of Section 9.1 regarding export controls.

6.8.13 The Parties agree Section 14.1 of the UTRF SARM License is fulfilled by compliance by the Parties with Section 2.9 of this Agreement.

6.8.14 To the extent that the obligations of the Parties under this Agreement are inconsistent with the provisions of the UTRF SARM License, GTx shall use reasonable efforts to obtain the agreement of UTRF to resolve any such inconsistent provisions.

6.9 **United States Bankruptcy Code.** In the event of the rejection of this Agreement by or on behalf of either Party under Section 365 of the United States Bankruptcy Code (the **"Code"**), all licenses and rights to licenses granted under or pursuant to this Agreement by one Party to the other are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Code. The Parties agree that each Party, as the licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Code, and that upon commencement of a bankruptcy proceeding by or against either Party under the Code, the other Party shall be entitled to a complete duplicate of or complete access to (as other Party deems appropriate), any such intellectual property and all embodiments of such intellectual property. Such intellectual property and all embodiments thereof shall be promptly delivered to non-rejecting Party (i) upon any such commencement of a bankruptcy proceeding upon written request therefore by the non-bankrupt Party, unless the bankrupt Party elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under (i) above, upon the rejection of this Agreement by or on behalf of a Party upon written request therefore by the other Party. The foregoing provisions of Section 6.8 are without prejudice to any rights the non-bankrupt Party may have arising under the Code or other applicable law.

ARTICLE 7 CONFIDENTIALITY AND PUBLICATION.

7.1 **Nondisclosure Obligation.** All Information disclosed by one Party (the "**Disclosing Party**") to the other Party or the other Party's Affiliates, including Information disclosed to directors, officers, employees or agents of any Party or the Party's Affiliates (each being hereinafter referred to as a "**Receiving Party**") pursuant to this Agreement or in connection with each Party's activities on behalf of the Collaboration (the **"Confidential Information**" of the Disclosing Party) shall be maintained in confidence by the Receiving Party and shall not be disclosed to any Third Party or used for any purpose except as expressly permitted in this Agreement, without the prior written consent of the Disclosing Party. The foregoing obligations as to particular Confidential Information of a Disclosing Party shall not apply to the extent that the Receiving Party can demonstrate that such Confidential Information:

7.1.1 is known by the Receiving Party at the time of its receipt, and not through a prior disclosure by the Disclosing Party, as documented by the Receiving Party's business records;

7.1.2 is in the public domain by use and/or publication before its receipt from the Disclosing Party, or thereafter enters the public domain through no fault of the Receiving Party;

7.1.3 is subsequently disclosed to the Receiving Party by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the Disclosing Party; or

7.1.4 is developed by the Receiving Party independently and without use of or reference to any Confidential Information received from the Disclosing Party, as documented by the Receiving Party's business records.

Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party.

7.2 **Exception to Nondisclosure Obligation**

Notwithstanding the obligations in Section 7.1, a Party may disclose the other Party's Confidential Information to the extent that such disclosure:

7.2.1 is to governmental or other regulatory agencies as required in order to obtain patents or to gain or maintain approval to conduct Clinical Trials or to market Product under this Agreement, or otherwise as required to comply with applicable laws or regulations, but such disclosure may be only to the extent reasonably necessary to obtain such patents or authorizations or comply with such applicable law or regulation, and provided that reasonable steps are taken to ensure confidential treatment of such Information (if applicable or available);

7.2.2 is deemed necessary by a Party to be disclosed to Related Parties, agent(s), consultant(s), and/or other Third Parties for the research and development, manufacturing and/or marketing of the Product (or for such entities to determine their interest in performing such activities) in accordance with this Agreement on the condition that such Third Parties agree to be bound by confidentiality and non-use obligations that substantially are no less stringent than those confidentiality and non-use provisions contained in this Agreement; *provided*, *however*, that the term of confidentiality for such Third Parties shall be no less than ten (10) years; or

7.2.3 is deemed necessary by counsel to the Receiving Party to be disclosed (i) to such Party's directors, attorneys, independent accountants or financial advisors for the sole purpose of enabling such attorneys, independent accountants or financial advisors to provide advice to the receiving Party, or (ii) to bona fide investors or potential bona fide investors, including potential acquirers or merger partners, *provided* that such

Confidential Information is limited to the financial terms of this Agreement, in each such case on the condition that such attorneys, independent accountants and financial advisors are bound by confidentiality and non-use obligations no less onerous than those contained in this Agreement; or

7.2.4 is required to be disclosed by judicial or administrative process, provided that in such event such Party shall promptly inform the other Party of the required disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure obligations. Confidential Information that is disclosed by judicial or administrative process shall remain otherwise subject to the confidentiality and non-use provisions of this Section 7.1 and Section 7.3, and the Party disclosing Confidential Information pursuant to law or court order shall take all steps reasonably necessary, including without limitation obtaining an order of confidentiality, to ensure the continued confidential treatment of such Confidential Information.

7.3 **SARM Know-How.** Both Parties agree to keep confidential all SARM Know-How Controlled by either Party, subject to Sections 7.1.2.

7.4 **Publication.** Publication strategy shall be managed by the PDC, which shall have the right to review and approve any publication, considering Merck's and GTx's interest in publishing the results of its research in order to obtain recognition within the scientific community and to advance the state of scientific knowledge, the need to protect the confidentiality of Information, and the interest of the Parties in having an integrated approach to developing one or more Products for one or more Indications. Consequently, except for disclosures permitted pursuant to Section 7.1, either Party or its Affiliates, or its or their employee(s) or consultant(s) wishing to make a publication shall deliver to the PDC a copy of the proposed written publication, abstract or manuscript, including a copy of any presentation materials to be utilized at a conference or at a meeting of persons which will include persons not employed by Merck and GTx, or an outline of an oral disclosure, at least sixty (60) days prior to submission for publication or presentation, provided that for purposes of any presentation materials or an outline of an oral disclosure, the copy of such proposed written materials shall be presented to the PDC at least thirty (30) days prior to submission or presentation. The PDC shall have the right to require modifications or delay of the publication or presentation. If the PDC requires modifications or delay of the publication or presentation, the publishing Party shall edit or delay such publication consistent with the requirements of the PDC, and when such modifications have been made or the need for any such delay shall have abated, the PDC will use Commercially Reasonable Efforts to approve the publication pursuant to the request of the Party, its Affiliates, employees or consultants requesting the publication. The PDC may refer certain publications regarding the Research Program to the JRC, and may, once a Product is under commercialization, refer publications regarding such Product to the Commercialization Committee.

7.5 **Publicity/Use of Names.** No disclosure of the existence, or the terms, of this Agreement may be made by either Party or its Affiliates, and no Party shall use the name, trademark, trade name or logo of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required be law. A Party may disclose this Agreement and its terms, and material developments or material Information generated under this Agreement, in securities filings with the Securities Exchange Commission ("SEC") (or equivalent foreign agency) to the extent required by law after complying with the procedure set forth in this Section 7.5. Since this Agreement will be deemed to be a "material"

agreement of GTx under applicable SEC rules and regulations, it will be filed with the SEC subsequent to the Closing Date. GTx will prepare a draft confidential treatment request and proposed redacted version of this Agreement to request confidential treatment for this Agreement, and Merck agrees to promptly (and in any event, no less than seven (7) days after receipt of such confidential treatment request and proposed redactions) give its input in a reasonable manner in order to allow GTx to file its request within the time lines proscribed by applicable SEC regulations. GTx shall exercise Commercially Reasonable Efforts to obtain confidential treatment of the Agreement from the SEC as represented by the redacted version reviewed by Merck.

Further, Merck acknowledges that GTx may be legally required to make public disclosures (including in filings with the SEC or other agency) of certain material developments or material Information generated under this Agreement and agrees that GTx may make such disclosures as required by law, *provided* that GTx first provides Merck a copy of the proposed disclosure, and provided further that (except to the extent that GTx is required to disclose such information to comply with applicable laws or regulations) if Merck demonstrates to GTx's reasonable satisfaction, within ten (10) days of GTx providing the copy, that the public disclosure of previously undisclosed information will materially adversely affect the development and/or commercialization of a Product being developed and/or commercialized by Merck, GTx will remove from the disclosure such specific previously undisclosed information as Merck shall reasonably request to be removed. Finally, Merck may request that GTx delay public disclosure of certain material developments or material Information generated under this Agreement for a reasonable period of time to allow Merck to present such developments and/or Information (e.g., at Merck's meetings with analysts), and GTx agrees to such delay, subject to GTx's obligations to disclose such developments and/or Information to the SEC or another regulatory agency.

Notwithstanding the foregoing, Merck and GTx have agreed on language of a joint press release and an associated mutually acceptable list of appropriate answers to anticipated questions (the "Q&A Attachment") announcing the Collaboration, which are collectively attached hereto as Schedule 7.5, to be issued after execution of the Agreement by both Parties on the Execution Date. GTx may make disclosures consistent with, and with no greater disclosure than in the agreed-upon press release and Q&A Attachment, in a conference call with analysts and interested investors.

The Parties agree that after a statement pertaining to this Agreement and/or the Collaboration has been approved by both Parties, either Party can repeat the statement in subsequent disclosures without first seeking the other Party's prior consent and approval.

ARTICLE 8 PAYMENTS; ROYALTIES AND REPORTS

8.1 **Research Funding.** In consideration for GTx's performance of its obligations under the Collaboration and in accordance with the provisions of Article 3 upon the terms and conditions contained in this Agreement (including, but not limited to, the meeting of all Closing Conditions), Merck shall pay GTx an amount equal to five million dollars per year ($5 million) for three (3) years beginning in 2008 and ending in 2010, to partially reimburse GTx for the basic research and medicinal chemistry activities it will undertake as approved by the JRC and as described in Section 3.1. Each annual payment amount shall be due and payable on the first, second and third anniversary dates of the Funding Trigger Date during 2008, 2009, and 2010. The "**Funding Trigger Date"** shall be the earlier of December 30, 2007, or the Closing Date. GTx shall apply the research funding it receives from Merck pursuant to this Section 8.1 solely to carry out its

Research Program activities in accordance with the terms and conditions of this Agreement. GTx will fund all of its other costs and expenses conducted in accordance with Section 3.1 in fulfilling its obligations to the Collaboration. **[*]**

8.2 **License Fee.** Upon the terms and conditions contained herein, Merck shall pay to GTx forty million dollars ($40 million) as a non-refundable, non-creditable License Fee. The License Fee shall be due and payable within thirty (30) days after the Closing Date.

8.3 **Equity Investment.** On the Closing Date, Merck shall purchase the Shares, on the terms and conditions set forth in the Stock Purchase Agreement.

8.4 **Milestone Payments.** Subject to the terms and conditions of this Agreement (including but not limited to the meeting of all Closing Conditions), Merck shall pay to GTx milestone payments as set forth in this Section 8.4.

8.4.1 **Development of [*].** Merck shall pay to GTx upon first achievement of the following milestones for a Product containing **[*]**:

[*]

8.4.2 **Development of [*].** Merck shall pay to GTx upon first achievement of the following milestones by a Product containing **[*]**:

[*]

8.4.3 **Development of [*].** Merck shall pay to GTx upon first achievement of the following milestones by a Product containing **[*]**:

[*]

8.4.4 **Development of [*].** If any Product containing **[*]**, then Merck shall pay to GTx upon first achievement of the following milestones by a Product containing **[*]**:

[*]

8.4.5 **Development of [*].** If a Product containing **[*]**, Merck shall pay to GTx upon first achievement **[*]** by such Product containing **[*]**.

[*]

8.4.6 **Development of [*].** Merck shall pay to GTx upon first achievement of the following milestones by **[*]**.

[*]

8.4.7 **Payment of Milestones.** Merck shall notify GTx in writing within thirty (30) days following the achievement of each milestone, and shall make the appropriate milestone payment within thirty (30) days after the achievement of such milestone. Milestones shall only be paid once for the initial achievement of such milestone for a particular Indication, regardless of how many Products have achieved such milestone for such Indication, and no amounts shall be due hereunder for subsequent or

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repeated achievement of a particular milestone. If the milestone is achieved for a particular Indication for a **[*]**, Merck shall pay **[*]** such milestone.

8.5 **Royalties.**

8.5.1 **Royalties Payable By Merck.** Subject to the terms and conditions of this Agreement (including but not limited to the meeting of all Closing Conditions), Merck shall pay GTx royalties, calculated on a Product-by-Product basis, as set forth in this Section 8.5.

(a) **Royalty Tiers for Products containing [*].** Subject to the remaining provisions of this Section 8.5, Merck shall pay GTx royalties for Net Sales by Merck or its Related Parties of each Product containing **[*]** in an amount equal to the following percentages:

(i) **[*]** of worldwide Net Sales in each Calendar Year up to and including **[*]**;

(ii) **[*]** of worldwide Net Sales in each Calendar Year for the portion of Net Sales exceeding **[*]** up to and including **[*]**; and

(iii) **[*]** of worldwide Net Sales in each Calendar Year for the portion of Net Sales exceeding **[*]**.

(b) **Royalty Tiers for Products containing [*].** Subject to the remaining provisions of this Section 8.5, Merck shall pay GTx royalties for Net Sales by Merck or its Related Parties of each Product containing **[*]** in an amount equal to **[*]**, as follows:

(i) **[*]** of worldwide Net Sales in each Calendar Year up to and including **[*]**;

(ii) **[*]** of worldwide Net Sales in each Calendar Year for the portion of Net Sales exceeding **[*]** up to and including **[*]**;and

(iii) **[*]** of worldwide Net Sales in each Calendar Year for the portion of Net Sales exceeding **[*]**.

(c) Royalty tiers pursuant to Sections 8.5.1(a) and 8.5.1(b) shall be calculated on a Product-by-Product basis, on worldwide Net Sales of each Product in the Territory. For purposes of calculating royalties hereunder, all formulations and/or doses of a Product containing the same Compound shall be deemed to be the same Product, regardless of the number of Indications for which such Product is approved, and any Product containing a different Compound shall be deemed to be a different Product. Royalties on each Product at the rates set forth above shall continue on a country-by-country basis until the later of (i) expiration of the last to expire Valid Patent Claim in the country of sale, or (ii) **[*]** years after first commercial sale of the first Product **[*]** (the **"Royalty Period"**).

(d) All royalties are subject to the following conditions:

(i) that only one royalty shall be due with respect to the same unit of Product;

(ii) that no royalties shall be due upon the sale or other transfer among Merck or its Related Parties, but in such cases the royalty shall be due and calculated upon Merck's or its Related Party's Net Sales to the first Third Party;

(iii) no royalties shall accrue on the sale or other disposition of Product by Merck or its Related Parties for use in a Clinical Trial; and

(iv) no royalties shall accrue on the disposition of Product in reasonable quantities by Merck or its Related Parties as samples (promotion or otherwise) or as donations (for example, to non-profit institutions or government agencies for a non-commercial purpose).

8.5.2 **Royalties for [*].** In those cases in which Merck sells to a Third Party **[*]**, the royalty obligations of this Section 8.5 shall be applicable to such sale of **[*]**.

8.5.3 **Compulsory Licenses.** If a compulsory license of GTx Patent Rights, Joint Patent Rights, or Merck Patent Rights is granted to a Third Party with respect to Product in any country in the Territory and such Third Party actually sells Product in the country under such compulsory license, then the royalty rate to be paid by Merck on Net Sales in that country under Section 8.5.1 shall be reduced to the rate paid by the compulsory licensee under such license for sale of the Product, for so long as such Third Party continues selling Product in such country.

8.5.4 **Third Party Licenses.**

(a) GTx shall be fully responsible for any payments owed to UTRF under the UTRF SARM License.

(b) Except as set forth in Section 8.5.4(a), in the event that one or more patent licenses from other Third Parties are required by Merck or its Related Parties in order to make, have made, use, offer to sell, sell or import Compound or Product(s) (hereinafter **"Third Party Patent Licenses"**), then:

(i) if such Compound is, or such Product contains, **[*]**, **[*]**, or

(ii) if such Compound is, or such Product contains, **[*]**, **[*]**

of any consideration actually paid under such Third Party Patent Licenses by Merck or its Related Parties for sale of such Compound or Product in a country for a Calendar Quarter shall be creditable against royalty payments due to GTx from Merck with respect to the sale of such Compound or Products in such country; provided, however, that in no event shall the royalties owed by Merck to GTx for such Compound or Product and such Calendar Quarter in such country be reduced by more than **[*]** in the case of **[*]**, or **[*]** in the case of **[*]**.

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8.6 **Reports; Payment of Royalty.** During the Term, following the First Commercial Sale of a Product, Merck shall furnish to GTx a quarterly written report for the Calendar Quarter showing the gross invoice price and aggregate deductions taken to determine Net Sales of all Products subject to royalty payments sold by Merck and its Related Parties in the Territory during the reporting period and the royalties payable under this Agreement, including such other information as GTx shall reasonably request to comply with its reporting obligations to UTRF under the UTRF SARM License to the extent that such other information is reasonably available to Merck consistent with its normal royalty accounting practices. Reports shall be due on the forty-fifth (45th) day following the close of each Calendar Quarter. Royalties shown to have accrued by each royalty report shall be due and payable on the date such royalty report is due. Merck shall keep complete and accurate records in sufficient detail to enable the royalties payable hereunder to be determined.

8.7 **Audits.**

8.7.1 Upon the written request of GTx and not more than once in each Calendar Year, Merck shall permit an independent certified public accounting firm of nationally recognized standing selected by GTx and reasonably acceptable to Merck (or if GTx shall fail to make a written request for an audit in the Calendar Year, upon the written request to Merck from GTx's licensor UTRF under the UTRF SARM License, *provided* that only one such request for an audit can be made by GTx and UTRF in any one Calendar Year), at GTx's expense, to have access during normal business hours to such of the records of Merck as may be reasonably necessary to verify the accuracy of the royalty reports hereunder for any Calendar Year ending not more than thirty-six (36) months prior to the date of such request. The accounting firm shall disclose to GTx only whether the royalty reports are correct or incorrect and the amount and nature of any discrepancy, and the details of the discrepancy. No other information shall be provided to GTx.

8.7.2 If such accounting firm identifies a discrepancy made during such period, the appropriate Party shall pay the other Party the amount of the discrepancy within thirty (30) days of the date GTx delivers to Merck such accounting firm's written report so correctly concluding, or as otherwise agreed upon by the Parties. The fees charged by such accounting firm shall be paid by GTx; *provided*, *however*, that if such audit uncovers an underpayment of royalties by Merck that either (i) exceeds **[*]** or (ii) **[*]** of the total royalties owed, then (subject to Section 15.6) all fees of such accounting firm shall be paid by Merck.

8.7.3 Merck shall include in each sublicense granted by it pursuant to this Agreement a provision requiring the sublicensee to make reports to Merck, to keep and maintain records of sales made pursuant to such sublicense and to grant access to such records by GTx's independent accountant to the same extent required of Merck under this Agreement.

8.7.4 Upon the expiration of thirty-six (36) months following the end of any Calendar Year, the calculation of royalties payable with respect to such Calendar Year shall be binding and conclusive upon GTx, and Merck and its Related Parties shall be released from any liability or accountability with respect to royalties for such Calendar Year.

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8.7.5 GTx shall treat all financial information subject to review under this Section 8.7 or under any sublicense agreement in accordance with the confidentiality and non-use provisions of this Agreement, and shall cause its accounting firm to enter into a reasonable confidentiality agreement with Merck and/or its Related Parties obligating it to retain all such information in confidence pursuant to such confidentiality agreement.

8.8 **Payment Exchange Rate.** All payments to be made by Merck to GTx under this Agreement shall be made in United States dollars and may be paid by check made to the order of GTx or bank wire transfer in immediately available funds to such bank account in the United States as may be designated in writing by GTx from time to time. In the case of sales outside the United States, the rate of exchange to be used in computing the monthly amount of currency equivalent in United States dollars due GTx shall be made at the monthly rate of exchange utilized by Merck in its worldwide accounting system, prevailing on the third to the last business day of the month preceding the month in which such sales are recorded by Merck.

8.9 **Income Tax Withholding.** If applicable laws, rules or regulations require withholding of income or other taxes imposed upon any payments made by Merck to GTx under Article 3 of the Agreement, Merck shall make such withholding payments as may be required and shall subtract such withholding payments from such payments. Merck shall promptly notify GTx of such withholding and submit appropriate proof of payment of the withholding taxes to GTx within a reasonable period of time. Merck shall promptly provide GTx with the official receipts. Merck shall render GTx reasonable assistance in order to allow it to obtain the benefit of any present or future treaty against double taxation which may apply to such payments. If Merck had a duty to withhold taxes in connection with any payment it made to GTx under the Agreement but Merck failed to withhold, and such taxes were assessed against and paid by Merck, then GTx will hold harmless and reimburse Merck from and against such taxes (including interest). If Merck makes a claim under this section, it will comply with the obligations imposed by this section as if Merck had withheld taxes from a payment to GTx.

ARTICLE 9 REGULATORY RESPONSIBILITIES; ADVERSE EXPERIENCE REPORTING

9.1 **Regulatory Responsibilities.** Except for the interactions GTx will be required to have with the Regulatory Authorities for the Cancer Trial, Merck shall have the sole right and responsibility with respect to interactions with Regulatory Authorities regarding the development, marketing, sale and/or manufacturing of Products, including but not limited to any IND, Marketing Authorization, and adverse experience reporting. In the event that a Party exercises its Opt-Out rights pursuant to Section 3.4.1, such Party shall have the sole right and responsibility for interactions with Regulatory Authorities regarding the Differentiated Compound and products containing such Differentiated Compound. Promptly after the Closing Date, GTx shall execute all documents necessary to transfer any open INDs to Merck; *provided* that the Parties may agree to delay transfer of particular INDs in order to allow completion of Clinical Trials or particular interactions with Regulatory Authorities.

9.2 **Adverse Experience Reporting.**

9.2.1 GTx agrees throughout the duration of this Agreement to notify the other Party within two (2) working days in English of any information of which GTx becomes aware concerning any side effect, injury, toxicity or sensitivity reaction, or any unexpected incident, and the severity thereof, whether or not determined to be

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attributable to any Product (hereinafter **"Adverse Experience"**), where such Adverse Experience is (i) serious and associated with the clinical uses, studies, investigations, tests and marketing of Product, whether or not determined to be attributable to Product. With respect to all other adverse experiences (non-serious expected or non-serious unexpected adverse experiences), GTx shall furnish the other Party with copies of such non-serious adverse experiences reported to GTx in connection with the marketing of Product, in English, within 10 working days after receipt. "Serious" as used in this Section refers to an experience which results in death, is immediately life threatening, results in persistent and significant disability/incapacity or requires in-patient hospitalization, or prolongation of existing hospitalization, or is a congenital anomaly, cancer or an overdose. Other important medical events that may jeopardize the patient or may require intervention to prevent one of the outcomes previously listed should also be considered serious. "Unexpected" as used in this Section refers to a condition or development not listed in the current labeling for Product, and includes an event that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differs from the event because of increased frequency or greater severity or specificity. Furthermore, GTx agrees throughout the Term to notify the other Party in English of any "Serious" Adverse Experience which occurs in the Territory within 2 working days after the Party becomes aware of such event and of any Non-serious Adverse Experience which occurs in the Territory within 10 working days after the Party becomes aware of such event.

9.2.2 With respect to Clinical Trials being carried out by or on behalf of GTx or Merck, adverse experience reports of unexpected and fatal or life-threatening events which are possibly, probably, definitely related or of unknown relationship to the use of Product must be forwarded to by one Party to the other Party within 3 calendar days after receipt of the information. In addition, GTx shall furnish to the other Party copies of the end of study summary of adverse experiences in English within the time period set forth in the applicable then-current Development Program for the Product.

9.2.3 It is understood and agreed that these adverse experience reporting requirement provisions are based on the policies and procedures of Merck and regulatory reporting requirements. Accordingly, in the event of changes to regulatory requirements for adverse experience reporting, GTx agrees to comply with such revised notification requirements.

9.2.4 In the event that GTx exercises its Opt-Out rights pursuant to Section 3.4.1, then as it relates to such Differentiated Compound and products containing such Differentiated Compound, the rights and obligations of GTx pursuant to Sections 9.2.1 and 9.2.2 shall apply to Merck, and the rights and obligations of Merck pursuant to this Sections 9.2.1 and 9.2.2 shall apply to GTx *mutatis mutandis*.

ARTICLE 10 REPRESENTATIONS AND WARRANTIES; LIMITATIONS ON LIABILITY

10.1 **Representations and Warranties of Each Party.** Each Party represents and warrants to the other Party that as of the Execution Date:

10.1.1 it has the full right, power and authority to enter into this Agreement, to perform its obligations hereunder, and to grant the licenses granted under Article 6; and

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10.1.2 this Agreement has been duly executed by it and is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

10.2 **GTx Representations and Warranties.** GTx represents and warrants to Merck that as of the Execution Date of this Agreement:

10.2.1 to GTx's knowledge and belief, the GTx Background Patent Rights are not invalid or unenforceable, in whole or in part;

10.2.2 except for the granting of certain rights in GTx's SARM, andarine, and certain other SARMs to a Third Party in 2004, which was subsequently terminated without any rights remaining in such Third Party, it has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in GTx Patent Rights or GTx SARM Know-How;

10.2.3 to GTx's knowledge, it is the sole and exclusive owner or sole and exclusive licensee of the GTx Patent Rights and GTx SARM Know-How, all of which are free and clear of any liens, charges and encumbrances, and no other person, corporate or other private entity, or governmental entity or subdivision thereof, has or shall have any claim of ownership whatsoever with respect to the GTx Patent Rights and GTx SARM Know-How, except as otherwise disclosed to Merck in Schedule 10.2.3 hereof;

10.2.4 to GTx's knowledge, the development, manufacture, use, sale and import of Compound(s) and Product(s) that GTx currently knows of, under and in accordance with the GTx Patent Rights and GTx Know-How, does not infringe any intellectual property rights owned or possessed by any Third Party;

10.2.5 to GTx's knowledge, there are no claims, judgments or settlements against or owed by GTx and no pending or threatened claims or litigation relating to the GTx Background Patent Rights and GTX Background SARM Know-How;

10.2.6 to GTx's knowledge, GTx has disclosed to Merck all reasonably relevant information regarding the GTx Patent Rights and GTx SARM Know-How licensed under this Agreement;

10.2.7 to GTx's knowledge, **[*]**;

10.2.8 GTx has the SARM scientific core competency and basic research infrastructure (scientists, equipment and facilities) to support its responsibilities for research and development as described in Section 3.1.

10.2.9 GTx has **[*]**.

10.3 **Merck Representations and Warranties.** Merck represents and warrants to GTx that as of the Execution Date of this Agreement:

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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.

10.3.1 to Merck's knowledge and belief, the Merck Background Patent Rights and Merck Background SARM Know-How exists and are not invalid or unenforceable, in whole or in part;

10.3.2 it has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in Merck Patent Rights or Merck SARM Know-How;

10.3.3 to Merck's knowledge, upon reasonable investigation, it is the sole and exclusive owner of the Merck Patent Rights and Merck SARM Know-How, all of which are (and shall be, in the case of Merck Information and Inventions) free and clear of any liens, charges and encumbrances, and no other person, corporate or other private entity, or governmental entity or subdivision thereof, has or shall have any claim of ownership whatsoever with respect to the Merck Patent Rights and Merck SARM Know-How;

10.3.4 to Merck's knowledge, upon reasonable investigation, the exercise of the license granted to GTx under the Merck Patent Rights and Merck SARM Know-How, including without limitation the development, manufacture, use, sale and import of Compound(s) and Product(s), do not interfere with or infringe any intellectual property rights owned or possessed by any Third Party;

10.3.5 to Merck's knowledge, there are no claims, judgments or settlements against or owed by Merck and no pending or threatened claims or litigation relating to the Merck Background Patent Rights and Merck Background SARM Know-How; and

10.3.6 to Merck's knowledge, there are no claims, judgments or settlements owed by Merck and no pending or threatened claims or litigation relating to the Merck Background Patent Rights and Merck Background SARM Know-How; and

10.3.7 Merck has the right to grant the licenses under Merck Know-How and Merck Patent Rights to the extent set forth in this Agreement.

10.4 **Limitation of Liability.** EXCEPT FOR A BREACH OF ARTICLE 7 OR EITHER PARTY'S OBLIGATIONS UNDER ARTICLE 11, IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR ANY INDIRECT, SPECIAL, PUNITIVE, INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING, WITHOUT LIMITATION, ANY LOSS OF PROFITS, LOSS OF BUSINESS, LOSS OF USE, LOSS OR INACCESSIBILITY OF DATA, OR INTERRUPTION OF BUSINESS, ARISING UNDER OR RELATING TO THIS AGREEMENT OR THE SUBJECT MATTER HEREOF, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

10.5 **Covenant of Merck**. As soon as reasonably practical after the Closing Date, but in any event prior to Merck and GTx scientists meeting together to exchange information about their respective Compounds and expertise, Merck will disclose to GTx all reasonably relevant information regarding the Merck Patent Rights claiming the Merck Compounds existing as of the Execution Date licensed under this Agreement and Merck SARM Know-How related to such Merck Compounds.

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ARTICLE 11 INDEMNIFICATION

11.1 **By Merck.** Merck agrees to indemnify, hold harmless and defend GTx, its Affiliates and its and their respective officers, directors, shareholders, employees, successors and assigns (collectively, the **"GTx Indemnified Parties"**) against any and all losses, costs, expenses, fees or damages arising out of or relating to claims, allegations, suits, actions or proceedings (including reasonable attorneys fees and expenses incurred in connection therewith, except as otherwise set forth in this Section 11.1) asserted by any Third Party (collectively, the "**Costs**"), whether governmental and private, to the extent arising out of or relating to (i) personal injury arising from the research, development, manufacture, use, sale or other disposition by Merck or its Related Parties or their respective distributors (A) of Product under this Agreement or (B) of any Product containing a Differentiated Compound pursuant to Merck's Opt-Out rights hereunder; (ii) Merck's breach of any of its representations and warranties set forth in Sections 10.1, 10.3 or 13.3(f) of this Agreement; (iii) Merck's failure to comply with all applicable laws, rules and regulations; (iv) Merck's sublicensing of rights under this Agreement or (v) the gross negligence or willful misconduct of any of the Merck Indemnified Parties as defined below, *provided* that Merck shall not be required to indemnify, hold harmless or defend any GTx Indemnified Party against any claim arising out of or related to any GTx Indemnified Party's (w) use, research, and/or development of any Product under this Agreement; (x) research, development, manufacture, use, sale or other disposition of any Product containing a Differentiated Compound which is developed and commercialized by GTx pursuant to GTx's Opt-Out rights hereunder; (y) gross negligence, willful misconduct, or breach of this Agreement, or (z) failure to comply with all applicable laws, rules and regulations, to the extent that any failure pursuant to 11.1(w), (x), (y), or (z) contributes to the Costs.

11.2 **By GTx.** Subject to the limitations set forth in this Section 11.2, GTx agrees to indemnify, hold harmless and defend Merck, its Affiliates and its respective officers, directors, shareholders, employees, successors and assigns (collectively, the **"Merck Indemnified Parties"**) against any and all Costs (as defined in Section 11.1) arising out of or relating to claims, allegations, suits, actions or proceedings asserted by any Third Party, whether governmental and private, to the extent arising out of or relating to (i) personal injury (A) occurring during the use, research or development of a Product under this Agreement by a GTx Indemnified Party or (B) arising from the research, development, manufacture, use, sale or other disposition, by GTx or its Affiliates or sublicensees or their respective distributors, of any Product (1) containing a Differentiated Compound, pursuant to GTx's Opt-Out rights hereunder or (2) upon termination of this Agreement, pursuant to a license granted by Merck pursuant to ARTICLE 14; (ii) GTx's breach of any of its representations and warranties set forth in Sections 10.1, 10.2 or 13.3(e) of this Agreement **[*]**; (iii) GTx's failure to comply with all applicable laws, rules and regulations; or (iv) the gross negligence or willful misconduct of any of the GTx Indemnified Parties, *provided* that GTx shall not be required to indemnify, hold harmless or defend any Merck Indemnified Party against any claim arising out of or related to any Merck Indemnified Party's (x) use, research, development, manufacture and/or commercialization of any Product under this Agreement or of any Product containing a Differentiated Compound which is developed and commercialized by Merck pursuant to Merck's Opt-Out rights hereunder; (y) gross negligence, willful misconduct, or breach of this Agreement, or (z) failure to comply with all applicable laws, rules and regulations, to the extent any failure pursuant to 11.2(x), (y), or (z) contributes to the Costs.

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11.3 **Procedure.** If either Party is seeking indemnification under Sections 11.1 or 11.2 (the **"Indemnified Party"**), it shall inform the other Party (the **"Indemnifying Party"**) of the claim giving rise to the obligation to indemnify pursuant to such section as soon as reasonably practicable after receiving notice of the claim. The Indemnifying Party shall have the right to assume the defense of any such claim for which it is obligated to indemnify the Indemnified Party. The Indemnified Party shall cooperate with the Indemnifying Party and the Indemnifying Party's insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party's cost and expense. The Indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any claim or suit that has been assumed by the Indemnifying Party. Neither Party shall have the obligation to indemnify the other Party in connection with any settlement made without the Indemnified Party's written consent, which consent shall not be unreasonably withheld or delayed. If the Parties cannot agree as to the application of Sections 11.1 or 11.2 as to any claim, pending resolution of the dispute pursuant to Section 12.6, the Parties may conduct separate defenses of such claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Sections 11.1 or 11.12 upon resolution of the underlying claim.

ARTICLE 12 PATENT AND TRADEMARK PROVISIONS.

12.1 **Filing, Prosecution and Maintenance of Patents.**

12.1.1 Subject to the remaining provisions of this Section 12.1, each Party agrees to exercise Commercially Reasonable Efforts to file, prosecute and maintain (**"Prosecute"**) in the Territory, upon appropriate consultation with each other, their respective Patent Rights, and Merck will be responsible for Prosecuting in the Territory, after consultation with GTx, any Joint Patent Rights and Merck Patent Rights.

12.1.2 The Parties agree, promptly after the Closing Date, to disclose to each other all relevant information regarding each others patent applications and prosecution efforts regarding their respective SARM Patent Rights, and to share information and collaborate with one another in order to devise a reasonably uniform and consistent patent strategy to Prosecute their respective Patent Rights.

12.1.3 The Party that is Prosecuting GTx Patent Rights, Merck Patent Rights or Joint Patent Rights, in each case (i) shall give the other Party an opportunity to review the text of the Material Patent Documents and Material Patent Drafts in a timely manner before filing, shall consult with the other Party with respect thereto, and shall supply the other Party with a copy of the Material Patent Documents and Material Patent Drafts and responses as filed, together with notice of its filing date and serial number; (ii) shall keep the other Party advised of the status of the actual and prospective patent filings; (iii) shall report and provide the other Party with all prosecution in a foreign jurisdiction in a timely manner; (iv) upon the other Party's request, shall provide advance copies of any papers related to the Prosecution of such patent filings; and (v) promptly give notice to the other Party of the grant, lapse, revocation, surrender, invalidation or abandonment of any GTx Patent Rights, Merck Patent Rights, or Joint Patent Rights for which such Party is responsible for Prosecution.

12.1.4 With respect to all filings occurring from and after the Closing Date, the Parties shall share equally in the out-of-pocket expenses incurred (other than outside attorneys'

fees) related to the Prosecution of their Patent Rights. In connection herewith, the Parties agree that they shall aggregate all out-of-pocket Third Party (but not including outside attorneys' fees) patent costs each quarter expended in the Prosecution of their respective Patent Rights and will share this information with the other Party within thirty (30) days of the end of each such quarter, with the agreement that the total out-of-pocket Third Party costs for both Parties shall be divided equally between the Parties and there shall be a settling up of expenses made by each such Party during the quarter so that each Party shall have paid only 50% of such aggregate amount.

12.2 **Interference, Opposition, Reexamination and Reissue.**

12.2.1 Each Party shall, within ten (10) days of learning of an interference, opposition proceeding, or reexamination and/or reissue of one of its patents, inform the other Party of any request for, or filing or declaration of, any interference, opposition, reissue or reexamination relating to each Party's Patent Rights. Merck and GTx shall thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. Merck shall have the right to review and approve any submission to be made in connection with such proceeding.

12.2.2 Each Party agrees that it will not initiate any opposition, reexamination, interference or reissue proceeding relating to their respective Patent Rights without the prior written consent of the other Party, such consent not to be unreasonably withheld.

12.2.3 In connection with any interference, opposition, reissue, or reexamination proceeding relating to GTx Patent Rights, GTx shall take the lead. Merck and GTx will cooperate fully and will provide each other with all Material Patent Documents and Material Patent Drafts relating to GTx Patent Rights, and provide any information or assistance that either may reasonably request. Merck shall have the right to approve any submission to be made in connection with such proceeding, such approval not to be unreasonably withheld. If GTx shall fail or refuse to take any action with regard to any interference, opposition, reissue, or reexamination proceeding pertaining to the GTx Patent Rights within thirty (30) days after GTx shall have been notified thereof, then Merck shall have the right to take the lead, and Merck and GTx will cooperate fully and will provide each other with any information or assistance that either may reasonably request.

12.2.4 In connection with any interference, opposition, reissue, or reexamination proceeding relating to Merck Patent Rights and/or Joint Patent Rights, Merck shall take the lead. Merck and GTx will cooperate fully and will provide each other with all Material Patent Documents and Material Patent Drafts relating to Merck Patent Rights and/or Joint Patent Rights, and provide any information or assistance that either may reasonably request. GTx shall have the right to approve any submission to be made in connection with such proceeding, such approval not to be unreasonably withheld. If Merck shall fail or refuse to take any action with regard to any interference, opposition, reissue, or reexamination proceeding pertaining to the Merck Patent Rights and/or Joint Patent Rights within thirty (30) days after Merck shall have been notified thereof, then GTx shall have the right to take the lead, and Merck and GTx will cooperate fully and will provide each other with any information or assistance that either may reasonably request.

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12.2.5 The Parties shall share equally in the expense of any interference, opposition, reexamination, or reissue proceeding relating to GTx Patent Rights, Merck Patent Rights or Joint Patent Rights.

12.2.6 Both Parties shall, as soon as practicable after receiving notice of such action, convene and consult with each other regarding the appropriate course of conduct for such action. Each Party shall have the right to be kept fully informed by the other Party and to participate in the decisions regarding the appropriate course of conduct for such action, and the right to join and participate in such action.

12.3 **Enforcement and Defense.**

12.3.1 Each Party shall give the other Party notice of either (i) any infringement of GTx Patent Rights, Merck Patent Rights and/or Joint Patent Rights, or (ii) any misappropriation or misuse of GTx SARM Know-How, Merck SARM Know-How and/or proprietary know-how developed through the Collaboration that may come to either Party's attention. Merck and GTx shall consult and cooperate fully to determine a course of action, including but not limited to the commencement of legal action to terminate any infringement of GTx Patent Rights, Merck Patent Rights, or Joint Patent Rights or any misappropriation or misuse of such GTx SARM Know-How, Merck SARM Know-How and/or other proprietary know-how. Merck, upon notice to GTx, shall have the right to initiate and prosecute such legal action in the name of GTx and Merck, or to control the defense of any declaratory judgment action relating to GTx Patent Rights or GTx SARM Know-How. If Merck shall fail or refuse to take any action with regard to infringement, misappropriation or misuse of GTx SARM Know-How, Merck SARM Know-How and/or other proprietary know-how within thirty (30) days after Merck shall have been notified thereof, then GTx shall have the right to take the lead in any such proceeding and Merck and GTx will cooperate fully and will provide each other with any information or assistance that either may reasonably request. Each Party shall have the right to be represented by counsel of its own choice.

12.3.2 The costs of any agreed-upon course of action to terminate infringement of GTx Patent Rights, Merck Patent Rights or Joint Patent Rights, or misappropriation or misuse of GTx SARM Know-How or Merck SARM Know-How, including without limitation the costs of any legal action commenced or the defense of any declaratory judgment shall be shared equally by GTx and Merck.

12.3.3 For any action to terminate any infringement of GTx Patent Rights or any misappropriation or misuse of GTx SARM Know-How, in the event that Merck is unable to initiate or prosecute such action solely in its own name, GTx will join such action voluntarily and will execute and cause its Affiliates to execute all documents necessary for Merck to initiate litigation to prosecute and maintain such action. In connection with any action, Merck and GTx will cooperate fully and will provide each other with any information or assistance that either may reasonably request. Each Party shall keep the other informed of developments in any action or proceeding, including, to the extent permissible by law, consultation on and approval of any settlement, the status of any settlement negotiations and the terms of any offer related thereto.

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12.3.4 Subject to the rights of UTRF under the UTRF SARM License as it pertains to GTx Patent Rights licensed from UTRF, any recovery obtained by either or both Merck and GTx in connection with or as a result of any action contemplated by this Section, whether by settlement or otherwise, shall be shared in order as follows:

(a) the Party which initiated and prosecuted the action shall recoup all of its costs and expenses incurred in connection with the action;

(b) the other Party shall then, to the extent possible, recover its costs and expenses incurred in connection with the action; and

(c) the amount of any recovery remaining shall then be allocated between the Parties **[*]**.

12.3.5 Each Party shall inform the other Party of any certification regarding any the Party's Patent Rights it shall have received pursuant to either 21 U.S.C. §§355(b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) or its successor provisions or any similar provisions in a country in the Territory other than the United States, and shall provide the other Party with a copy of such certification within five (5) days of receipt. Merck's rights with respect to the initiation and prosecution of any legal action as a result of such certification or any recovery obtained as a result of such legal action shall be as defined in Sections 12.3.1 through 12.3.4. Both Parties shall, as soon as practicable after receiving notice of such certification, convene and consult with each other regarding the appropriate course of conduct for such action. GTx shall have the right to be kept fully informed and participate in decisions regarding the appropriate course of conduct for such action, and the right to join and participate in such action.

12.4 **Cooperation on Patent Matters.** The Parties agree to cooperate and to take reasonable actions to maximize the protections available under the safe harbor provisions of 35 U.S.C. 103(c) for US patents and patent applications. The Parties shall cooperate with each other, including without limitation to provide necessary information and assistance as the other Party may reasonably request, in obtaining patent term restoration or supplemental protection certificates or their equivalents in any country in the Territory where applicable to GTx Patent Rights and/or Merck Patent Rights. In the event that elections with respect to obtaining such patent term restoration are to be made, Merck shall have the right to make the election and GTx agrees to abide by such election, subject to the following: if patent term restoration arises in connection with GTx's development of a Differentiated Compound under Section 3.4.1 as to which Merck did not exercise the Merck Opt-In under Section 3.4.3, and if an election by GTx of patent term restoration does not undermine Merck's position regarding patent term restoration as set forth in this Section 12.4 or if no other Product is in Phase III development or being commercialized as of the time of such election, then GTx shall have the right to make the election and Merck agrees to abide by such election.

12.5 **Trademarks**. Merck will be responsible for Prosecuting in the Territory any trademarks and/or trade names for use in connection with Product, except in the case of any Products licensed to GTx under Section 6.4.1, as to which GTx shall be responsible for such Prosecution. The Parties will disclose to each other, promptly after the Closing Date, all relevant information regarding their respective SARM-related trademarks, including (in the case of GTx) the GTx Trademarks.

ARTICLE 13 CONDITIONS TO CLOSING; HSR ACT

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13.1 **HSR Filing.** Unless otherwise exempted from filing, each of Merck and GTx shall, within fifteen (15) days after the Execution Date, file with the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice, any HSR Filing required of it under the HSR Act with respect to the transactions contemplated hereby. The Parties will cooperate with one another to the extent necessary in the preparation of any such HSR Filing. Each Party will be responsible for its own costs, expenses, and filing fees associated with any HSR Filing.

13.2 **Cooperation.** In respect of any HSR Filing, each of Merck and GTx will use its good faith, diligent efforts to resolve and address any concerns on the part of any court or Governmental Authority regarding the legality of the proposed transaction, including cooperating in good faith with any government investigation and the prompt production of documents and information demanded by a second request for documents and of witnesses if requested, and to cause the Closing Date of this Agreement to occur as soon as practicable, as provided in Section 13.3.

13.3 **Closing Date of Agreement.** The "Closing Date" shall not occur until (a) the waiting period under the HSR Act shall have expired or earlier been terminated; (b) no injunction (whether temporary, preliminary or permanent) prohibiting consummation of the transactions contemplated by this Agreement or any material portion hereof shall be in effect; (c) no requirements or conditions shall have been imposed in connection therewith which are not reasonably satisfactory to the Parties; (d) each Party shall certify that the representations set forth in Section 10.1 (Representations and Warranties) remain true and correct as of the Closing Date; (e) GTx shall certify that the representations set forth in Sections 10.2.1 and 10.2.2 remain true and correct as of the Closing Date; (f) Merck shall certify that the representations set forth in Sections 10.3.1, 10.3.2 and 10.3.7 remain true and correct as of the Closing Date; and (g) the "Closing" (as such term is defined in the Stock Purchase Agreement) of the sale and purchase of the Shares under Section 2.1 of the Stock Purchase Agreement shall have occurred on or before the Closing Date (collectively, the **"Closing Conditions"**). In the event that the Closing Conditions are not satisfied on or before termination of the Stock Purchase Agreement, this Agreement shall terminate, and the Parties acknowledge that the provisions of Sections 14.2, 14.3 and 15.10 shall not survive such termination.

13.4 **Portions of Agreement effective as of Execution Date.** Notwithstanding Section 13.3, the following provisions of the Agreement shall be in full force and effect as of the Execution Date: ARTICLE 1 (Definitions), ARTICLE 7 (Confidentiality and Publications), ARTICLE 10 (Representations and Warranties), ARTICLE 13 (Conditions to Closing), ARTICLE 14 (Termination), and ARTICLE 15 (Miscellaneous).

13.5 **Activities between Execution Date and Closing Date.** Effective upon the Closing Date: (i) GTx SARM Know-How and GTx Patent Rights resulting from the independent activities of GTx between the Execution Date and Closing Date shall be deemed to be GTx Background SARM Know-How and GTx Background Patent Rights, respectively, and subject to the licenses granted by GTx to Merck hereunder; and (ii) Merck SARM Know-How and Merck Patent Rights resulting from the independent activities of Merck between the Execution Date and Closing Date shall be deemed to be Merck Background SARM Know-How and Merck Background Patent Rights, respectively, and subject to the licenses granted by Merck to GTx hereunder.

ARTICLE 14 TERM AND TERMINATION

14.1 **Term and Expiration.** Except as set forth in Section 13.4, this Agreement shall be effective as of the Closing Date and unless terminated earlier pursuant to Sections 14.2 or 14.3, this

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Agreement shall continue in full force and effect until one or more Products has received Marketing Authorization and, thereafter, until expiration of all royalty obligations hereunder (the **"Term"**). Upon expiration of this Agreement, the licenses granted hereunder pursuant to Sections 6.1, 6.3 and 6.4 shall become fully paid-up, non-exclusive, perpetual licenses.

14.2 **Termination by Merck.**

14.2.1 Notwithstanding anything contained herein to the contrary, from and after **[*]** following the Closing Date, Merck shall have the right to terminate this Agreement at any time in its sole discretion by giving ninety (90) days' advance written notice to GTx.

14.2.2 If Merck terminates this Agreement pursuant to Section 14.2.1, (i) Merck shall pay all amounts then due and owing to GTx as of the termination date; (ii) Merck shall continue to be obligated during the termination notice period to perform all of its obligations under this Agreement, including its obligation to pay all expenses associated with any ongoing Development Program (including the expense of any Clinical Trials *provided*, that Merck shall not be obligated to continue such funding if Merck in good faith believes that any such Clinical Trials should be terminated for Safety reasons); and (iii) Merck shall continue to be obligated to provide any research funding pursuant to Section 8.1 that would become due in the period between Merck's notice of termination and the third anniversary date of the Funding Trigger Date in 2010. In addition, as a result of any such termination by Merck under Section 14.2.1:

(i) all licenses and rights to GTx Patent Rights, GTx SARM Know-How, and GTx Trademarks granted to Merck hereunder shall terminate;

(ii) all Information in tangible form and all substances or compositions delivered or provided by GTx to Merck, as well as any other material provided by GTx to Merck in any medium, shall be returned to GTx, except that Merck may retain one copy of such Information solely for legal archive purposes;

(iii) subject to the remaining provisions of this Section 14.2.2, all Information in tangible form and all substances or compositions delivered or provided by Merck to GTx, as well as any other material provided by Merck to GTx in any medium, shall be returned to Merck, except that GTx may retain one copy of such Information solely for legal archive purposes;

(iv) Merck shall transfer to GTx such technology and information reasonably necessary to allow GTx to manufacture and supply Compounds and Products covered under the GTx Patent Rights, GTx SARM Know-How and/or Joint Patent Rights for which plans shall have been approved by the PDC to commence Phase I Clinical Studies or which are in clinical development or being marketed, including any finished Product inventory or Product supply Merck then may have on hand to manufacture Product under such Patent Rights, *provided* that Merck shall be relieved of this obligation in the event Merck in good faith believes

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there is a question of Safety pertaining to any such inventory or Product supply;

(v) If Merck's election to terminate this Agreement is effective prior to completion of a Clinical Trial for any Compound covered by GTx Patent Rights, GTx SARM Know-How and/or Joint Patent Rights that already has been Initiated, Merck shall be obligated for the period ending thirty (30) days after the effective date of such termination to continue to fund the Clinical Trial at its expense in accordance with the protocol for the Clinical Trial approved by the PDC, and to transfer any clinical data and Clinical Trial results generated from such Clinical Trials during such period to GTx unless Merck shall reasonably believe the Clinical Trial should not be continued or completed for reasons of Safety.

(vi) Merck shall promptly transfer and assign ownership to GTx of all INDs, Marketing Authorizations and NDAs for Compounds and Products covered by GTx Patent Rights, GTx SARM Know-How, and/or Joint Patent Rights, shall enter into an agreement granting GTx a royalty-free exclusive license under all trademarks owned by Merck covering such Compounds and Products, but only if such trademarks have been publicly associated with such Compound or Product, and shall take such other actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights hereunder to GTx;

(vii) Merck shall agree that any SARM that is owned by or licensed in by Merck or any Affiliate of Merck that (i) is in clinical development or is commercialized for any Indication, including any Identified Indication, as of the effective date of termination of the Agreement on account of Merck's exercise of its right to terminate under Section 14.2.1, or (ii) enters clinical development or is commercialized for any Indication, including any Identified Indication, during the period of **[*]** from and after the effective date of termination, shall **[*]** notwithstanding the termination by Merck;

(viii) GTx shall grant to Merck a non-exclusive license under GTx Patent Rights and GTx SARM Know-How (but not GTX Background SARM Know-How) (i) to use Merck Compounds and Collaboration Compounds on a fully paid up basis for research purposes, and (ii) to develop, make, have made, use, sell and offer to sell Products containing (A) Merck Compounds or (B) Collaboration Compounds that have been identified by the JRC as Development Candidates, or are in clinical development or are being commercialized as of the termination date and Products embodying such Collaboration Compounds and Merck Compounds; *provided, however*, that any development and/or sale of such Products shall **[*]** notwithstanding Merck's termination of this Agreement, in each case in the form that such Collaboration Compounds and Products exist as of such termination date, and excluding any GTx SARM Know-How that is, and claims of GTx Patent Rights that specifically claim,

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proprietary manufacturing methods or techniques developed independent of this Agreement and generally applicable to other GTx compounds.

(ix) Merck shall grant to GTx a non-exclusive license under Merck Patent Rights and Merck SARM Know-How (but not Merck Background SARM Know-How) (i) to use GTx Compounds and Collaboration Compounds on a fully paid up basis for research purposes, and (ii) to develop, make, have made, use, offer to sell, sell and/or import (A) GTx Compounds and (B) Collaboration Compounds that have been identified by the JRC as Development Candidates, or are in clinical development, or are being commercialized as of the termination date, and Products embodying such Collaboration Compounds and GTx Compounds, in each case in the form that such Collaboration Compounds and Products exist as of such termination date, and excluding any Merck SARM Know-How that is, and claims of Merck Patent Rights that specifically claim, proprietary manufacturing methods or techniques developed independent of this Agreement and generally applicable to other Merck compounds; and

(x) All Collaboration Compounds that are not subject to Section 14.2.2(viii and ix) above (i.e,,Collaboration Compounds that have not been identified by the JRC as Development Candidates as of the termination date) will be fully transferred by Merck to GTx, and Merck shall have no other or further rights in such Collaboration Compounds. Merck shall grant to GTx (i) a non-exclusive license under the Merck Patent Rights and Merck SARM Know-How (but not Merck Background SARM Know-How) and (ii) an exclusive license under its rights in Joint Patent Rights and Joint Information and Inventions, to make, have made, use, offer to sell, sell and/or import any such Collaboration Compounds and Products embodying such Collaboration Compounds.

14.2.3 Except for the surviving provisions set forth above and in Section 14.4, the rights and obligations of the Parties hereunder shall terminate as of the date of such termination.

14.3 **Termination for Cause.**

14.3.1 **Cause for Termination.** This Agreement may be terminated at any time during the Term:

(a) upon written notice by either Party if the other Party materially breaches one or more of its obligations under this Agreement, and has not cured such breach within ninety (90) days after notice requesting cure of the breach; *provided*, *however*, in the event of a good faith dispute with respect to the existence of a material breach, the ninety (90) day cure period shall be tolled until such time as the dispute is resolved pursuant to Section 15.6; or

(b) by either Party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; *provided*, *however*, that in the case of any involuntary bankruptcy proceeding such right to

terminate shall only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within ninety (90) days after the filing thereof.

14.3.2 **Effect of Termination for Cause.**

(a) If Merck terminates this Agreement under Section 14.3.1, then it may proceed under this Section 14.3.2(a) or under Section 14.3.3. If Merck determines, at its option and sole discretion to terminate the Agreement under this Section 14.3.2(a), then:

(i) All licenses and rights to Merck Patent Rights and Merck SARM Know-How granted to GTx hereunder shall terminate.

(ii) All Information in tangible form and all substances or compositions delivered or provided by Merck to GTx, as well as any other material provided by Merck to GTx in any medium, shall be returned to Merck except that GTx may retain one copy of such Information solely for legal archive purposes.

(iii) Subject to GTx's retained rights under Section 6.4.1 for any Differentiated Compound that is not a Merck Compound that GTx is developing or commercializing as of the date of such termination, and further subject to Section 14.3.2(a)(iv), GTx will grant Merck (a) an exclusive license under GTx Patent Rights, GTx SARM Know-How, GTx Information and Inventions, GTx Joint Information and Inventions and Joint Patent Rights to conduct research and to develop, make, have made, use, offer to sell, sell and import (but also subject to GTx's obligations to Third Parties) any GTx Compound or Product containing a GTx Compound which has been identified as a Development Candidate and for which a Phase I Clinical Study has been Initiated.

(iv) Subject to any set-off for damages incurred by Merck as a result of GTx's breach of the Agreement, Merck shall pay all amounts then due and owing to GTx under this Agreement as of the termination date, and notwithstanding Merck's termination of this Agreement, shall **[*]**. GTx and Merck agree that **[*]**.

(v) GTx shall agree that for a period of **[*]** from and after the effective date of termination of the Agreement on account of the exercise by Merck of its rights under this Section 14.3.2(a) on account of GTx's uncured material breach of this Agreement, **[*]**.

(b) If GTx terminates this Agreement under Section 14.3.1:

(i) All licenses and rights to GTx Patent Rights, GTx SARM Know-How, and GTx Trademarks granted to Merck hereunder shall terminate.

(ii) All Information in tangible form and all substances or compositions delivered or provided by GTx to Merck, as well as any other material

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provided by GTx to Merck in any medium, shall be returned to GTx, except that Merck may retain one copy of such Information solely for legal archive purposes.

(iii) Merck (a) shall grant GTx an exclusive license in and to any Joint Patent Rights and Joint Information and Inventions, to conduct research and to develop, make, have made, use, offer to sell, sell and import (i) GTx Compounds, (ii) Collaboration Compounds within the scope of Joint Patent Rights, and (iii) Products comprising any of the foregoing, but subject to Merck's obligations to Third Parties, if any, and excluding from the foregoing any Merck SARM Know-How that is, and any claims of Merck Patent Rights that specifically claim, proprietary manufacturing methods or techniques developed independent of this Agreement and generally applicable to other Merck compounds; (b) shall enter into an agreement granting GTx a royalty-free exclusive license under all trademarks owned by Merck covering such Compounds covered by any GTx Patent Rights, GTx SARM Know-How and/or Joint Patent Rights, but only if such trademarks have been publicly associated with such Compound, and (c) shall grant a non-exclusive license in and to Merck Patent Rights and Merck SARM Know-How that has been applied to the formulation, manufacture or use of such GTx Compounds, Collaboration Compounds or Products as of the date of such termination, excluding, however, the proprietary manufacturing methods or techniques described above.

(iv) For any Product containing a Collaboration Compound that is either (a) undergoing a Phase III Clinical Study at the time GTx notifies Merck of its intention to terminate this Agreement under Section 14.3.1, or (b) has concluded a Phase III Clinical Study and has filed or expects to file for Marketing Authorization, Merck shall **[*]**.

(v) Merck shall transfer to GTx such Joint Information and Inventions and Merck Information and Inventions reasonably necessary to allow GTx to manufacture and supply Compounds and Products covered under the GTx Patent Rights, GTx SARM Know-How, and/or Joint Patent Rights for which Phase I Clinical Studies have been commenced and which are being actively developed at the time of termination, including any finished Product inventory or Product supply Merck then may have on hand to manufacture Product under such Patent Rights, *provided* that Merck shall be relieved of this obligation in the event Merck has a good faith question of Safety pertaining to any such inventory or Product supply.

(vi) Merck shall promptly transfer and assign ownership to GTx of all INDs, Marketing Authorizations and NDAs for Compounds and Products covered by GTx Patent Rights, GTx SARM Know-How, Joint Patent Rights, and shall take such other actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights hereunder to GTx.

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(vii) Merck shall have a non-exclusive license to use Collaboration Compounds, Joint Patent Rights, GTx Information and Inventions and GTx's interest in Joint Information and Inventions (but not GTX Background SARM Know-How) on a fully paid up basis for internal research purposes only.

14.3.3 **Merck Limited Termination for Cause.** If GTx materially breaches one or more of its obligations under this Agreement, and does not cure a material breach within the period set forth under Section 14.3.1(a), then Merck shall have the option, in lieu of electing (at its sole discretion) to terminate this Agreement in its entirety as provided in Section 14.3.2(a) to terminate the Agreement only with respect to the following specific provisions: ARTICLE 3 (Research Program) and ARTICLE 4 (Development). If Merck elects so to terminate this Agreement solely with respect to such provisions after GTx's uncured material breach, Merck shall give GTx written notice of such termination, and in such event: (a) GTx shall cease work on the Research Program immediately; (b) GTx will reimburse Merck for any amounts of Research Program funding provided by Merck pursuant to Section 8.1 for the then-current quarter that have not been expended by GTx on Research Program activities undertaken prior to and up to the effective date of the termination hereunder; (c) GTx shall provide to Merck (to the extent not previously provided) copies of all GTx Information and Inventions generated under the Research Program, for use by Merck as licensed under this Agreement; (d) Merck shall not be obligated to pay GTx any further amounts for Research Program funding, except for reimbursement of amounts contracted for outsourced studies that were authorized prior to such date and that cannot be canceled: and (e) the remainder of the Agreement shall remain in full force and effect, including all milestone and royalty payment provisions. Notwithstanding the foregoing, all other claims and unpaid payment obligations, if any, that accrued prior to such termination date shall survive termination of the Agreement in accordance with, and to the extent provided in the Agreement.

14.4 **Effect of Expiration or Termination; Survival.**

14.4.1 Upon termination of this Agreement by Merck pursuant to Section 14.2 or by GTx pursuant to Section 14.3.1, Merck and its Affiliates, sublicensees and distributors shall be entitled, **[*]** following the effective date of termination, to finish any work-in-progress and to sell any Products or Compound remaining in inventory, in accordance with the terms of this Agreement, provided that Merck shall pay GTx all royalties under Section 8.5 to which GTx is entitled on account of any sales of such Product or Compound. Notwithstanding the preceding sentence, GTx shall have the option to purchase from Merck any finished Product and/or Compounds at Merck's fully allocated cost calculated according to GAAP for such Products and/or Compounds in lieu of Merck selling the inventory. Merck agrees to promptly notify GTx of any finished Product and Compound inventory and to allow GTx to purchase from Merck such amounts as GTx shall elect.

14.4.2 Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Any expiration or termination of this Agreement shall be without prejudice to the rights of either Party

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against the other accrued or accruing under this Agreement prior to expiration or termination, including without limitation the obligation to pay royalties for Product(s) or Compound sold prior to such expiration or termination. The provisions of ARTICLE 7 shall survive the expiration or termination of this Agreement and shall continue in effect for ten (10) years. In addition, except as set forth in Section 13.3, the provisions of ARTICLE 1 (Definitions), ARTICLE 10 (Representations and Warranties), ARTICLE 11 (Indemnification), ARTICLE 13 (Conditions to Closing), ARTICLE 14 (Termination), and ARTICLE 15 (Miscellaneous) other than Section 15.2, and Sections 2.11, 6.4 and 8.7 shall survive any expiration or termination of this Agreement.

14.4.3 ARTICLE 12 shall expire upon termination of this Agreement for any reason. Following expiration of such Article, each Party shall be responsible for the prosecution, maintenance and enforcement of its own Patent Rights. To the extent Joint Patent Rights have been exclusively licensed to one Party under this ARTICLE 14 following termination, such Party shall have the rights assigned to Merck under ARTICLE 12 with respect to the patents and patent applications which are the subject of such exclusive license, and the other Party shall have the rights assigned to GTx under ARTICLE 12. To the extent Joint Patent Rights have not been exclusively licensed to one Party following termination, the Parties shall confer in good faith as to the best mechanism for preserving and sharing the benefit of such Joint Patent Rights.

ARTICLE 15 MISCELLANEOUS

15.1 **Force Majeure.** Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, potentially including, but not limited to, embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any governmental authority or the other Party. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake and continue diligently all reasonable efforts necessary to cure such force majeure circumstances or to perform its obligations in spite of the ongoing circumstances.

15.2 **Assignment/ Change of Control/ Competing Pharma Change of Control.**

15.2.1 Except as otherwise provided in this Section 15.2, this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the consent of the other Party.

15.2.2 Merck may, without consent of GTx, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate of Merck, or in whole to its successor in interest in connection with a Change of Control. GTx may, without Merck's consent, assign this Agreement and its rights and obligations hereunder (except as specified below) in whole to its successor in interest in connection with a Change of Control.

15.2.3 In the event that there is a GTx Change of Control that is a Competing Pharma Change of Control, then GTx shall provide written notice to Merck at least thirty (30) days prior to the completion of such Change of Control and Merck shall have the right, at Merck election at any time after such Change of Control, to implement some or all of the following revisions to this Agreement:

(a) Merck may limit some of the detail required as a part of its obligations to provide GTx royalty related reports pursuant to Section 8.6; *provided* that Merck shall not limit such reporting in a manner that would cause GTx to be in breach of its obligations to UTRF to provide the related royalty reports required under the UTRF License; *provided* further that GTx shall exercise diligent efforts to permit Merck to make such disclosures directly to UTRF without copy to GTx; *provided* further that, Merck will, if requested by GTx, provide royalty reports specified in such Section 8.6 to an independent certified public accounting firm for auditing in accordance with Section 8.7.

(b) Merck may terminate any GTx activities relating to commercialization of any Product;

(c) Merck may terminate, without penalty, one or more of the Joint Steering Committee, the Joint Research Committee, the Development Committee and the Commercialization Committee. Regardless of such termination, effective upon such Competing Pharma Change of Control, any decision rights of such committees shall be exercised by Merck in its sole discretion, and regardless of whether such meetings are terminated, any affirmative obligation of Merck to disclose confidential Information in connection with such committee meetings shall be terminated;

(d) If GTx shall not have already exercised such right, Merck may terminate, without penalty, GTx's Opt-Out right pursuant to Section 3.4.1 and/or the GTx Opt-In pursuant to Section 3.4.4; *provided*, *however*, that if GTx has exercised its Opt-Out right pursuant to Section 3.4.1 and Merck has not exercised the Merck Opt-In pursuant to Section 3.4.3, then the license rights set forth in Section 6.4.1 shall continue in effect;

(e) In the event that such Competing Pharma Change of Control occurs during the term of the Research Program, Merck shall have the right to immediately terminate the Research Program and any remaining funding obligations pursuant to Section 8.1 that would be owed after such termination; and

(f) Merck shall have the right to require GTx, including the Change of Control party, to adopt reasonable procedures to be agreed upon in writing with Merck to prevent the disclosure of all Information of Merck and other information with respect to the research, development and commercialization of Compounds and Products (collectively "Sensitive Information") beyond GTx personnel having access to and knowledge of Sensitive Information prior to the Change of Control and to control the dissemination of Sensitive Information disclosed after the Change of Control. The purposes of such procedures shall be to strictly limit such disclosures to only those personnel having a need to know Sensitive Information in order for GTx to perform its obligations under this Agreement and

to prohibit the use of Sensitive Information for competitive reasons against Merck and its Related Parties and Compounds or Products, including without limitation, the use of Sensitive Information for the development or commercialization of competing products.

(g) Merck may immediately terminate its obligations pursuant to Section 2.4 as to the Exclusivity Period.

Any attempted assignment not in accordance with this Section 15.2 shall be void. Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement. For clarity, the intellectual property rights of the assignee in a Change of Control transaction, as existing on the date of closing of such transaction, shall be automatically excluded from the rights licensed to the other Party under this Agreement.

15.3 **Severability.** If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

15.4 **Notices.** All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to GTx, to: GTx, Inc.
Mitchell S. Steiner
Vice Chairman & CEO
3 North Dunlap Ave.
Memphis, TN 38163
Facsimile No.: (901)507-8608

and: Henry P. Doggrell
Vice President, General Counsel
Attention: Office of Counsel
Facsimile No.: 901-844-8075

if to Merck, to: Merck & Co., Inc.
One Merck Drive
P.O. Box 100, WS3A-65
Whitehouse Station, NJ 08889-0100
Attention: Office of Secretary
Facsimile No.: (908)735-1246

and Merck & Co., Inc.
One Merck Drive
Attention: Chief Licensing Officer

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P.O. Box 100, WS2A-30
Whitehouse Station, NJ 08889-0100
Facsimile: (908)735-1214

or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered or sent by facsimile on a business day (or if delivered or sent on a non-business day, then on the next business day); (b) on the business day after dispatch if sent by nationally-recognized overnight courier; or (c) on the fifth (5th) business day following the date of mailing, if sent by mail.

15.5 **Applicable Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware and the patent laws of the United States without reference to any rules of conflict of laws or *renvoi.*

15.6 **Dispute Resolution.**

15.6.1 The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the breach thereof. If the Parties do not fully settle, and a Party wishes to pursue the matter, each such dispute, controversy or claim that is not an "Excluded Claim" (defined below) shall be finally resolved by binding arbitration in accordance with the Commercial Arbitration Rules and Supplementary Procedures for Large Complex Disputes of the American Arbitration Association (**"AAA"**), and judgment on the arbitration award may be entered in any court having jurisdiction thereof.

15.6.2 The arbitration shall be conducted by a panel of three persons experienced in the pharmaceutical business: within thirty (30) days after initiation of arbitration, each Party shall select one person to act as arbitrator and the two Party-selected arbitrators shall select a third arbitrator within thirty (30) days of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the AAA. The place of arbitration shall be New York, New York, and all proceedings and communications shall be in English.

15.6.3 Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damages. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' fees and any administrative fees of arbitration.

15.6.4 Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. 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 Delaware statute of limitations.

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15.6.5 The Parties agree that, in the event of a dispute over the nature or quality of performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other judicial determination. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the dispute shall be refunded if an arbitrator or court determines that such payments are not due.

15.6.6 As used in this Section, the term "Excluded Claim" shall mean a dispute, controversy or claim that concerns (a) the scope, validity, enforceability, inventorship or infringement of a patent, patent application, trademark or copyright; or (b) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.

15.7 **Entire Agreement; Amendments.** This Agreement, together with the Schedules and Exhibits hereto, contains the entire understanding of the Parties with respect to the Collaboration and the licenses granted hereunder. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the Collaboration and the licenses granted hereunder are superseded by the terms of this Agreement. The Schedules and Exhibits to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representative(s) of both Parties hereto. The Parties agree that, effective as of the Closing Date, that certain Bilateral Disclosure Agreement between the Parties dated as of May 9, 2007 ("Confidentiality Agreement") shall be superseded by this Agreement, and that disclosures made prior to the Closing Date pursuant to the Confidentiality Agreement shall be subject to the confidentiality and non-disclosure provisions of this Agreement.

15.8 **Headings.** The captions to the several Articles, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.

15.9 **Independent Contractors.** It is expressly agreed that GTx and Merck shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither GTx nor Merck shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

15.10 **No Solicitation.** During the R&D Collaboration Term, Merck and its Affiliates shall not, directly or indirectly, solicit for employment in Merck's or its Affiliates' United States operations (or hire as a result of such solicitation), any employee of GTx (a) who is principally involved in research, development, regulatory, or clinical responsibilities related to SARMs, and (b) whose gross annual salary **[*]**; *provided*, *however*, that nothing in this Section 15.10 shall prohibit general advertising or solicitations or the hiring of persons responding solely to such general advertising or solicitations.

15.11 **Waiver.** The waiver by either Party hereto of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise.

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15.12 **Cumulative Remedies.** No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

15.13 **Waiver of Rule of Construction.** Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

15.14 **Certain Conventions.** Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit shall be deemed to be a reference to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit, of or to, as the case may be, this Agreement, unless otherwise indicated. Unless the context of this Agreement otherwise requires, (a) words of any gender include each other gender, (b) words such as “herein”, “hereof”, and “hereunder” refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (c) words using the singular shall include the plural, and vice versa.

15.15 **Business Day Requirements.** In the event that any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a business day then such notice or other action or omission shall be deemed to required to be taken on the next occurring business day.

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

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IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Execution Date.

MERCK & CO., INC.		**GTx, INC.**	
BY:	/s/ Peter N. Kellogg Peter N. Kellogg	BY:	/s/ Mitchell S. Steiner, M.D. Mitchell S. Steiner, M.D.
TITLE:	Executive Vice President and Chief Financial Officer	TITLE:	Vice Chairman, Chief Executive Officer

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SCHEDULES

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Exclusive License and Collaboration Agreement
Schedule 1.32 GTx Patents

DOCKET NO.	TITLE	INVENTOR (S)	SERIAL NO. PATENT NO.	FILING DATE	STATUS
[*]	[*]	[*]	[*]	[*]	[*]

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Exclusive License and Collaboration Agreement
Schedule 1.34 GTx Compounds

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Exclusive License and Collaboration Agreement
Schedule 1.40 GTx Trademarks

Trademark	Country	Class	Description	Application Date
Ostarine	European Community	05	Pharmaceutical preparations for use in the prevention or treatment of any disease related to androgen (testosterone) deficiency, including but not limited to cardiovascular disease, atherosclerosis, osteoporosis, bone disorders, cancer cachexia, kidney disease, muscle wasting, dry eye, appetite disorders, frailty, metabolic syndrome, obesity, wasting disorders, depression or sexual dysfunction	March 2, 2007
Ostarine	United States	05	Pharmaceutical preparations for use in the prevention or treatment of any disease related to androgen (testosterone) deficiency, including but not limited to cardiovascular disease, atherosclerosis, osteoporosis, bone disorders, cancer cachexia, kidney disease, muscle wasting, dry eye, appetite disorders, frailty, metabolic syndrome, obesity, wasting disorders, depression or sexual dysfunction	August 29, 2007

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SCHEDULE 1.59

CASE #	TITLE	COUNTRY	APPLICATION NUMBER	APPLICATION DATE	PATENT NUMBER	GRANT DATE	PUBLICATION NUMBER	PUBLICATION DATE
[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]

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Exclusive License and Collaboration Agreement

Schedule 4.3.2

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Exclusive License and Collaboration Agreement
Schedule 7.5

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News Release

Merck Contacts:

Investor Relations
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Investor Relations
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Ian R. McConnell
Media
1-908-423-3046

GTx Inc Contact:

Investor Relations
Media
McDavid Stilwell
901-507-2667

GTx, Inc. and Merck & Co., Inc. Enter Global Strategic Collaboration for the Development of SARMs, a Novel Investigational Class of Drugs to Treat Muscle Loss and other Musculoskeletal Conditions

MEMPHIS, Tenn., and WHITEHOUSE STATION, N.J., Nov. 6, 2007 — GTx, Inc. (NASDAQ: GTXI) and Merck & Co., Inc. (NYSE: MRK) today announced an agreement providing for a research and development and global strategic collaboration for selective androgen receptor modulators (SARMs), a new class of drugs with the potential to treat age-related muscle loss (sarcopenia) as well as other musculoskeletal conditions. This collaboration includes GTx's lead SARM candidate, Ostarine™, which is currently being evaluated in a Phase II clinical trial for the treatment of muscle loss in patients with cancer, and establishes a broad SARM collaboration under which GTx and Merck will pool their programs and partner to discover, develop, and commercialize current as well as future SARM molecules. As part of this global agreement, Merck will be responsible for all future costs associated with ongoing development and, if approved, commercialization of Ostarine and other investigational SARMs resulting from the collaboration.

Under the terms of the collaboration agreement and related stock purchase agreement, GTx and Merck will combine their respective SARM research programs. GTx will receive an upfront payment of $40 million plus $15 million in research reimbursements to be paid over the initial three years of the collaboration. In addition, Merck will make an equity investment of $30

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million in GTx common stock at a 40 percent premium to the 30 day average closing price. GTx will also be eligible to receive up to $422 million in future milestone payments associated with the development and approval of a drug candidate if multiple indications receive regulatory approval. Additional milestones may be received for the development and approval of other collaboration drug candidates. GTx will receive royalties on any resulting worldwide product revenue.

"By combining our drug candidates, resources and talents, this Merck-GTx collaboration positions both companies for success in the development and commercialization of SARMs," said Mitchell S. Steiner, M.D., chief executive officer of GTx. "We believe that Ostarine and our other SARMs offer the potential to address a number of unmet medical needs focused on musculoskeletal disorders. GTx believes that Merck has the world class scientific, clinical development, and commercial expertise to capture the potential of the SARM class."

"By selectively targeting the androgen receptor, SARMs offer a promising alternative to androgen therapy with the potential advantages of oral dosing, tissue selectivity and improved safety and tolerability," said Alan B. Ezekowitz, MBChB, D.Phil., senior vice president and franchise head, Bone, Respiratory, Immunology, and Endocrine, Merck Research Laboratories. "GTx has established a strong scientific reputation in the research and development of novel SARMs and we look forward to working with Dr. Steiner and his team."

The effectiveness of the collaboration agreement and the investment in GTx common stock by Merck are subject to the expiration or earlier termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act, if applicable, as well as other customary closing conditions.

Conference Call

GTx will host a conference call at 9 a.m. Eastern Time today to discuss the GTx-Merck collaboration as well as GTx's third quarter 2007 financial results. To listen to the conference call, please dial: 800-901-5248 from the United States and Canada or 617-786-4512 (International). The passcode for the call is #62291111.

A playback of the call will be available beginning today at 11:00 a.m. Eastern Time through November 20, and may be accessed by dialing: 888-286-8010 from the United States and Canada or 617-801-6888 (International). The reservation number for the replay is #89187183.

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About SARMs

Selective androgen receptor modulators (SARM) are a new class of drugs with the potential to treat sarcopenia (age-related muscle loss) and other musculoskeletal conditions. Ostarine, a first in class SARM, has demonstrated the ability to build lean body mass (muscle) in a proof of concept clinical trial and may have the potential to improve physical performance. Ostarine is currently being evaluated in a Phase II clinical trial for the treatment of muscle loss in patients with cancer.

About GTx

GTx, headquartered in Memphis, Tenn., is a biopharmaceutical company dedicated to the discovery, development, and commercialization of small molecules that selectively target hormone pathways to treat cancer, osteoporosis and bone loss, muscle wasting and other serious medical conditions. GTx 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 for advanced prostate cancer, and second, a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia, or PIN. GTx has licensed to Ipsen Limited exclusive rights in Europe to develop and commercialize ACAPODENE. GTx has agreed to a collaboration with Merck & Co., Inc. for the development and global commercialization of selective androgen receptor modulators, or SARMs, a new class of drugs with the potential to treat a variety of indications associated with muscle wasting and bone loss including sarcopenia and osteoporosis, cancer cachexia, and chronic kidney disease muscle wasting. GTx is also developing GTx-878, an estrogen receptor beta agonist for the treatment of benign prostatic hyperplasia and chronic prostatitis. GTx is planning to initiate human clinical studies for GTx-878 in 2009.

About Merck

Merck & Co., Inc. is a global research-driven pharmaceutical company dedicated to putting patients first. Established in 1891, Merck currently discovers, develops, manufactures and markets vaccines and medicine to address unmet medical needs. The company devotes extensive efforts to increase access to medicines through far-reaching programs that not only donate Merck medicines but help deliver them to the people who need them. Merck also publishes unbiased health information as a not-for-profit service. For more information, visit http://www.merck.com.

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- more -

GTx Forward-Looking Statement

This press release contains forward-looking statements based upon GTx's current expectations, including all statements (i) that reflect the completion of the proposed collaboration with Merck (including statements related to GTx's receipt of upfront licensing fees, guaranteed preclinical development reimbursements, development and approval milestone payments and royalty payments, as well as proceeds from the sale of GTx common stock to Merck); and (ii) relating to the prospects for, and the development and commercialization of, Ostarine and other SARMs. Forward-looking statements involve risks and uncertainties. GTx's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, the risks that (i) the collaboration agreement may not become effective and the investment by Merck in GTx common stock may not occur as a result of the failure to satisfy certain closing conditions under the agreements with Merck, including relating to the Hart-Scott-Rodino Antitrust Improvements Act of 1974; (ii) even if the collaboration agreement becomes effective, future payments to GTx may not be realized due to the inability to achieve certain milestones under the collaboration agreement or the failure to develop and commercialize Ostarine and other SARMs included in or arising from the collaboration; (iii) product candidates developed under the collaboration may not be commercialized as a result of the failure to obtain required regulatory approvals, including if clinical trials do not demonstrate safety and efficacy in humans; (iv) even if required regulatory approvals are obtained, products developed under the collaboration may not gain market acceptance among physicians, patients, health care payors and the medical community; and (v) GTx could utilize its available cash resources sooner than it currently expects and may be unable to raise capital when needed, which would force GTx to delay, reduce or eliminate its product development programs or commercialization efforts. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this press release. GTx's quarterly report on form 10-Q filed with the U.S. Securities and Exchange Commission on August 1, 2007, contains under the heading "Risk Factors," a more comprehensive description of these and other risks to which GTx is subject. GTx expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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Merck Forward-Looking Statement

This press release contains “forward-looking statements” as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management’s current expectations and involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential or financial performance. No forward-looking statement can be guaranteed and actual results may differ materially from those projected. Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Merck’s business, particularly those mentioned in the risk factors and cautionary statements in Item 1A of Merck’s Form 10-K for the year ended December 31, 2006, and in its periodic reports on Form 10-Q and Form 8-K, which the Company incorporates by reference.

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GTx Questions & Answers
Draft: 11/5

BACKGROUND

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Exclusive License and Collaboration Agreement
Schedule 10.2.3

NONE

GTx Confidential Information
October 31, 2007

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Exhibit 10.44

2008 COMPENSATION INFORMATION FOR REGISTRANT'S EXECUTIVE OFFICERS

The table below provides information regarding (i) the base salary of each executive officer of GTx, Inc. (the "Company"), effective as of January 1, 2008, and (ii) the target cash bonus award for each of the Company's executive officers under the Company's Executive Bonus Compensation Plan for fiscal 2008, expressed as a percentage of applicable base salary:

Executive Officer	Title	2008 Annual Salary ($)	2008 Target Bonus (%)
Mitchell S. Steiner	Chief Executive Officer and Vice-Chairman of the Board of Directors	500,000	50
Marc S. Hanover	President and Chief Operating Officer	435,000	45
Ronald A. Morton, Jr.	Vice President, Chief Medical Officer	430,500	30
James T. Dalton	Vice President, Preclinical Research and Development	311,879	30
Henry P. Doggrell	Vice President, General Counsel and Secretary	286,934	30
Mark E. Mosteller	Vice President, Chief Financial Officer and Treasurer	283,889	30
K. Gary Barnette	Vice President, Clinical Research and Development Strategy	251,160	30
Gregory A. Deener	Vice President, Sales and Marketing, Product Commercialization	245,700	30
Jeffery G. Hesselberg	Vice President, Regulatory Affairs	220,500	30
Christopher K. West	Vice President, Sales	200,000	30

Exhibit 10.45

NON-EMPLOYEE DIRECTOR COMPENSATION ARRANGEMENTS

Effective July 24, 2007, non-employee directors of GTx, Inc. (the "Company") receive the following compensation for their service on the Company's Board of Directors (the "Board") and its committees. The stock option grants referenced below are automatically granted under the Company's Amended and Restated 2004 Non-Employee Directors' Stock Option Plan. Non-employee directors may elect to defer all or a portion of their cash fees under the Company's Directors' Deferred Compensation Plan.

Non-Employee Directors:

1) Cash retainers payable in quarterly increments based on an annualized rate of $20,000 a year, or $30,000 a year for the Chair of the Audit Committee.

2) Meeting fees: $1,500 for each Board and committee meeting attended in person and $750 for each Board and committee meeting attended by phone, payable quarterly in arrears.

3) Annual stock option grant to purchase 8,000 shares of the Company's common stock (automatically granted one day following each year's annual meeting of stockholders) that vests in a series of three successive equal annual installments measured from the date of grant; provided, however, that if a non-employee director has not been serving as a non-employee director for the entire period since the preceding annual meeting of stockholders, the number of shares subject to such individual's annual grant is 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. The number of shares subject to these annual grants may be increased or decreased by the Board in its sole discretion.

New Non-Employee Directors—One Time Grant: Upon each non-employee director first becoming a director, he or she will be automatically granted on the date on which such person first becomes a director, a stock option to purchase 10,000 shares of the Company's common stock that vests in a series of three successive equal annual installments measured from the date of grant. The number of shares subject to these initial grants may be increased or decreased by the Board in its sole discretion.

Exhibit 10.46

SUBLEASE AGREEMENT

This Sublease (this "**Sublease**"), made and entered into as of December 17, 2007, by and between ESS SUSA HOLDINGS, LLC, a Delaware limited liability company ("**Landlord**"), and GTx, Inc. a Delaware corporation ("**Tenant**").

In consideration of the mutual covenants set forth herein, Landlord and Tenant hereby agree as follows:

SUBLEASE ACKNOWLEDGMENT AND AGREEMENT

Tenant acknowledges and agrees that this Sublease and all of Tenant's rights under this Sublease shall at all times be subject and subordinate to all terms and provisions of that certain Lease Agreement between Landlord, as successor in interest to SUSA Partnership, L.P., as tenant, and Moore Building Associates LP or its successors or assigns, as landlord ("**Primary Landlord**"), dated December 29, 1998, as amended by First Amendment and Second Amendment **("Primary Lease**"). Except as otherwise provided in this Sublease or to the extent the terms of the Primary Lease are inconsistent with the express terms of this Sublease, all rights and obligations of and limitations on "Tenant" under the Primary Lease including, without limitation, payment of certain operating expense reimbursements, lien prohibitions, maintenance, repair, alterations, replacements and restoration obligations, required insurance coverages, provision of services, cure rights, quiet possession and restrictions on use of insurance and condemnation proceeds, shall be binding on, inure to the benefit of and be the responsibility of Tenant as such relate to the Premises and Tenant's use thereof. Moreover, Tenant agrees that all indemnifications, guaranties, releases, waivers and other obligations of Tenant hereunder shall run to the benefit of and be enforceable by both Landlord and Primary Landlord and that all notices and rights granted to or consents or approvals required by "Landlord" hereunder shall also run to the benefit of Primary Landlord and shall also require the consent and approval of Primary Landlord. Tenant hereby agrees, if requested by Primary Landlord and as provided herein, to attorn to Primary Landlord in all respects as the "Landlord" hereunder as if this Sublease was a direct lease between Tenant and Primary Landlord from and after the date Primary Landlord so requests. In the event of a default by Landlord as tenant under the Primary Lease, Primary Landlord shall provide Tenant written notice of such default and the opportunity to cure such default, however, in the event Primary Landlord terminates the Primary Lease solely due to a default by Landlord thereunder, Tenant shall attorn to Primary Landlord in all respects as the "Landlord" hereunder and this Sublease shall become a direct lease between Tenant and Primary Landlord from and after termination of the Primary Lease. Tenant shall cure any and all then existing Tenant defaults under this Sublease, if any. Notwithstanding any of the provisions of this Sublease or the Primary Lease, neither conversion of this Sublease to a direct lease nor any assignment of any rights or obligations hereunder shall in any manner release or modify the obligations of Landlord to Primary Landlord under the Primary Lease.

BASIC TERMS AND DEFINITIONS

1. The following definitions and basic terms shall be construed in conjunction with and limited by the reference thereto in other provisions of this Sublease:

(a) "**Tenant's Address**": GTx, Inc.
3 N. Dunlap St
Memphis, TN 38163
Attn: Mark Mosteller, VP, CFO

With a copy to :
GTx, Inc.
3 N. Dunlap St
Memphis, TN 38163
Attn: Henry Doggrell, VP, General Counsel

(b) "**Premises**": Floor Seventh and Eighth floors of the Building.

(c) "**Building**" The building located at 50 South Third Street, City of Memphis, County of Shelby, Tennessee (also known for USPS purposes as Toyota Center, 175 Toyota Plaza, Memphis, TN 38103)

(d) "**Land**": That certain land described on Exhibit A.

(e) "**Rentable Area of Premises**": approximately 30,748 square feet comprised of 21,500 square feet on the seventh floor and 9,248 square feet on the eighth floor.

(f) "**Rentable Area of Building**": 174,700 square feet

(g) "**Term**": January 1, 2008 thru April 30, 2015.

Tenant shall have the option to cancel the lease effective 12/31/2010 upon six months prior written notice and payment of $150,000.

Tenant shall have the option to cancel the lease effective 12/31/2011 upon six months prior written notice and payment of $75,000.

Tenant shall have the option to cancel the lease effective 12/31/2012 upon six months prior written notice and payment of $50,000.

Tenant shall have the option to cancel the lease effective 12/31/2013 upon six months prior written notice and payment of $50,000.00.

(h) "**Base Operating Expenses**": Equals the actual per square foot amount of Operating Expenses for the calender year 2008, calculated under a 95% gross up method.

(i) "**Base Rent**": The monthly rent schedule shall be as follows:

1/1/2008-6/30/2008	$17,936.33 monthly
7/1/2008-12/31/2008	$35,872.67monthly
1/1/2009-12/31/2009	$37,153.83 monthly
1/1/2010-12/31/2010	$38,435.00 monthly
1/1/2011-12/31/2011	$40,997.33 monthly
1/1/2012-12/31/2012	$43,559.67 monthly
1/1/2013-12/31/2013	$44,840.83 monthly
1/1/2014-4/30/2015	$46,122.00 monthly

(j) "**Improvement Allowance**": None

(k) "**Security Deposit**": None

(l) "**Guarantor**": None

(m) "**Parking":** 75 unreserved parking spaces (with additional unreserved parking spaces being provided pursuant to Section 46 of the Primary Lease and modified by Section 13 of this Sublease) at a monthly cost of $0.00 dollars per space for such initial 75 spaces; and for any additional unreserved spaces, at a monthly cost of $75.00 per space and, with such unreserved parking spaces being provided pursuant to the terms and provisions of the Parking Sublicense Agreement attached hereto as Exhibit E.

(n) "**Rent Commencement Date":** January 1, 2008; provided that upon full execution of this Sublease, Tenant shall pay January, February and March, 2008 Base Rent in advance.

(o) "**Tenant Improvements":** Those improvements to the Premises completed by Tenant pursuant to Section 9 hereof.

PREMISES

2. Subject to and upon the terms, provisions and conditions herein, Landlord subleases to Tenant and Tenant subleases from Landlord the Premises as designated by the area outlined on Exhibit B in the Building which is commonly known as Toyota Plaza, formerly the William R. Moore Building, subject to the terms and provisions of the Primary Lease as such relates to the Premises and Tenant's use thereof. The Premises contain the number of square feet of Rentable Area indicated in Section 1(e) and the Building contains the number of square feet of Rentable Area indicated in Section 1(f). Tenant acknowledges that the Rentable Area of the Premises contains an allocation of a portion of the common areas of the Building and the Base Rent is based on Rentable Area which is larger than the number of square feet physically contained in the Premises.

The Rentable Area of the Premises is hereby stipulated for all purposes hereof to be as set forth in Section 1(e) and such area shall not be adjusted as a result of variations resulting from actual construction of the Premises for occupancy so long as such work is done in accordance with the terms and provisions of this Sublease.

AUTHORIZED USE

3. Tenant shall use the Premises solely for general office purposes, consistent with the uses of first class office buildings in the metropolitan area where the Building is located, and for no other purpose other than related or similar uses which may be deemed proper by Landlord.

TERM

4. Subject to and upon the terms and conditions set forth herein, the Term of this Sublease shall begin on January 1, 2008 (the "**Commencement Date**").

Unless otherwise terminated pursuant to this Sublease, the Term shall end at 6:00 p.m. on April 30, 2015 (the "**Termination Date**").

Tenant shall have the option to cancel the lease effective 12/31/2010 upon six months prior written notice and payment of $150,000.

Tenant shall have the option to cancel the lease effective 12/31/2011 upon six months prior written notice and payment of $75,000.

Tenant shall have the option to cancel the lease effective 12/31/2012 upon six months prior written notice and payment of $50,000.

Tenant shall have the option to cancel the lease effective 12/31/2013 upon six months prior written notice and payment of $50,000.00.

RENTAL PAYMENT

5. Commencing on the Commencement Date and continuing thereafter throughout the entire Term, Tenant agrees to pay Base Rent (defined below) as adjusted by the Base Rent Adjustment (defined below) in accordance with this Section and Section 6. Except for Base Rent for the months of January, February and March 2008, which Tenant shall pay in advance to Landlord in accordance with Section 1(n) hereof, Base Rent as adjusted by the Base Rent Adjustment shall be due and payable in monthly installments on the first day of each calendar month during the Term (subject to proration of the first and last month provided below), in lawful money of the United States of America to Landlord's address set forth herein or such other address as Landlord may designate from time to time in writing. Subject to the terms hereof, Tenant agrees to pay all rent and other sums of money as shall become due from and payable by Tenant to Landlord under this Sublease (collectively "Rent") at the times and in the manner provided in this Sublease, without abatement, demand, offset, deduction or counterclaim unless otherwise expressly provided herein. If Tenant fails to pay part or all of the Rent within seven (7) days after it is due, the Tenant shall also pay (i) interest at the Default Rate (defined below) on the unpaid balance from the date originally due until paid, plus (ii) a late charge equal to $1,000. If the Term does not begin on the first day or end on the last day of a calendar month, the installment of Base Rent for that partial month shall be prorated be multiplying

the monthly Base Rent by a fraction the numerator of which is the number of days of the partial month included in the Term and the denominator of which is the total number of days in the full calendar month.

RENT

6. Tenant shall pay to Landlord, or with Landlord's consent directly to Primary Landlord, as the base rent for the Premises (the "**Base Rent**") the amount set in Section 1(i), subject to adjustment as hereinafter provided. Nothing contained herein shall be construed at any time so as to reduce the Base Rent payable hereunder below the amount set forth above.

Base Rent shall be adjusted in accordance with the following provisions (any such adjustment hereinafter the "**Base Rent Adjustment**"). Base Rent includes a 2008 base year attributable to Base Operating Expenses as specified in Section 1(h) ("**Base Operating Expenses**"). In the event actual Operating Expenses are below Base Operating Expenses, Tenant shall not be entitled to any credit or offset in any manner. Upon receipt of Primary Landlord's estimate, Landlord shall provide Tenant with an estimate of Operating Expenses for the 2009 calendar year and each subsequent calendar year in the Term (each, an **"Operating Period**"). If Operating Expenses (exclusive of Taxes) per square foot of Rentable Area of the Premises during the 2009 Operating Period or each subsequent Operating Period, as estimated by Primary Landlord, exceed Base Operating Expenses (exclusive of Taxes), Tenant shall pay Base Rent for such Operating Period equal to the Base Rent set forth above adjusted upward by an amount equal to the product of (i) the difference between Operating Expenses per square foot of Rentable Area of the Premises for such Operating Period and the Base Operating Expenses, multiplied by (ii) the Rentable Area of the Premises. The Base Rent Adjustment for 2009 shall not exceed 105% of the Base Operating Expenses. Thereafter, the Base Rent Adjustment shall not exceed 105% of the prior year's Operating Expenses. This annual 5% limitation shall not apply to insurance or utilities. Landlord shall pay any Base Rent Adjustment attributable to Taxes and any special assessments paid in lieu of taxes that are in excess of the 2008 base year attributable to Taxes.

Landlord shall, within thirty (30) days after receipt by Primary Landlord, furnish Tenant with a statement of the Base Operating Expenses and Operating Expenses during each subsequent Operating Period as well as a computation of the Base Rent Adjustment each as received by Landlord without adjustment of any type ("**Expense Statement**"). Except as provided herein, failure of Landlord to provide such statement within said time period shall not be a waiver of Landlord's right to collect any Base Rent Adjustment. If such statement shows that the actual amount Tenant owes is more than the estimated Base Rent Adjustment paid by Tenant, Tenant shall pay the difference within thirty (30) days after delivery of the Expense Statement. If the Expense Statement shows that Tenant paid more than the actual amount owed, Tenant shall receive a credit therefor within thirty (30) days after delivery of the Expense Statement.

OPERATING EXPENSES

7. **"Operating Expenses"** as used herein, shall mean all expenses, costs and disbursements of every kind and nature relating to or incurred or paid by Primary Landlord during any Operating Period in connection with the ownership, operation, repair and maintenance of the Building, Land, all adjacent plaza areas, equipment, fixtures and facilities used in connection therewith (collectively, the "**Project**") including, but not limited to, wages and salaries of all employees directly engaged in the operation, maintenance or security of the Project, including taxes, insurance and benefits relating thereto; the cost of all labor, supplies, equipment, materials and tools used in the operation and maintenance of the Project; management fees (not exceeding the standard for first class office building in the relevant Memphis, Tennessee market area); the cost of all legal and accounting expenses incurred in connection with the ownership and operation of the Project; the cost of all utilities for the Project, including, but not limited to, the cost of water, sewer, waste disposal, gas, electricity and power for heating, lighting, air conditioning and ventilating; the cost of all maintenance and service agreements for the Project, including but not limited to, security service, window cleaning, elevator maintenance and janitorial service; the cost of all insurance relating to the Project (maintained consistent with other properties owned and operated by Primary Landlord), including, but not limited to, the cost of fire and extended coverage, rental loss or abatement and casualty and liability insurance

applicable to the Project and Primary Landlord's personal property used in connection therewith, plus the cost of all deductible payments made by Primary Landlord in connection therewith; Taxes (defined below); the cost of all license and permit fees; the cost of repairs, refurbishing, restoration and general maintenance; a reasonable amortization charge on account of any capital expenditure, incurred in an effort (i) to comply with any applicable governmental rule, regulation, law or otherwise, or (ii) to reduce the Operating Expenses of the Project; and, all other items constituting operating and maintenance costs in connection with the Project according to generally accepted accounting principles. Except as specifically provided in the immediately preceding sentence, Operating Expenses shall not include the following: (i) depreciation, (ii) leasing commissions, (iii) repairs and restorations paid for by the proceeds of any insurance policy, (iv) construction of improvements of a capital nature, (v) income and franchise taxes other than that portion, if any, of income and franchise taxes which, may hereafter be assessed and paid in lieu of or as a substitute in whole or in part for Taxes, (vi) costs of utilities directly charged to and reimbursed by Tenant or other tenants, including, without limitation, the occupants of the Baseball Stadium, (vii) costs of alterations of space or other improvements made by other tenants, (viii) mortgage principal or interest payments on any initial construction or acquisition of the Building and other capital expenditure items which are not covered above as an Operating Expense, (ix) costs of repairs due to casualty or condemnation that are reimbursed by third parties, (x) any income, estate, inheritance or other transfer tax or excess profit, franchise, or similar taxes on Primary Landlord's business, (xi) all costs, including legal fees, relating to the activities for the solicitation and execution of leases of space in the Building, and (xii) any legal fees incurred by Landlord in enforcing its rights under other leases for space in the Building. In an effort to normalize the Operating Expenses, if less than one-hundred percent (100%) of the Rentable Area of the Building is actually occupied during any Operating Period, Operating Expenses shall be calculated under a ninety-five (95%) gross up method using ANSI/BOMA standards as determined by Landlord. Tenant, at its cost, shall have the right to inspect, in Primary Landlord's offices, during Primary Landlord's usual business hours, within the sixty (60) day period following delivery of the Expense Statement, Primary Landlord's records of the Operating Expenses referred to in such statement. If requested by Tenant, Landlord will cooperate in an annual audit of the Operating Expense records at no cost to Landlord. Any such excess shall be returned to the Tenant and any amounts due shall be paid Tenant within thirty (30) days of delivery of the expense statement. If within such sixty (60) day period neither party hereto delivers to the other party a notice referring in reasonable detail to one or more errors in such statement, it shall be deemed conclusively that the information set forth in the Expense Statement is correct.

"Taxes" means all ad valorem taxes, personal property taxes, payments in lieu of taxes **("PILOT")** to and Central Business Improvement District Assessments payable under the lease agreement between Primary Landlord and Memphis Center City Revenue Finance Corporation **("MCCRFC")** with respect to the Building and all other similar charges, if any, which are levied, assessed, or imposed upon or become due and payable in connection with, or a lien upon, the land, the Building or facilities used in connection therewith, and all taxes of whatsoever nature that are imposed in substitution for or in lieu of any of the taxes, assessments, or other charges included in this definition of Taxes; but excluding, however, taxes and assessments attributable to the personal property of tenants and paid by such tenants as a separate charge. If a rental tax, gross receipts tax or sales tax on rent is imposed on Primary Landlord by any Governmental Authority (defined below), Tenant shall, as additional rent, reimburse Landlord, at the same time as each monthly payment of Rent is due, an amount equal to all such taxes Landlord is required to pay by reason of the Rent paid hereunder, Taxes shall not include any historic tax credit recapture which relates to the rehabilitation of the Building.

Landlord and Tenant acknowledge that Primary Landlord has entered into a payment in lieu of tax (PILOT) lease agreement with the MCCRFC **("PILOT Lease**"). In the event of a termination of the PILOT Lease solely due to a payment default by Primary Landlord or a default by Primary Landlord to maintain required insurance, Primary Landlord shall be solely responsible for the increase in Taxes levied as a result of the termination of the PILOT Lease over the payments required by the terms of the PILOT Lease if it had continued in force. So long as Primary Landlord fully pays within any cure period all obligations under the PILOT Lease, Tenant will have no claim against Landlord or Primary Landlord by virtue of the occurrence of the termination of the PILOT Lease. Any Taxes payable with respect to the Premises in excess of the 2008 base year amount shall be paid by Landlord and Tenant shall have no liability therefor.

SECURITY DEPOSIT

8. Landlord hereby waives any obligations of Tenant to deposit any funds as a security deposit for the performance by Tenant of the terms, provisions and conditions of this Sublease.

9. Intentionally Omitted

NOTICE ADDRESS

10.

Landlord:
ESS SUSA HOLDINGS LLC
2795 E. Cottonwood Parkway, suite 400
Salt Lake City, UT 84121
Attn: Sr VP of Accounting

With copy to:
Extra Space Storage
2795 E. Cottonwood Parkway, suite 400
Salt Lake City, UT 84121
Attn: General Counsel

With copy to Primary Landlord:
Moore Building Associates LP
c/o Parkway Moore LLC
Attn: Memphis Asset Manager
188 East Capitol Street, Suite 1000
Jackson, MS 39201

And a Copy to:
Parkway Realty Services LLC
Attn:
50 North Front Street
Morgan Keegan Tower
Memphis, TN 38103

Prior to May 1, 2008, the address for notices to Tenant shall be the address set forth for Tenant on the first page of this Sublease; beginning May 1, 2008 and thereafter, the address for Tenant shall be the Premises. The addresses stated herein shall be effective for all notices to the respective parties until written notice of a change in address is given pursuant to the provisions hereof. A notice, request, instruction or other documents shall be deemed to be given (a) when delivered personally, (b) if sent by certified mail, at the time of delivery or refusal of delivery as indicated on the return receipt, or (c) if sent by overnight courier, at the time of delivery or refusal of delivery as indicated on the records of or certificates provided by the overnight delivery service.

OPTION TO EXTEND

11. Tenant shall have no option to extend this Sublease or direct Landlord to extend the Primary Lease pursuant to sections 44 and 45 of the Primary Lease. In the event Tenant desires to continue to lease the Premises, Tenant shall enter into a lease directly with the Primary Landlord and Landlord shall have no further obligations or liability under the Primary Lease or this Sublease.

12. INTENTIONALLY DELETED.

PARKING

13. During the Term of this Sublease, Tenant shall sublicense from Landlord 75 parking spaces in the Parking Garage at no cost to Tenant, subject to rules and regulations promulgated from time to time by Primary Landlord and Moore Garage and in accordance with the terms and provisions of the sublicense agreement attached hereto as Exhibit E. Notwithstanding the foregoing, in the event that Tenant shall need any additional parking spaces, such spaces shall be sublicensed from Landlord at a monthly rate of $75.00 per space, which spaces shall also be subject to the rules and regulations promulgated from time to time by Primary Landlord and Moore Garage

and in accordance with the terms and provisions of the sublicense agreement attached hereto as Exhibit E.

In the event Tenant occupies the Offer Space as provided in Section 15 hereof, Tenant shall sublicense from Landlord additional unreserved parking spaces in the Parking Garage at a rate to be mutually agreed upon between Landlord and Tenant, the number of which shall be determined by dividing the total square footage of the Offer Space (as defined in Section 15) by 400.

ROOFTOP ANTENNA

14. Intentionally Deleted.

OPTION TO EXPAND

15. As long as no Event of Default exists or is continuing under this Sublease, Tenant shall have an on going right of first refusal ("ROFR") throughout the Term to lease the 3rd and 4th floor space of the Building (the "ROFR"). Upon Landlord's receipt of a bona fide written offer from a prospect ("Offer Prospect") to lease all or a portion of the space subject to the ROFR (the "Offer Space"), Landlord will deliver the terms of this bona fide offer to Tenant in writing ("Offer Notice"). The terms of the Offer Notice shall contain (a) the base rental rate, (b) tenant improvement allowance, (c) other concessions provided in the bona fide offer, (d) the lease commencement and expiration and (f) the delineation and amount of the Offer Space. Tenant must respond to Landlord on or within ten (10) business days of receipt of the Offer Notice of its intent to accept the terms thereunder. If Tenant declines to accept the terms of the Offer Notice, Landlord is free to lease the Offer Space to the Offer Prospect on the same terms and conditions as the Offer Notice and Tenant waives its right to such Offer Space, except as provided herein. In the event Landlord does not lease the Offer Space to the Offer Prospect within ninety (90) days after the expiration of such ten (10) business day period, the Tenant's right hereunder shall be restored as to the Offer Space.

In the event Tenant accepts said Offer Notice, Tenant shall have thirty (30) days to obtain financial and legal approval and shall amend this Sublease to include the Offer Space, provided that the Base Rent on such Offer Space shall be at the rate set forth in the Offer Notice.

CONFERENCE ROOM, KITCHEN, AND AUDIO VISUAL EQUIPMENT

16. All equipment owned by Landlord and located in the Premises or the Temporary Space (defined below) will remain for Tenant's use throughout the Term and the Temporary Space Term (defined below), respectively.

EARLY ACCESS

17. Tenant will be provided access to the space for purposes of installing phone, data, and furniture; provided Tenant provides an executed indemnification agreement in favor of Landlord in form and substance reasonably agreed upon by Landlord.

ADDITIONAL PROVISIONS

18. No oral statements or prior written material not specifically incorporated herein shall be of any force or effect. Tenant agrees that in entering into and taking this Sublease, it relies solely upon the representations and agreements contained in this Sublease and no others. This Sublease, including the Exhibits which are attached hereto and a part hereof for all purposes, constitutes the whole agreement of the parties and shall in no way be conditioned, modified or supplemented except by a written agreement executed by and delivered to both parties.

DEFAULT OF PRIMARY LANDLORD

19. If Primary Landlord fails to perform an obligation or provide a service which Primary Landlord is required by the Primary Lease to perform or provide, then Landlord's sole obligation is to cooperate with Tenant, and to use reasonable efforts, without, however, incurring any liabilities or expenses, by taking whatever action shall

be reasonably required, to enforce for the benefit of Tenant the obligations of Primary Landlord to Landlord under the Primary Lease insofar as they relate to the Premises and/or the Temporary Space.

ALTERATIONS

20. In connection with any alterations (as defined in Section 16 of the Primary Lease) desired to be made by Tenant to the Premises and/or the Temporary Space, the terms of Section 16 shall be applicable to this Sublease. Tenant shall also obtain the Landlord's prior written consent to the making of any alterations, changes or additions, notwithstanding the cost thereof. Landlord agrees, subject to the Primary Lease, to consider such request concurrently with the Primary Landlord, provided Tenant makes concurrent requests for such consent to Primary Landlord and to Landlord. Tenant shall, provided Primary Landlord cooperates with Tenant, contact Primary Landlord directly for the Primary Landlord's consent, if required. In securing Landlord's consent to such alterations, changes or additions, Tenant shall only be required to submit to Landlord those plans, specifications and information also submitted to Primary Landlord to secure its consent. Any consent of the Primary Landlord of such alterations shall be deemed to be approval of such alterations by the Landlord.

DEFAULTS OF TENANT AND LANDLORD

21. If Tenant shall default in the performance of any of its obligations under this Sublease, other than its obligation to pay Rent to Landlord, Landlord, without being under any obligation to do so and without thereby waiving such default, shall have the right, upon reasonable notice (except in an emergency or where delay could result in a default under the Primary Lease), to cure such default for the account and at the expense of Tenant without prior notice in the case of emergency and, in all other cases, upon five (5) business days' written notice by Landlord to Tenant.

If Landlord shall default in the performance of any of its obligations under the Primary Lease, Tenant, without being under any obligation to do so and without thereby waiving such default, shall have the right, upon reasonable notice (except in an emergency or where delay could result in a default under the Primary Lease), to cure such default for the account and at the expense of Landlord without prior notice in the case of emergency and, in all other cases, upon five (5) business days' written notice by Tenant to Landlord. Any sums expended by Tenant (including reasonable attorney's fees) in curing Landlord's defaults under the Primary Lease shall be reimbursed by Landlord to Tenant upon demand, or at Tenant's option, may be setoff against any Base Rent or any other payments to be paid by Tenant hereunder to Landlord.

NOTICES

22. Tenant shall promptly furnish Landlord with copies of all notices relating to the Premises and/or the Temporary Space which Tenant shall receive from Primary Landlord, and Landlord shall promptly furnish Tenant with copies of all notices relating to the Premises and/or the Temporary Space which Landlord receives from Primary Landlord.

CASUALTY OR CONDEMNATION

23. Notwithstanding any contrary provision of the Sublease or the provisions of the Primary Lease herein incorporated by reference, and in addition to any and all other rights thereunder, Tenant shall have the right, at Tenant's option, regarding any casualty or condemnation that is not the result of the willful or intentional misconduct of Tenant or its employees, agents, contractors or invitees: (i) to abate the Rent for the period and proportionately to the extent that such casualty to or condemnation of the Project, the Building and/or the Premises prevents access to the Premises, disrupts the business operations of Tenant in the Premises, and/or otherwise substantially inhibits the extent and purposes of Tenant's use of the Premises prior thereto, or (ii) to terminate the Sublease (x) if such casualty to the Premises requires more than four (4) months to restore or repair, or (y) if such casualty to or condemnation of the Project, the Building and/or the Premises prevents access to the Premises, disrupts the business operations of Tenant in the Premises, and/or otherwise substantially inhibits the extent and purposes of Tenant's use of the Premises prior thereto, for a period of more than four (4) months.

INDEMNIFICATION

24. Intentionally Deleted.

SUBORDINATION

25. Tenant acknowledges that this Sublease is subject and subordinate to the Primary Lease and, to the extent that the Primary Lease is also subject and subordinate to the hereinafter described instruments, this Sublease shall be subject and subordinate to all ground and underlying leases and all mortgages which might now or hereafter affect the Primary Lease (provided that Tenant shall have the right to request and receive a customary non-disturbance agreement from the existing mortgage holder), the leasehold estate thereby created or the real property of which the Premises form a part, and to any and all renewals, modifications, consolidations, replacements and extensions thereof. Subject to Section 28 hereof, Landlord shall have the right to modify the Primary Lease without Tenant's prior consent, provided, that if the modification in question would materially affect any right or obligation of Tenant hereunder or would materially affect the Premises and/or the Temporary Space and/or the Sublease then such modification shall not be effective against Tenant without Tenant's prior written consent.

ATTORNMENT

26. Intentionally Deleted.

QUIET POSSESSION

27. Landlord covenants that Tenant, on paying the Rent and performing all the terms, covenants and conditions of this Sublease, may peacefully and quietly have, hold and enjoy the Premises and the Temporary Space for the Term, free from any hindrance by Landlord, but subject to the exceptions, reservations and conditions hereof.

LEASE AGREEMENT

28. Landlord hereby represents that, to the best of its knowledge, the Primary Lease is valid and in full force and effect. Landlord further represents that to the best of its knowledge, no default exists under the terms of the Primary Lease, nor has any notice thereof been given by Primary Landlord to Landlord. The representations made in this Section shall be true and accurate as of the Commencement Date. Landlord agrees that it will not enter into any modification, termination or other agreement or take or omit to take any action with respect to the Primary Lease that would prevent or adversely affect the use by Tenant of the Premises and/or the Temporary Space in accordance with the terms of this Sublease or increase the obligations of Tenant hereunder during the respective term thereof. Landlord agrees to perform all of its obligations as tenant under the Primary Lease as and when due, except to the extent expressly assumed by Tenant with respect to the Premises and/or the Temporary Space pursuant to the terms of this Sublease. Landlord agrees to use its reasonable efforts to assure performance by Primary Landlord of its obligations under the Primary Lease. Landlord further represents that Tenant shall be entitled to the same level of services to which Landlord is entitled under the Primary Lease and/or actually receiving from Primary Landlord notwithstanding any silence of the Primary Lease as to such services, including without limitation those services set forth in Section 11 of the Primary Lease and security services provided for the Project and/or the Premises by Landlord, at the level of such services provided as of the Commencement Date. If such services should be discontinued or reduced, such discontinuation or reduction shall be an Event of Default by Landlord resulting, inter alia and at the option of Tenant, in the right of Tenant to terminate the Sublease or to engage in self-help for the provision of such services and abate Rent by the reasonable expense thereof; provided that Tenant shall give Landlord ten (10) business days prior written notice of such discontinuance or reduction prior to declaring an Event of Default.

TEMPORARY OCCUPANCY

29. (a) Landlord shall permit Tenant to occupy the area of the third floor of the Building, consisting of approximately five thousand (5,000) rentable square feet of floor area, as more particularly delineated on Exhibit G attached hereto and made a part hereof (the "**Temporary Space**"), for the authorized use as set forth in Section 3 of this Sublease for the period commencing on the Commencement Date and ending on the earliest of (i)

Tenant's relocation of all operations from the Temporary Space to the Premises, such relocation to be completed within twenty (20) business days following the substantial completion of construction of the Tenant Improvements or (ii) March 31, 2008 in the event that Tenant has declined to accept the terms of an Offer Notice, pursuant to the procedure set forth in Section 15 of the Sublease, regarding all or a portion of the Temporary Space (the "**Temporary Space Term**").

(b) No Rent shall be charged or due and payable regarding the Temporary Space during the Temporary Space Term.

(c) Except as otherwise provided in Section 29(b) above, all rights and obligations of and limitations on Tenant under this Sublease, including, without limitation, lien prohibitions, maintenance, repair, alterations, replacements and restoration obligations, required insurance coverages, provision of services, cure rights, quiet possession, and restrictions on use of insurance and condemnation proceeds, and all obligations of and limitations on Landlord hereunder, regarding the Premises shall apply with equal force and effect regarding the Temporary Space.

(d) If Tenant has not vacated the Temporary Space following the expiration of the Temporary Space Term, the provisions of Section 29(b) above shall no longer apply, Landlord shall sublease to Tenant and Tenant shall sublease from Landlord the Temporary Space for the authorized use on a month-to-month basis thereafter, and Tenant shall pay to Landlord, or with Landlord's consent directly to Primary Landlord, Base Rent for the Temporary Space at the same rate per rentable square foot as for the Premises, as it may be adjusted in accordance with Section 6 of this Sublease; provided that in the event that Tenant has declined to accept the terms of an Offer Notice regarding all or a portion of the Temporary Space, then Landlord shall be under no obligation to sublease the space to Tenant and may begin eviction proceedings immediately upon the expiration of the Temporary Space Term.

(e) With respect to the installations, removal, replacement or use of any communication or computer wires, cables and related devices as defined in the Primary Lease as Lines, Tenant shall have the right to construct a computer or communication closet or cage to house the Lines in the Temporary Space for use during the Temporary Space Term and for any Term applicable to any Offer Space as described in Section 15 hereof. Any new Lines installed by Tenant or existing Lines utilized by Tenant in the Premises, the Temporary Space or Offer Space shall be removed by Tenant at the option of Landlord upon termination of this Sublease at Tenant's cost in accordance with Section 13 of the Primary Lease. Any existing Lines not used by Tenant in the Premises, the Temporary Space and/or the Offer Space shall be removed by Landlord at Landlord's cost at the option of Tenant upon reasonable notice to Landlord.

IN WITNESS WHEREOF, this Sublease is hereby executed as of the date first above set forth.

Landlord:

ESS SUSA HOLDINGS, LLC,
a Delaware limited liability company

By: Extra Space Storage LLC, sole member

By: /s/ Charles L. Allen
Name: Charles L. Allen
Title: Manager

Tenant:

GTx, Inc.
a Delaware corporation

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

EXHIBIT “A”

Parcel 14: Moore Building

Beginning at a point in the easterly right of way line of South Third Street (66 ft. R.O.W.) a distance of 158.17 ft. northeastwardly, as measured along said easterly right of way line, from its tangent intersection with the northerly right of way line of Union Avenue (80 ft. R.O.W.); thence North 20 degrees, 38 minutes, 10 seconds East along said easterly right of way line a distance of 148.95 ft. to a point; thence South 69 degrees, 31 minutes, 15 seconds East a distance of 149.45 ft. to a point; thence South 20 degrees, 38 minutes, 10 seconds West a distance of 148.91 ft. to a point; thence North 69 degrees, 32 minutes, 16 seconds West a distance of 149.45 ft. to the point of beginning.

EXHIBIT B-1

PICTURE OF FLOOR PLAN — 7TH FLOOR

EXHIBIT B-2

PICTURE OF FLOOR PLAN — 8TH FLOOR

EXHIBIT C
CLEANING AND JANITORIAL SERVICES

NIGHTLY CLEANING	1.	Empty all waste receptacles, clean as necessary.
	2.	Vacuum all carpeted traffic areas and other areas as needed.
	3.	Dust furniture, files, fixtures, etc.
	4.	Damp wipe and polish all glass furniture tops.
	5.	Remove finger marks and smudges from vertical surfaces.
	6.	Clean all water coolers.
	7.	Sweep all private stairways nightly, vacuum if carpeted.
	8.	Damp mop spillage in office and public areas as required.
WEEKLY CLEANING	1.	Twice weekly, detail vacuum all rugs and carpeted areas.
	2.	Once weekly, dust all cleared surfaces of furniture, files, fixtures, etc.
WASH ROOMS (NIGHTLY)	1.	Damp mop, rinse and dry floors nightly.
	2.	Scrub floors as necessary.
	3.	Clean all mirrors, bright work and enameled surfaces nightly.
	4.	Wash and disinfect all fixtures.
	5.	Damp wipe and disinfect all partitions, tile walls, etc.
	6.	Empty and sanitize all receptacles.
	7.	Fill toilet tissue, soap, towel, and sanitary napkin dispensers.
	8.	Clean flushometers and other metal work.
	9.	Wash and polish all wall partitions, tile walls and enamel surfaces from trim to floor monthly.
	10.	Vacuum all louvers, ventilating grilles and dust light fixtures monthly.
FLOORS	1.	Ceramic tile, marble and terrazzo floors to be swept nightly and washed or scrubbed as necessary.
	2.	Vinyl floors and bases to be swept nightly.
	3.	Tile floors to be waxed and buffed monthly.
	4.	All carpeted areas and rugs to be detailed vacuumed twice weekly and all carpeted traffic areas and other areas as needed to be vacuumed nightly.
	5.	Carpet shampooing will be performed at Tenant’s request and billed to Tenant.
GLASS	1.	Clean inside of all perimeter windows as needed, but not more frequently than once every eighteen (18) months.
	2.	Clean outside of all perimeter windows as needed, but not more frequently than once every eighteen (18) months.
	3.	Clean glass entrance doors and adjacent glass panels nightly.
HIGH DUSTING (QUARTERLY)	1.	Dust and wipe clean all closet shelving when empty.
	2.	Dust all picture frames, charts, graphs, etc.
	3.	Dust clean all vertical surfaces.
	4.	Damp dust all ceiling air conditioning diffusers.
	5.	Dust the exterior surfaces of lighting fixtures.
DAY SERVICE	1.	Check men’s washrooms for toilet tissue replacement.
	2.	Check ladies’ washrooms for toilet tissue and sanitary napkin replacements.
	3.	Supply toilet tissue, soap and towels in men’s and ladies’ washrooms.

Neither Landlord nor the janitorial company will be responsible for removing items from surfaces in order to dust them. It is understood that while dusting is completed nightly in the common areas, it is only completed in the Premises once a week and on no particular day. In addition, neither Landlord nor the janitorial company will be responsible for moving, dusting or cleaning any computer, copier, printer or other office equipment. Notwithstanding anything herein to the contrary, it is understood that no services of the character provided for in this Exhibit shall be performed on Saturdays, Sunday or Holidays.

EXHIBIT D

RULES AND REGULATIONS OF BUILDING

1. No smoking shall be permitted within any portion of the Building or within twenty (20) feet of the Building's exterior doors, including tenant spaces and common areas.

2. Landlord may provide and maintain a directory for all tenants of the Building. No signs, advertisements or notices visible to the general public shall be permitted within the Project without the prior written consent of Landlord. Landlord shall have the right to remove any such sign, placard, picture, advertisement, name or notice placed in violation of this rule without notice to and at the expense of the applicable tenant.

3. Sidewalks, doorways, vestibules, halls, stairways and other similar areas shall not be obstructed by tenants or used by any tenant for any purpose other than ingress and egress to and from the leased premises and for going from one to another part of the Building. At no time shall any tenant permit its employees, agents, contractors or invitees to loiter in common areas or elsewhere in or about the Building or Project.

4. Corridor doors, when not in use, shall be kept closed.

5. Plumbing fixtures and appliances shall be used only for the purposes for which designed, and no sweepings, rubbish, rags, food or other unsuitable material shall be thrown or placed therein. Every tenant shall be responsible for ensuring that its employees, agents, contractors and invitees utilize Common Area restrooms in accordance with generally accepted practices of health, cleanliness and decency.

6. Landlord shall provide all locks for doors into each tenant's leased area, and no tenant shall place any additional lock or locks on any door in its leased area without Landlord's prior written consent. Two keys for each lock on the doors in each tenant's leased area shall be furnished by Landlord. Additional keys shall be made available to tenants at the cost of the tenant requesting such keys. No tenant shall have any duplicate keys made except by Landlord. All keys shall be returned to Landlord at the expiration or earlier termination of the applicable lease.

7. A tenant may use microwave ovens and coffee brewers in kitchen or break areas. Except as expressly authorized by Landlord in writing, no other appliances or other devices are permitted for cooking or heating of food or beverages in the Building. No portable heaters, space heaters or any other type of supplemental heating device or equipment shall be permitted in the Building. All tenants shall notify their employees that such heaters are not permitted.

8. All tenants will refer all contractors, subcontractors, contractors' representatives and installation technicians who are to perform any work within the Building to Landlord before the performance of any work. This provision shall apply to all work performed in the Building including, but not limited to installation of telephone and communication equipment, medical type equipment, electrical devices and attachments, and any and all installations of every nature affecting floors, walls, woodwork, trim, windows, ceilings, equipment and any other physical portion of the Building.

9. Movement in or out of the Building of furniture or office equipment, or dispatch or receipt by a tenant of any heavy equipment, bulky material or merchandise which require the use of elevators, stairways, lobby areas or loading dock areas, shall be restricted to hours designated by Landlord. A tenant must seek Landlord's prior approval by providing in writing a detailed listing of any such activity. If approved by Landlord, such activity shall be performed in the manner stated by Landlord.

10. All deliveries to or from the Building shall be made only at such times, in the manner and through the areas, entrances and exits designated by Landlord.

11. No portion of any tenant's leased area shall at any time be used for sleeping or lodging quarters. No birds, animals or pets of any type, with the exception of guide dogs accompanying visually impaired persons, shall be brought into or kept in, on or about any tenant's leased area.

12. No tenant shall make or permit any loud or improper noises in the Building or otherwise interfere in any way with other tenants or persons having business with them.

13. Each tenant shall endeavor to keep its leased area neat and clean. Nothing shall be swept or thrown into the corridors, halls, elevator shafts, stairways or other common areas, nor shall tenants place any trash receptacles in these areas.

14. No tenant shall employ any person for the purpose of cleaning other than the authorized cleaning and maintenance personnel for the Building unless otherwise approved in writing by Service Provider. The work of cleaning personnel shall not be hindered by a tenant after 5:30 PM local time, and such cleaning work may be done at any time when the offices are vacant. Exterior windows and common areas may be cleaned at any time.

15. To insure orderly operation of the Building, Service Provider reserves the right to approve all concessionaires, vending machine operators or other distributors of cold drinks, coffee, food or other concessions, water, towels or newspapers. No tenant shall install a vending machine in the Building without obtaining Service Provider's prior written approval, which shall not be unreasonably withheld; provided, however, any vending machine installed in the Building shall not exceed the weight load capacity of the floor where such machine is to be installed; and, Service Provider reserves the right to require that such vending machine be separately metered in accordance with this Service Agreement, and that such vending machine be equipped with an automatic device that reduces the power consumption of such machine during non-peak hours of use of such machine.

16. Service Provider shall not be responsible to tenants, their agents, contractors, employees or invitees for any loss of money, jewelry or other personal property from the leased premises or public areas or for any damages to any property therein from any cause whatsoever whether such loss or damage occurs when an area is locked against entry or not.

17. All tenants shall exercise reasonable precautions in protection of their personal property from loss or damage by keeping doors to unattended areas locked. Tenants shall also report any thefts or losses to the Building Manager and security personnel as soon as reasonably possible after discovery and shall also notify the Building Manager and security personnel of the presence of any persons whose conduct is suspicious or causes a disturbance. The tenant shall be responsible for notifying appropriate law enforcement agencies of any theft or loss of any property of tenant or its employees, agents, contractors, or invitees.

18. All tenants, their employees, agents, contractors and invitees may be called upon to show suitable identification and sign a building register when entering or leaving the Building at any and all times designated by Service Provider form time to time, and all tenants shall cooperate fully with Building personnel in complying with such requirements.

19. No tenant shall solicit from or circulate advertising material among other tenants of the Building except through the regular use of the U.S. Postal Service. A tenant shall notify the Building Manager or the Building personnel promptly if it comes to its attention that any unauthorized persons are soliciting from or causing annoyance to tenants, their employees, guests or invitees.

20. Service Provider reserves the right to deny entrance to the Building or remove any person or persons from the Building in any case where the conduct of such person or persons involves a hazard or nuisance to any tenant of the Building or to the public or in the event or other emergency, riot, civil commotion or similar disturbance involving risk to the Building, tenants or the general public.

21. Unless expressly authorized by Service Provider in writing, no tenant shall tamper with or attempt to adjust temperature control thermostats in the Building. Upon request, Service Provider shall adjust thermostats as required to maintain the Building Standard temperature.

22. All requests for overtime air conditioning or heating must be submitted in writing to the Building management office by noon on the day desired for weekday requests, by noon Friday for weekend requests, and by noon on the preceding business day for Holiday requests.

23. Tenants shall only utilize the termite and pest extermination service designated or approved by Service Provider.

24. No tenant shall install, operate or maintain in its leased premises or in any other area of the Building, any electrical equipment which does not bear the U/L (Underwriters Laboratories) seal of approval, or which would overload the electrical system or any part thereof beyond its capacity for proper, efficient and safe operation as determined by Service Provider, taking into consideration the overall electrical system and the present and future requirements therefor in the Building.

25. Parking in the Parking Facility shall be in compliance with all parking rules and regulations including any sticker or other identification system established by Service Provider. Failure to observe the rules and regulations shall terminate an individual's right to use the Parking Facility and subject the vehicle in violation to removal and/or impoundment. Parking stickers or other forms of identification supplied by Service Provider shall remain the property of Service Provider and not the property of a tenant and are not transferable. The owner of the vehicle or its driver assumes all risk and responsibility for damage, loss or theft to vehicles, personal property or persons while such vehicle is in the Parking Facility.

26. Each tenant shall observe Service Provider's reasonable rules with respect to maintaining standard window coverings at all windows in its leased premises so that the Building presents a uniform exterior appearance. Each tenant shall ensure that to the extent reasonably practical, window coverings are closed on all windows in its leased premises while they are exposed to the direct rays of the sun.

27. Bicycles and other vehicles are not permitted inside or on the walkways outside the Building, except in those areas specifically designated by Service Provider for such purposes and except as may be needed or used by a physically handicapped person.

28. Landlord reserves the right to rescind any of these rules and regulations and to make such other and further rules and regulations as in its judgment shall from time to time be needful for the safety, protection, care and cleanliness of the Building, the operation thereof, the preservation of good order therein and the protection and comfort of the tenants and their agents, employees and invitees, which rules and regulations, when made and written notice thereof is given to a tenant, shall be binding upon it in like manner as if originally herein prescribed.

EXHIBIT E
Parking Sublicense Agreement

This Parking Sublicense Agreement (this "Agreement") is made and entered into as of the ___ day of December, 2007 ("Effective Date"), by and between ESS SUSA Holdings LLC, a Utah limited liability company ("Licensor"), and GTx, Inc., a Delaware corporation ("Licensee").

WHEREAS, Licensor has entered into that certain Parking License Agreement with Moore Garage LLC ("Owner") dated as of December 29, 1998, as amended (the "Parking License") pursuant to which Licensor was granted a license to use up to 260 parking spaces in a certain parking facility situated upon real property situated at the northeast corner of Monroe Avenue and Third Street in Memphis, Tennessee (the "Parking Facility"); and

WHEREAS, Licensee desires to obtain from Licensor, and Licensor is willing to grant to Licensee, a sublicense for the use of 75 parking spaces in the Parking Facility, subject to and in accordance with the terms and conditions set forth in this Agreement;

NOW, THEREFORE, in consideration of the foregoing Recitals (which are incorporated herein by this reference), the mutual covenants and conditions hereinafter Set forth, arid other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged and intending to be legally bound, Licensor and Licensee hereby agree as follows:

SUBLICENSE ACKNOWLEDGMENT AND AGREEMENT

Licensee acknowledges and agrees that this Agreement and all of Licensee's rights under this Agreement shall at all times be subject and subordinate to all terms and provisions of the Parking License. Except as otherwise provided in this Agreement, all obligations of and limitations on "Licensee" under the Parking License shall be binding upon and be the responsibility of Licensee as such relate to the Parking Facility and Licensee's use thereof. Moreover, Licensee agrees that all indemnifications, releases, waivers and other obligations of Licensee hereunder shall run to the benefit of and be enforceable by Owner and that all, notices and rights granted to or consents or approvals required by "Licensor" hereunder shall also run to the benefit of Owner and shall also require the consent and approval of Owner. Licensee hereby agrees. if requested by Owner, to attorn to Owner in all respects as the "Licensor" hereunder as if this Agreement was a direct license between Licensee and Owner from and after the date Owner so requests. In the event of a default by Licensor as licensee under the Parking License, Owner shall provide Licensee written notice of such default and the opportunity to cure such default. In the event Owner terminates the Parking License solely due to a default by Licensor thereunder, Licensee shall attorn to Owner in all respects as the "Licensor" hereunder and this Agreement shall become a direct license between Licensee and Owner from and after termination of the Parking License. Licensee shall cure any and all then existing Licensee defaults under this Agreement, if any. Notwithstanding any of the provisions of this Agreement or the Parking License, neither conversion of this Agreement to a direct license nor any assignment of any rights or obligations hereunder shall in any mariner release or modify the obligations of Licensor to Owner under the Parking License.

1. Definitions. As used in this Agreement, the following terms shall have the meanings indicated:

Access Card shall have the meaning set forth in Section 5.

Access Hours shall have the meaning set forth in Section 6.

Applicable Law shall mean any and all present and future statutes, ordinances, rules, regulations,

judicial decisions, permits and/or certificates of any Governmental Authority in any way applicable to the Land, the Parking Facility, the License, Licensor or Licensee, as the case may be.

Business Day shall mean any day other than a Saturday, Sunday or the following legal holidays New Year's Day, Memorial Day, July 4th**,** Labor Day, Thanksgiving Day, day after Thanksgiving Day and Christmas Day.

Effective Date shall have the meaning set forth in the initial paragraph of this Agreement.

Expiration Date shall have the meaning set forth in Section 3.

Governmental Authority shall mean any federal, state, local or other governmental entity, or any agency thereof, having jurisdiction over the Land, Parking Facility, License, Licensor or Licensee, as the case may be.

Land shall have the meaning set forth in the first Recital.

License shall have the meaning set forth in Section 2.

Parking Spaces shall mean any of the unreserved parking spaces located in the Parking Facility.

Users shall mean any individual who is a tenant, employee or invitee of Licensee and who is granted the right to use an Access Card by Licensee. Licensee shall provide to Licensor a written list which identifies each User and shall update such list as reasonably necessary. As between Licensor and Licensee, arty individual who has possession of an Access Card shall be conclusive evidence that such individual is a User hereunder.

2. **Grant of License**. Licensor hereby grants to Licensee, and Licensee hereby accepts, a license (the "License") for the use of up to 75 Parking Spaces ("Initial Spaces") during the Access Hours by Users, which License shall be subject to, and used in accordance with, the terms and conditions of this Agreement and the Parking License. Licensee hereby accepts the License of 75 Parking Spaces. In addition, in the event that Licensee requests any additional Parking Spaces, Licensor hereby agrees to grant such spaces (so long as Licensor has additional spaces not already licensed to a sub-tenant of Licensor) pursuant to the terms hereof ("Additional Spaces"). In addition, in the event that Licensee occupies the Offer Space (as defined in the Sublease), Licensor shall license additional Parking Spaces to Licensee pursuant to the requirements of the Sublease ("ROFR Spaces"). Except as otherwise expressly provided herein, the License shall be irrevocable by Licensor. Nothing herein contained shall be construed to grant to Licensee any estate in real property nor the exclusive right to a particular Parking Space, but rather a license only.

3. Term. The term of this Agreement and the License (the "Term") shall commence on the Effective Date and shall expire at 5:00 p.m. Memphis, Tennessee time on April 30, 2015, or such earlier date on which this Agreement and the License are terminated in accordance with the provisions of this Agreement (the "Expiration Date").

4. Monthly Parking Fee.

a. In connection with the Initial Spaces, commencing on the Effective Date and continuing thereafter throughout the entire term of this Agreement, Licensee agrees to pay to Licensor, or with Licensor's consent directly to Owner, for the parking rights granted herein a rate of Zero Dollars ($0.00) per month.

b. In connection with the Additional Spaces, commencing upon request of such Additional Spaces by Licensee and continuing thereafter through the entire term of this Agreement, Licensee agrees to pay to Licensor, or with Licensor's consent directly to Owner, for the parking rights granted herein, a rate of Seventy Five Dollars ($75.00) per month, which monthly rental shall be paid on or before the first day of each calendar month during the Term. In the event the Term of this Agreement commences or expires on a day other than the first day of a calendar month, the applicable Monthly Parking Rate shall be prorated for the applicable period.

c. In connection with the ROFR Spaces, commencing upon Licensee's occupancy of the Offer Space and continuing thereafter through the entire term of this Agreement, Licensee agrees to pay to Licensor, or with Licensor's consent directly to Owner, for the parking rights granted herein, a rate to be mutually agreed upon between Licensor and Licensee, which monthly rental shall be paid on or before the first day of each calendar month during the Term. In the event the Term of this Agreement commences or expires on a day other than the first day of a calendar month, the applicable Monthly Parking Rate shall be prorated for the applicable period.

5. **Access.** Access to the Parking Facility shall be obtained by way of an access card (an "Access Card") issued by Owner to Licensee. Owner shall provide to Licensee 75 Access Cards (which amount shall be increased proportionately in the event Licensee obtains Additional Spaces or ROFR Spaces). Licensee may distribute the Access Cards to such Users as Licensee may elect. By accepting an Access Card, each User shall be conclusively deemed to have agreed to all terms and conditions of this Agreement. Owner may exchange Access Cards for new Access Cards from time to time in its sole discretion, and Licensee agrees to cause each User to promptly deliver its Access Card in exchange for the replacement Access Card. If any Access Card is lost, stolen or damaged, the same shall be immediately reported to Owner, and Owner agrees to replace such Access Card upon receipt of Owner's then-standard replacement fee . Only one (1) automobile may enter the Parking Facility with each use of an Access Card, and each entry to the Parking Facility using an Access Card must be followed by an exit from the Parking Facility using the Access Card before another entry using such Access Card will be permitted. Owner shall have the right to so program the Access Cards.

6. **Access Hours**. License granted hereunder shall be valid for entry to and exit from the Parking Facility twenty-four (24) hours a day seven days a week; provided, however, that Users will not be permitted to enter or exit the Parking Facility at any time after 6:00 p.m. on Business Days on which any event is scheduled at the adjacent baseball stadium ("Stadium") and will not be permitted to enter or exit the Parking Facility on non-Business Days on which any event is scheduled at the Stadium during the period of time commencing three hours before, arid ending two hours after the conclusion of, the scheduled event. Notwithstanding anything herein to the contrary, if any User gains entry to or exits from the Parking Facility at any time other than the Access Hours, then Licensee shall pay to Licensor, upon demand, the parking rate in effect at the time of such entry or exit regardless of when such User actually gained access to the Parking Facility. Licensor shall have the right, but not the obligation, to program the Access Cards to permit entry to the Parking Facility only during the Access Hours.

7. **No After Hours Personnel**. Licensee acknowledges and agrees that Owner shall have no obligation to provide security and may not have any personnel on site at the Parking Facility between the hours of 10:00 p.m. and 6:00 a.m. on Business Days or any time on non-Business Days. Licensee shall notify all of its Users of this fact and that upon request a security guard from the Moore Building will be available to accompany Users to their vehicles during the above referenced time periods.

8. **Reserved Spaces**. Licensee acknowledges and agrees that none of the Parking Spaces shall be reserved parking spaces. In no event shall Licensor reimburse Licensee the amount of any fine or penalty imposed on such User for parking in violation of any Applicable Law. At the discretion of Owner, Owner may at any time designate assigned parking spaces or may eliminate assigned parking spaces altogether and may provide attendant parking or such other system or management of parking as Owner deems necessary or desirable.

9. **Maintenance and Use**. Throughout the Term, Owner shall use commercially reasonable efforts to maintain the Parking Facility in good working order and repair and shall use and maintain the Parking Facility in accordance with all Applicable Law. Licensee shall use, and shall cause each User to use, the Parking Spaces and the Parking Facility in accordance with, and shall comply and cause each User to comply with, all Applicable Law and all of the terms and conditions of this Agreement and any rules and regulations relating to the use of the Parking Facility as Owner may adopt from time to time. Neither Licensee nor any User shall use or permit its Users to use the Parking Facility or any part thereof in any manner which would in any way (i) violate any Applicable Law or this Agreement, (ii) cause structural injury or damage to the Parking Facility or any part thereof, (iii) constitute a public or private nuisance, (iv) be reasonably likely to damage any personal property (including automobiles) or result in injury or death to any person, or (v) alter the appearance of the exterior or any portion of the interior of the Parking Facility.

10. **Licensee's Insurance**. At all times after the execution of this Agreement, Licensee will carry and maintain, at its expense with insurance companies reasonably acceptable to Licensor, (i) a commercial (comprehensive) liability insurance policy, including insurance against assumed or contractual liability under this Agreement, with respect to liability arising out of the ownership, use, occupancy or maintenance of the Parking Facility and all areas appurtenant thereto, to afford protection with respect to bodily injury, death or property damage of not less than Five Million Dollars ($5,000,000) combined single limit; and (ii) automobile liability with single limit coverage of at least $1,000,000 for all owned, hired or non-owned vehicles. Each liability policy shall include an "Additional Insured Endorsement" in favor of Licensor and Licensor's designees. A certificate of such insurance in a form reasonably satisfactory to Licensor shall be furnished to Licensor reflecting the limits and endorsements required herein. Each policy shall require notice of non-renewal to Licensor and shall further provide that it may not be altered or canceled without thirty (30) days' notice being first given to Licensor. Licensor agrees to cooperate with Licensee to the extent reasonably requested by Licensee to enable Licensee to obtain such insurance with respect to improvements. Licensor shall have the right to require increased limits if, in Licensor's reasonable judgment, such increase is necessary. All policies required to be maintained hereunder shall include a waiver of subrogation in favor of Licensor.

11. **Owner's Insurance**. Pursuant to the terms of the Parking License, Owner will maintain, during the Term of this Agreement, (i) a commercial (comprehensive) liability insurance policy and a garage keepers legal liability policy, including insurance against assumed or contractual liability with respect to liability arising out of the ownership, use, occupancy or maintenance of the Parking Facility and all areas appurtenant thereto, to afford protection with respect to bodily injury, death or property damage of not less than Five Million Dollars ($5,000,000) combined single limit; and (ii) fire and extended coverage insurance insuring the Parking Facility against damage or loss from fire or other casualty normally insured against under the terms of standard policies of fire and extended coverage insurance. Licensor shall not be obligated to insure any property of Licensee or any User. All policies required to be maintained hereunder shall include a waiver of subrogation in favor of Licensee.

12. **Waiver of Claims**. Notwithstanding anything in this Agreement to the contrary, each

party hereto releases and waives all claims, rights of recovery, and causes of action that either such party or any party claiming by, through, or under such party by subrogation or otherwise may now or hereafter have against the other party or any of the other party's directors, officers, shareholders, partners, members, employees or agents for any loss or damage that may occur to the Parking Facility or any of the personal property located thereon by reason of fire, act of God, the elements, or any other cause, excluding willful misconduct but including negligence of the parties hereto or their directors, officers, shareholders, partners, members, employees or agents that was required to be insured under the terms of this Agreement. Licensor shall not be liable to Licensee or any User for any inconvenience or loss to Licensee or any User in connection with any of the repair, maintenance, damage, destruction, restoration, or replacement referred to in this Agreement. Licensor shall not be liable to Licensee or any User and Licensee, for itself and on behalf of each User, hereby waives all claims against Licensor and its directors, officers, shareholders, partners, members, employees, or agents for any incidental or consequential damages, loss of profits, business interruption, acts of other users, licensees, vandalism, loss of trade secrets or other confidential information, and any damage, loss or injury caused by a defect in the Parking Facility or any other cause in, on, or about the Parking Facility or any part thereof, unless caused solely by the intentional or willful misconduct of Licensor. The waivers in this Section shall survive the expiration or earlier termination of this Agreement.

13. **No Liability**. Without limiting the generality of the foregoing waivers, Licensee expressly acknowledges and agrees, for itself and on behalf of each User, that Licensor and its directors, officers, shareholders, partners, members, employees, agents and contractors shall have no liability for any of the following (unless the same arises solely as a result of the gross negligence or willful misconduct of Licensor): (a) any damage to property; (b) any loss of or damage to persons or property by theft, vandalism, malicious mischief or otherwise; (c) any injury or damage to persons or property resulting from fire, explosion, falling plaster, steam, gas, oil, electricity, water, rain or snow, leaks from any part of the Parking Facility (including, without limitation, pipes, appliances, plumbing works, cooling systems, the roof, the street or subsurface) or from any other place or by any other cause of whatever nature, or dampness; (d) any of the foregoing which may be caused by any tenant, invitee, User, guest or other person in the Parking Facility or by operations in construction of any private, public or quasi-public work; and (e) damage or injury sustained as a result of faulty brakes or other equipment failure. In addition, Licensor shall not be responsible for vehicles stolen from the Parking Facility, nor for articles left in vehicles (including, without limitation, cellular telephones, CB radios, antennas, tape decks and tape cartridges, stereos, CD players and compact discs and any other personal property). No employee or other agent of Licensor shall ever have the authority to vary the limitations on liability set forth herein. Licensee shall provide a copy of the foregoing waiver in the form attached hereto as Exhibit A to each User as a condition to their use of the Parking Facility. The waivers in this Section shall survive the expiration or earlier termination of this Agreement.

14. **Indemnity.** Except for the claims, rights of recovery and causes of action waived in Sections 12 and 13, Licensee shall indemnify and hold harmless Licensor and Licensor's directors, officers, shareholders, partners, members, employees, agents and contractors, from all claims, losses, costs, damages, or expenses (including reasonable attorneys' fees) in connection with any injury to, including death of, any person or damage to any property arising, wholly or in part, out of any action, omission, or neglect of Licensee or Licensee's directors, officers, shareholders, partners, members, employees, agents, invitees, Users, guests, or any parties contracting with Licensee relating to the Parking Facility. If Licensor shall without fault on its part, be made a party to any action commenced by or against Licensee, the Licensee shall protect and hold Licensor harmless and shall pay all costs, expenses, including reasonable attorneys fees in connection therewith. Licensee's obligations under this Section shall not be limited by the amount or types of insurance maintained or required to be maintained by Licensee under this Agreement.

The obligations under this Section shall survive the expiration or earlier termination of this Agreement.

15. **Revocation and Termination**. It is the intent of Licensor and Licensee that the License granted herein shall be irrevocable for the duration of the Term, and neither Licensor nor Licensee shall be entitled to revoke the License or terminate this Agreement except under the limited circumstances expressly set forth in this Agreement. Notwithstanding the foregoing, Licensee acknowledges and agrees that any User's right to enjoy the benefits of the License may be terminated by Licensor under the circumstances set forth in this Agreement, and no such termination by Licensor shall be deemed a revocation of the License or a default under this Agreement. Notwithstanding any other provision of this Agreement, Licensee shall have the right to terminate this Agreement upon the termination of that certain Sublease Agreement entered into between Licensor as Landlord and Licensee as Tenant concurrently herewith.

16. **Assignment**. Licensor shall have the unqualified right to assign its interest and obligations to any person or entity without the consent of Licensee, so long as Licensor's assignee expressly assumes the obligations of Licensor hereunder, and Licensor shall be released from all obligations and liabilities hereunder from and after the effective date of such assignment and assumption. Licensee may not assign its interest under this Agreement without the prior written consent of Licensor, which consent Licensor may grant or withhold in Licensor' s sole discretion. If Licensor consents to any such assignment, unless expressly consented to by Licensor, no such assignment shall release Licensee from any of its obligations hereunder.

17. **Surrender**. On the Expiration Date, or on such earlier date as this Agreement and the License may be terminated in accordance with the provisions hereof, Licensee covenants and agrees to cause all Access Cards to be returned to Owner and shall quit and surrender use of the Parking Facility and all Parking Spaces. Licensee's obligation to observe and perform this covenant shall survive the expiration or earlier termination of the Term.

18. **Subordination**. This Agreement, the Sublicense and the rights of Licensee hereunder are expressly subject and subordinate to (i) the terms, conditions and provisions of any ground lease of the Land pursuant to which Owner holds its interest in the Land and/or the Parking Facility, and (ii) the lien of any mortgage against Owner's interest in the Land and/or the Parking Facility (whether fee simple or leasehold under a ground lease); provided, however, that so long as Licensee performs its obligations hereunder, no ground lessor under a ground lease nor any mortgagee under a mortgage shall disturb the License or Licensee's right to use the Parking Facility in the event any such ground lessor or mortgagee succeeds to Owner's interest in the Land and/or the Parking Facility. The foregoing subordination and nondisturbance shall be self-operative upon the execution and delivery of this Agreement by Licensor and Licensee, no further instrument of subordination shall be necessary or required, and any third party may rely on this provision as confirmation of Licensee's subordination of its interests hereunder as aforesaid, subject to the right of nondisturbance set forth above. If, in connection with any temporary and/or permanent financing in connection with the Land and/or the Parking Facility, any lender requests reasonable modifications of this Agreement as a condition to such financing, Licensee shall not unreasonably withhold or delay the execution and/or delivery of such modification so long as the same does not increase Licensee's financial obligations hereunder or materially adversely affect the License or Licensee's use of the Parking Facility.

19. **Notices**. All notices and other communications under or with respect to this Agreement and/or the License shall be in writing and shall be deemed delivered (i) upon receipted delivery, if sent by messenger or personal courier, (ii) one Business Day after being deposited in the U.S. Mail, registered or certified, return receipt requested, in any case with postage/delivery prepaid or billed to sender and

addressed as follows:

If to Licensor:

ESS SUSA Holdings LLC
2795 E. Cottonwood Parkway, Suite 400
Salt Lake City, UT
Attn: General Counsel

If to Licensee:

GTx, Inc.

_____

_____

Attn:

Either party may change its address for purposes of notice hereunder by delivering written notice thereto to the other in the manner set forth above. Notwithstanding the foregoing, any delivery which is rejected by the addressee or which is undeliverable because of an address change of which no notice was given shall be deemed delivered upon the attempted delivery thereof.

20. **No Waiver**. No waiver of any provision of this Agreement shall be considered a waiver of any other provision hereof nor a waiver of subsequent application of such provision. No waiver shall be enforceable unless in writing and signed by the party against whom enforcement is sought. No delay or omission in exercising or enforcing the rights herein granted shall be construed as a waiver of such rights. The acceptance by any party of a partial payment of any amount due and owing to such party hereunder shall not be deemed a waiver of the right to receive the balance of such account.

21. **Interest**. All amounts payable by Licensee to Licensor under this Agreement, if not paid when due, shall bear interest from the date due until paid at the then maximum lawful rate (the "Default Rate").

22. **Holding Over**. If Licensee does not surrender possession of the Leased Spaces at the end of the Term or upon earlier termination of this Agreement, at the election of Licensor, Licensee shall be a licensee-at-sufferance of Licensor from day to day and the Monthly Rental Rate during the period of such holdover shall be two (2) times the amount which Licensee was obligated to pay for the month immediately preceding the end of the Term or termination of this Agreement.

23. **Entire Agreement**. This Agreement and any exhibits attached hereto constitute the entire agreement of the parties with respect to the subject matter hereof. This Agreement may be amended, supplemented or otherwise modified only by a written instrument executed by all of the parties hereto. If any term or provision of this Agreement is deemed to be invalid or unenforceable to any extent, the remainder of this Agreement shall not be affected thereby and shall continue in full force and effect to the fullest extent permitted by Applicable Law.

24. **No Representations**. Licensee acknowledges and agrees that neither Licensor nor any party acting by, through or under Licensor has made any representations or warranties of any kind with respect to the Land, the Parking Facility, the License or the Parking Spaces except as expressly set forth in this Agreement, and no such representations or warranties shall be implied or inferred from the actions of Licensor or any party acting by, through or under Licensor nor from any provision of this Agreement.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed and delivered as of the date first written above.

LICENSOR:

ESS SUSA HOLDINGS, LLC,
a Delaware limited liability company

By: _____, member

By: _____

Name: _____

Title: _____

LICENSEE:

GTX, INC., a Delaware corporation

By: _____
Name: Henry P. Doggrell
Title: Vice President, General Counsel and Secretary

Consented to by Owner as of the date first above set forth.

OWNER:

Moore Garage LLC

By: Parkway Properties LP, its sole general member

By: Parkway Properties General Partners, Inc., its

sole general partner

By _____

Name: John J. Buckley
Title: Senior Vice President

Exhibit A

Waiver of Liabilities

Use of the Parking Facility is subject to (i) the terms and conditions of that certain Parking License Agreement dated December 29, 1998 by and between Moore Garage LLC ("Owner") and ESS SUSA Holdings, LLC, as successor in interest to SUSA-TN LLC as such may be amended from time to time, and (ii) any and all rules and regulations adopted by Licensor from time to time. A copy of the Parking License Agreement is available from Owner upon request.

Owner shall not be liable to Licensee or any User, and User hereby waives all claims against Owner and its directors, officers, shareholders, partners, members, employees or agents for any incidental or consequential damages, loss of profits, business interruption, acts of other users, licensees, vandalism, loss of trade secrets or other confidential information, and any damage, loss or injury caused by a defect in the Parking Facility or any other cause in, on, or about the Parking Facility or any part thereof, unless caused solely by the gross negligence or willful misconduct of Owner.

Without limiting the generality of the foregoing, each User by use of the Access Card expressly acknowledges and agrees that Owner and its directors, officers, shareholders, partners, members, employees, agents and contractors shall have no liability for any of the following (unless the same arises as a result of the gross negligence or willful misconduct of Owner): (a) any damage to property; (b) any loss of or damage to persons or property by theft, vandalism, malicious mischief or otherwise; (c) any injury or damage to persons or property resulting from fire, explosion, falling plaster, steam, gas, oil, electricity, water, rain or snow, leaks from any part of the Parking Facility (including, without limitation, pipes, appliances, plumbing works, cooling systems, the roof, the street or subsurface) or from any other place or by any other cause of whatever nature, or dampness; (d) any of the foregoing which may be caused by any tenant. invitee, User, guest or other person in the Parking Facility or by operations in construction of any private, public or quasi-public work; and (e) damage or injury sustained as a result of faulty brakes or other equipment failure. In addition, Owner shall not be responsible for vehicles stolen from the Parking Facility, nor for articles left in vehicles (including, without limitation, cellular telephones, CB radios, antennas, tape decks and tape cartridges, stereos, CD players and compact discs and any other personal property). No employee or other agent of Owner shall ever have the authority to vary the limitations on liability set forth herein.

These waivers shall survive the expiration or earlier termination of the Parking License Agreement.

EXHIBIT F

STATE OF TENNESSEE
COUNTY OF SHELBY

MEMORANDUM OF SUBLEASE

This Memorandum of Sublease will evidence and, when recorded, serve as notice that ESS SUSA HOLDINGS, LLC, a Delaware limited liability company ("Landlord"), the lessor of certain real property described on Exhibit A attached hereto (the "Subject Property") has subleased the 7th and 8th floors within the William R. Moore Building ("Building") which is located on the Subject Property to GTx, Inc., a Delaware corporation ("Tenant") pursuant to the terms and provisions of the certain Sublease Agreement of even date herewith (the "Sublease"). Capitalized terms used but not otherwise defined in this Memorandum of Sublease shall have the meaning set forth in the Sublease. The Sublease provides in part as follows:

1. **TERM.** Subject to the provisions contained in the Sublease, Landlord has granted to Tenant a lease of certain space within the Building through April 30, 2015.

2. **RIGHT OF FIRST REFUSAL.** Subject to the provisions contained in the Sublease, Landlord has granted Tenant a right of first refusal with respect to the leasing of the 3rd and 4th floors of the Building.

Upon the termination or expiration of the Sublease for any reason, Landlord shall have the right without the necessity of obtaining the signature of Tenant to record a cancellation of this Memorandum of Sublease.

The terms and provisions of the Sublease are incorporated herein by reference. Copies of the Sublease are on file at the respective offices of Landlord and Tenant. This document is not intended to alter or modify in any manner any of the terms and conditions of the Sublease referred to herein, but rather to serve as a written memorandum thereof for purposes of recordation and notice. The terms of the Sublease shall govern all matters referenced herein.

Executed as of this ____ day of December, 2007.

Landlord:

ESS SUSA HOLDINGS, LLC
a Delaware limited liability company

By: Extra Space Storage LLC, sole member

By: _____
Name: _____
Title: _____

Tenant:

GTx, Inc.
a Delaware corporation

By:
_____, member

By: _____
Name: _____
Title: _____

EXHIBIT G

TEMPORARY SPACE

[DIAGRAM OF 3RD FLOOR TEMPORARY OFFICE SPACE]

Exhibit 12.1

GTx, Inc.
Computation of Deficiency of Earnings Available to Cover Fixed Charges

	Year Ended December 31,				
	2007	2006	2005	2004	2003
Loss:					
Pretax loss from continuing operations	$ (40,359)	$ (35,510)	$ (36,839)	$ (22,348)	$ (14,194)
Fixed charges (from below)	35	32	32	21	18
Total loss	$ (40,324)	$ (35,478)	$ (36,807)	$ (22,327)	$ (14,176)
Fixed charges:					
Estimated interest portion of rent expenses	$ 35	$ 32	$ 32	$ 21	$ 18
Total fixed charges	$ 35	$ 32	$ 32	$ 21	$ 18
Coverage deficiency	$ (40,359)	$ (35,510)	$ (36,839)	$ (22,348)	$ (14,194)

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-118882) pertaining to the GTx, Inc. Directors' Deferred Compensation Plan,

(2) Registration Statement (Form S-8 No. 333-112576) pertaining to the GTx, Inc. 2004 Equity Incentive Plan, 2004 Non-Employee Directors' Stock Option Plan, 2002 Stock Option Plan, 2001 Stock Option Plan, 2000 Stock Option Plan, and 1999 Stock Option Plan,

(3) Registration Statement (Form S-8 No. 333-136527) pertaining to the GTx, Inc. Amended and Restated 2004 Non-Employee Directors' Stock Option Plan,

(4) Registration Statement (Form S-3 No. 333-148321) pertaining to the offer and sale by GTx, Inc. of shares of its common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, in one or more offerings, up to a total dollar amount of $100,000,000, and

(5) Registration Statement (Form S-3 No. 333-148325) pertaining to the offer and sale of up to 1,285,347 shares of the common stock of GTx, Inc. by the selling stockholder named in the prospectus included therein;

of our reports dated March 6, 2008, with respect to the financial statements of GTx, Inc. and with respect to the effectiveness of internal control over financial reporting of GTx, Inc., included in this Annual Report (Form 10-K) of GTx, Inc. for the year ended December 31, 2007.

/s/ Ernst & Young LLP

Memphis, TN
March 6, 2008

Exhibit 31.1

CERTIFICATIONS

I, Mitchell S. Steiner, certify that:

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

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding 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: March 11, 2008

/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

CERTIFICATIONS

I, Mark E. Mosteller, certify that:

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

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding 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: March 11, 2008

/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 Annual Report of GTx, Inc. (the "Company") on Form 10-K for the year ended December 31, 2007, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mitchell S. Steiner, Chief Executive Officer of the Company certify, pursuant to Rule 13a-14(b) or Rule 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 11, 2008

/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-K 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-K), 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 Annual Report of GTx, Inc. (the "Company") on Form 10-K for the year ended December 31, 2007, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mark E. Mosteller, Chief Financial Officer of the Company certify, pursuant to Rule 13a-14(b) or Rule 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 11, 2008

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

This certification accompanies the Form 10-K 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-K), irrespective of any general incorporation language contained in such filing.