Table of Contents

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, 2010

OR

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

For the transition period from _____ to _____

Commission file number 000-50549

GTx, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**62-1715807**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
175 Toyota Plaza 7th Floor Memphis, Tennessee	**38103**
(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 ☐ 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 ☐ 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 ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

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:

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ 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 30, 2010 as reported on The NASDAQ Global Market was $56,844,168.

There were 51,719,187 shares of registrant's common stock issued and outstanding as of March 3, 2011.

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 2011 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

TABLE OF CONTENTS

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 research, development and clinical programs, including whether any future clinical trials we conduct will achieve similar results to clinical trials that we have successfully concluded;
- the timing, scope and anticipated initiation and completion of any future clinical trials that we may conduct;
- the timing of regulatory submissions and the timing, scope and anticipated outcome of related regulatory actions;
- our ability to establish and maintain potential new collaborative arrangements for the development and commercialization of our product candidates;
- our ability to obtain and maintain regulatory approvals of our product candidates and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our ability to market, commercialize and achieve market acceptance for our product candidates or products that we may develop;
- our ability to generate additional product candidates for clinical testing;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; and
- our estimates regarding the sufficiency of our cash resources, expenses, capital requirements and needs for additional financing, and our ability to obtain additional financing.

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 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 and headquartered in Memphis, Tennessee, is a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules that selectively target hormone pathways for the treatment of cancer and the side effects of anticancer therapy, cancer supportive care, and other serious medical conditions.

We are developing selective androgen receptor modulators, or SARMs, a new class of drugs with the potential to prevent and treat muscle wasting in patients with cancer, and other musculoskeletal wasting or muscle loss conditions, including chronic sarcopenia (age related muscle loss). In March 2010, we reacquired full rights to our SARM program, including Ostarine™ (GTx-024), our lead SARM, following the termination by us and Merck & Co., Inc., or Merck, of our exclusive license and collaboration agreement for SARM compounds and related SARM products. In December 2010, we held an End of Phase II meeting with the U.S. Food and Drug Administration, or FDA, to discuss our proposed Phase III clinical development of Ostarine™ for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer. We expect to initiate a pivotal Phase III clinical trial for this indication in the third quarter of 2011, following additional input from the FDA.

Additionally, we are developing Capesaris™ (GTx-758), a selective estrogen receptor, or ER, alpha agonist for first line treatment of advanced prostate cancer. As a selective ER alpha agonist, Capesaris™ has the potential to achieve medical castration by feedback inhibition of the hypothalamic- pituitary-gonadal axis. Because of the mechanism of action of Capesaris™, castration is expected to be achieved without concomitant bone loss or the development of hot flashes. In 2009, we completed two Phase I clinical trials, a single ascending dose clinical trial and a multiple ascending dose clinical trial, evaluating Capesaris™ in healthy male volunteers. Capesaris™ was well tolerated in both trials. In September 2010, we announced that in a Phase II, open label, pharmacokinetic and pharmacodynamic clinical trial in young healthy male volunteers, Capesaris™ suppressed serum total testosterone to castrate levels, increased serum sex hormone binding globulin, or SHBG, and reduced serum free testosterone, the form of testosterone which is available to prostate cancer cells for growth. Medical castration (levels of serum total testosterone less than 50ng/dL) was achieved in the 1000 mg and 1500 mg treatment groups. Capesaris™ was well tolerated and no serious adverse events were reported in the study. We met with the FDA in February 2011 and confirmed that the primary endpoint acceptable for approval for this indication is total testosterone levels (achieve and maintain serum total testosterone levels less than 50ng/dL). In the second quarter of 2011, we plan to initiate a Phase IIb open label clinical trial evaluating Capesaris™ compared to Lupron® (leuprolide acetate), a luteinizing hormone releasing hormone, or LHRH, agonist for first line treatment in men with advanced prostate cancer.

In December 2008, we submitted a New Drug Application, or NDA, for toremifene 80 mg, a selective estrogen receptor modulator, or SERM, to reduce fractures in men with prostate cancer on androgen deprivation therapy, or ADT, to the FDA. In October 2009, we received a Complete Response Letter from the FDA regarding our NDA for toremifene 80 mg notifying us that the FDA would not approve our NDA in its present form as a result of certain clinical deficiencies identified in the Complete Response Letter. In April 2010, we submitted a proposed protocol to the FDA for a second pivotal Phase III clinical trial evaluating toremifene 80 mg to reduce fractures in men with prostate cancer on ADT to address in a single clinical trial the deficiencies identified by the FDA in the Complete Response Letter. Based on our discussions with the FDA to date, we believe that we have finalized the protocol for a second pivotal Phase III clinical trial (which we previously referred to as the TREAT 2 trial).

In March 2011, we reacquired full rights to our toremifene program following the termination by us and Ipsen Biopharm Limited, or Ipsen, of our collaboration and license agreement, which was entered into in September 2006 and amended in March 2010. In exchange for reacquiring all of Ipsen's rights under the collaboration agreement, we agreed to pay Ipsen a low single digit royalty on net sales of toremifene 80 mg in the United States if approved for commercial sale. Pending our ongoing discussions with the FDA regarding whether an additional single Phase III clinical trial of toremifene 80 mg to address the deficiencies identified in the Complete Response Letter can be conducted as a post-approval study, we do not plan to continue any further clinical development of toremifene 80 mg. In the event that the FDA allows this clinical trial to be conducted as a post-approval study and we are able to secure sufficient funding for the study through new partnerships or collaborations or through other financing, we will reevaluate whether to continue the development of toremifene 80 mg.

In May 2010, we announced that toremifene 20 mg failed to meet the primary efficacy endpoint in a completed Phase III clinical trial evaluating toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia, or high grade PIN. We do not expect to conduct additional clinical trials evaluating toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN or to submit a NDA to the FDA for this indication.

We market FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of advanced metastatic breast cancer in postmenopausal women in the United States.

We believe that our current cash resources, together with interest income and product revenue from the sale of FARESTON®, will be sufficient to enable us to initiate in 2011 our planned Phase III clinical trial of Ostarine™ for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer and to initiate and complete our planned Phase IIb clinical trial to evaluate Capesaris™ for first line treatment of advanced prostate cancer. To complete the Phase III clinical trial we expect to initiate in 2011 for Ostarine™, we may need to obtain additional funding. However to conduct any additional clinical trials for our product candidates, we will need to raise additional capital through partnerships and/or collaborations or the sale of our securities. We do not expect to obtain FDA or any other regulatory approvals to market any of our product candidates in the near future.

Scientific Background on Estrogen and Androgen Hormones and Selective Hormone Receptor Modulators

Estrogens and androgens are hormones that play critical roles in regulating the reproductive system and contributing to the homeostasis of the muscular, skeletal, cardiovascular, metabolic and central nervous systems.

Testosterone, the predominant androgen, is important for masculine physical characteristics, such as muscle size and strength and bone strength, as well as for mental well-being. Male reproductive health is dependent on testosterone for 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. In aging men, there is a gradual decline in testosterone levels, which contributes to a loss of muscle mass and strength, erectile dysfunction, decreased sexual interest, depression and mood changes. Moreover, in men, testosterone is converted to estradiol, the primary estrogen in men and women. Estrogens improve bone quality and reduce the risk of skeletal fractures.

Estrogens and androgens perform their physiologic functions by binding to and activating their respective hormone receptors located in various tissues. Once a hormone binds with its receptor, this activates a series of cellular events that results in the hormone specific 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 are generally believed to 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 lack of selectivity of testosterone and its conversion to DHT may result in unwanted side effects, such as the potential stimulation of latent into clinical prostate cancer, worsening of benign prostatic hyperplasia, or BPH, development or worsening of acne and gynecomastia, or loss of hair in men. Hair growth, acne and masculinization are also of concern in women who are exposed to exogenous testosterone. To date, no orally available testosterone products have been approved for use in the United States. 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 in this manner is called a selective hormone receptor modulator. A selective hormone receptor modulator may be able to mimic the beneficial, while minimizing the unwanted, effects of natural or synthetic steroid hormones.

A SARM is a small molecule that binds to and selectively modulates androgen receptors, the primary receptor to which testosterone binds. SARMs potentially have beneficial effects in muscle and bone while avoiding testosterone's unwanted effects in the prostate in men or skin in men and women. Although no SARMs have been commercialized to date, we believe that SARMs, without the harmful side effects of testosterone or other exogenous anabolic steroid therapies, can potentially be developed to treat a range of medical conditions, including: (1) muscle loss conditions of chronic diseases, such as cancer, AIDS, chronic kidney disease, end-stage renal disease, and neurodegenerative disorders; (2) muscle loss of acute conditions such as trauma, burns, and rehabilitation; (3) muscle loss conditions associated with aging such as frailty and chronic sarcopenia; (4) the prevention and/or treatment of osteoporosis; (5) prostate disorders, such as BPH; (6) disorders of the central nervous system, such as low libido, depression and other mood disorders; (7) low testosterone conditions, such as primary and secondary hypogonadism; (8) disorders of male reproductive functions, such as infertility, male contraception and erectile dysfunction; and (9) other conditions, such as anemia and male hair loss.

A selective estrogen receptor alpha agonist is a nonsteroidal compound with the ability to preferentially bind and activate estrogen receptor alpha as compared to estrogen receptor beta. A selective estrogen receptor alpha agonist may have the ability to achieve medical castration without hot flashes, bone loss or other side effects related to nonselective estrogens or LHRH agonists and antagonists.

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. 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 metastatic breast cancer in postmenopausal women, and raloxifene, which is used to prevent and treat postmenopausal female osteoporosis.

Marketed Product

FARESTON®

We market FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of advanced metastatic breast cancer in postmenopausal women in the United States. Toremifene is a SERM owned and manufactured by Orion and is the active pharmaceutical ingredient in FARESTON®. On January 1, 2005, we entered into an amended and restated 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.

As part of our effort to complete the requirements for the submission of applications for regulatory approval of toremifene 80 mg and toremifene 20 mg, we have conducted a number of studies of toremifene in addition to our clinical trials, including a Thorough QT study. The results of the Thorough QT study of 250 healthy male volunteers showed that toremifene prolonged the QT interval in a dose dependent manner. Since we market FARESTON® in the United States under a license agreement with Orion, we notified the FDA in October 2008 of the Thorough QT study results and have proposed modifications to the FARESTON® label in the United States. FDA action on the proposed label changes is pending. The study results could lead to the inclusion of restrictions, limitations and/or warnings in the label of FARESTON® or an approved toremifene product candidate, which may adversely affect the marketability of the product or limit the patients to whom the product is prescribed. Separately, Orion recommended label changes to the European Medicines Agency, or EMA. In January 2009, the EMA recommended that the FARESTON® label within the European Union reflect that toremifene should not be given to patients at risk of prolonged QT intervals or other certain heart problems.

We sell FARESTON® primarily through wholesale drug distributors. Our top three distributors, McKesson Corporation, Cardinal Health, Inc. and AmerisourceBergen Corporation, accounted for approximately 95% of our product sales generated from the sale of FARESTON® for the year ended December 31, 2010. The loss of any of these three distributors could have a material adverse effect on continued FARESTON® sales. FARESTON® net product sales accounted for 6%, 22%, and 8% of our total revenue for the years ended December 31, 2010, 2009 and 2008, respectively.

Product Candidates

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

Product Candidate/ Proposed Indication	Program	Clinical Development Phase	Status
Ostarine™ Prevention and treatment of muscle wasting in patients with cancer	SARM	Phase III	Phase II clinical trial completed in September 2008; held End of Phase II meeting with the FDA in December 2010; plan to initiate a pivotal Phase III clinical trial in the third quarter of 2011 for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer.
Capesaris™ First line treatment of advanced prostate cancer	Selective ER alpha agonist	Phase IIb	Phase II clinical trial results reported in September 2010; plan to initiate a Phase IIb clinical trial in the second quarter of 2011 for first line treatment in men with advanced prostate cancer.
Toremifene 80 mg To reduce fractures in men with prostate cancer on ADT	SERM	Phase III	Received a Complete Response Letter from the FDA regarding our NDA in October 2009; second Phase III clinical trial protocol finalized following FDA input; further development subject to ongoing discussions with the FDA.

SARMs

SARMs are a new class of drugs with the potential to treat muscle wasting in patients with cancer, as well as other musculoskeletal wasting or muscle loss conditions, including sarcopenia (age related muscle loss). In March 2010, we reacquired full rights to our SARM program, including Ostarine™, our lead SARM, following the termination by us and Merck of our exclusive license and collaboration agreement for SARM compounds and related SARM products.

Ostarine™ for the Prevention and Treatment of Muscle Wasting in Patients with Cancer

Scientific Overview. Muscle wasting, a cancer related symptom, can begin early in the course of cancer and frequently leads to cancer cachexia, a complex metabolic condition characterized by accelerated loss of skeletal muscle and severe weight loss. Cancer cachexia is usually viewed as an end of life condition in patients with advanced or incurable malignancies. The common clinical symptoms attributed to muscle wasting include decline in physical function and impaired immune function which contribute to increased disability, fatigue, diminished quality of life, and reduced survival.

Although muscle wasting associated with cancer can be partially attributed to poor nutrition, treatment with appetite stimulants and nutritional intervention alone is not effective, likely because they do not address the underlying catabolic processes responsible for muscle wasting. Additionally, patients with severe weight loss, low performance status, and metastatic cancer that is no longer responding to cancer treatment may be less likely to respond to single therapies designed to increase muscle mass and physical function. Because muscle wasting, which often leads to refractory cancer cachexia, has a significant negative impact on the patient and their family, early prevention and treatment of muscle wasting are critical.

Ostarine™ is an oral nonsteroidal SARM which means that Ostarine™ is similar to testosterone in activating androgen receptors in muscle, thereby promoting lean body mass (muscle) and improving physical function, while avoiding stimulation of sebaceous glands, the cause of hair growth and acne, or epithelial cells of the prostate, which may exacerbate BPH or stimulate prostate cancer. Ostarine™, as a selective anabolic agent, may play an important role in the prevention and treatment of muscle wasting in cancer patients.

Potential Market. There are approximately twelve million cancer survivors in the United States. Nearly 60 percent of cancer survivors have functional limitations such as the inability to climb or descend stairs without pausing or the inability to lift or carry 10 pounds.

Lung cancer remains the most common malignancy. Worldwide, there are an estimated 1.5 million new cases and approximately 1.35 million deaths annually. In the United States, there are approximately 220,000 new cases and 157,000 deaths each year. Of non-small cell lung cancer patients, 50% have severe muscle wasting at diagnosis, 73% lose muscle post diagnosis, and 88% will develop lower body functional limitations.

There are no drugs approved for the prevention or treatment of muscle loss in patients with cancer. Supplemental nutritional support alone has little or no benefit in counteracting muscle wasting in cancer patients. Although there are two commercially available anabolic steroids being prescribed off-label for the treatment of weight loss in cancer patients, 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.

Cancer supportive care is a large and growing therapeutic category. In 2008 in the seven largest markets worldwide, sales of cancer supportive care drugs including treatments for neutropenia, nausea, loss of appetite, skeletal related events and other therapeutic categories exceeded $11 billion. No drugs have been approved for the prevention or treatment of muscle wasting in patients with cancer.

Clinical Trials. Ostarine™ has been evaluated in eight clinical trials enrolling approximately 600 subjects.

In a 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.

Another Phase I clinical trial was a double blind, multiple ascending dose 14 day study to evaluate the safety, tolerability, pharmacokinetics, and 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 DXA scanning for body composition. Overall, clinical laboratory values and hormonal effects for the 71 volunteers were consistent with anabolic activity. Comparisons of DXA assessments from the beginning of the study (baseline) to Day 14 showed positive changes in body composition at clinically relevant doses including increases in lean body mass and decreases in fat mass. Unwanted side effects on the prostate (serum PSA) or the skin (sebum analysis) were not observed in the Ostarine™ treated subjects. Ostarine™ was well tolerated with no drug-related serious adverse events.

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 lean muscle mass, as well as to assess safety in both elderly men and postmenopausal women. 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 of total lean body mass. Treatment with Ostarine™ also resulted in a dose dependent improvement in functional performance, a secondary endpoint, measured by stair climb. 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 clinically relevant changes in measurements of serum PSA, sebum production, or serum LH.

In July 2007, we initiated a Phase IIb randomized, double blind, placebo controlled clinical trial evaluating Ostarine™ for the treatment of muscle wasting in 159 patients diagnosed with non-small cell lung cancer, colorectal cancer, non-Hodgkin's lymphoma, chronic lymphocytic leukemia, or breast cancer. In October 2008, we announced top line results of this clinical trial. The study met its primary endpoint of absolute change in total lean body mass compared to placebo and the secondary endpoint of physical function, measured by stair climb, after 16 weeks of treatment.

In 2009, Ostarine™ was evaluated in a 12 week, randomized Phase Ib clinical trial comparing Ostarine™ to two doses of another SARM (Merck compound MK-3984) and to placebo in 88 postmenopausal women. Total lean body mass was measured at baseline and 12 weeks, and physical performance was evaluated at the same interval by bilateral leg press machine. After 12 weeks of treatment, Ostarine™ 3 mg significantly increased total lean body mass. Ostarine™ treatment also resulted in increased leg muscle strength. Ostarine™ treatment did not cause virilization, as there was no change in sebaceous gland volume, rate of sebum excretion, or hair follicle gene expression.

In December 2010, we held an End of Phase II meeting with the FDA to discuss our proposed Phase III clinical development of Ostarine™ for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer. We expect to initiate a pivotal Phase III clinical trial for this indication in the third quarter of 2011, following additional input from the FDA.

Selective ER Alpha Agonist

Capesaris™ for First Line Treatment of Advanced Prostate Cancer

Scientific Overview. We are developing Capesaris™, an oral selective ER alpha agonist, for first line treatment of advanced prostate cancer. Capesaris™ has the potential to achieve medical castration by feedback inhibition of the hypothalamic- pituitary-gonadal axis. Because of the mechanism of action of Capesaris™, castration is expected to be achieved without concomitant bone loss or the development of hot flashes.

ADT is the most common treatment for patients who have advanced prostate cancer. ADT reduces testosterone, a primary growth factor for prostate cancer, to castrate levels. ADT is currently accomplished either surgically by removal of the testes, or chemically by injection with LHRH agonists or antagonists. These LHRH agents work by shutting off LH secretion by the pituitary gland thereby stopping testosterone production by the testes. The reduction in testosterone by ADT also results in very low estrogen levels in men, because estrogen is derived from testosterone in men. Estrogen deficiency side effects associated with LHRH therapies may include bone loss and fractures, adverse lipid changes, hot flashes, gynecomastia, decreased libido, impaired cognitive function, increase in body fat composition, metabolic syndrome, diabetes and cardiovascular disease.

Potential Market. Capesaris™ is being developed as an oral form of androgen deprivation therapy, which is able to achieve medical castration without concomitant bone loss or the development of hot flashes. In the United States, we believe that approximately 700,000 prostate cancer patients are currently being treated with ADT, and approximately 100,000 new patients are started on this therapy each year. The annual U.S. sales of hormonal agents for prostate cancer, which include currently marketed LHRH agonist and antagonist ADT drugs, are approximately $1.7 billion, and worldwide sales exceed $3 billion.

There are no approved androgen deprivation therapies which avoid the potential for estrogen deficiency side effects, including bone loss, fractures, and hot flashes. For many men on ADT, physicians are currently prescribing certain drugs on an off-label basis to help ameliorate some of the specific estrogen deficiency related side effects of ADT. These drugs include off-label use of bisphosphonates for osteoporosis and Megace® (megestrol acetate) and antidepressants for hot flashes.

Clinical Trials. In 2009, we evaluated Capesaris™ in healthy male volunteers in two Phase I clinical trials. In a single ascending dose study in 96 subjects, Capesaris™ was well tolerated and demonstrated a pharmacokinetic profile compatible with daily oral dosing. In a ten day multiple ascending dose study in 50 subjects, Capesaris™ was well tolerated and demonstrated the ability to increase serum SHBG and to reduce serum total and free testosterone. In September 2010, we announced that in a Phase II, open label, pharmacokinetic and pharmacodynamic clinical trial in young healthy male volunteers, Capesaris™ suppressed serum total testosterone to castrate levels, increased serum SHBG, and reduced serum free testosterone, the form of testosterone which is available to prostate cancer cells for growth. Medical castration (levels of serum total testosterone less than 50ng/dL) was achieved in the 1000 mg and 1500 mg treatment groups. The percentage of treatment compliant subjects receiving 1500 mg of Capesaris™ who achieved medical castration was comparable to rates of castration observed with LHRH agonists or antagonists therapies. Capesaris™ was well tolerated and no serious adverse events were reported in the study. We met with the FDA in February 2011 and confirmed that the primary endpoint acceptable for approval for this indication is total testosterone levels (achieve and maintain serum total testosterone levels less than 50ng/dL). In the second quarter of 2011, we plan to initiate a Phase IIb open label clinical trial evaluating Capesaris™ compared to Lupron® (leuprolide acetate), a LHRH agonist for first line treatment in men with advanced prostate cancer.

Toremifene

We have evaluated toremifene 80 mg, a SERM, as a once-a-day oral tablet to reduce fractures and treat other estrogen deficiency side effects of ADT in men with prostate cancer. In January 2005, we exclusively licensed toremifene from Orion for all indications in humans, except for breast cancer outside of the United States. We licensed rights to toremifene based on toremifene's established record of safety in the treatment of postmenopausal women with metastatic breast cancer and our belief that SERMs can treat estrogen related complications resulting from ADT. 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 metastatic breast cancer in postmenopausal women. Additionally, Orion has agreed to manufacture our clinical supply and, if FDA approval of toremifene 80 mg is obtained, our commercial supply of toremifene 80 mg. In March 2011, we reacquired full rights to our toremifene program following the termination by us and Ipsen of our collaboration and license agreement, which was entered into in September 2006 and amended in March 2010. In exchange for reacquiring all of Ipsen's rights under the collaboration agreement, we agreed to pay Ipsen a low single digit royalty on net sales of toremifene 80 mg in the United States if approved for commercial sale. Pending our ongoing discussions with the FDA regarding whether an additional single Phase III clinical trial of toremifene 80 mg to address the deficiencies identified in the Complete Response Letter can be conducted as a post-approval study, we do not plan to continue any further clinical development of toremifene 80 mg. In the event that the FDA allows this clinical trial to be conducted as a post-approval study and we are able to secure sufficient funding for the study through new partnerships or collaborations or through other financing, we will reevaluate whether to continue the development of toremifene 80 mg.

In May 2010, we announced that toremifene 20 mg failed to meet the primary efficacy endpoint in a completed Phase III clinical trial evaluating toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN. We do not expect to conduct additional clinical trials evaluating toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN or to submit a NDA to the FDA for this indication.

Toremifene 80 mg to Reduce Fractures and Treat Other Estrogen Deficiency Side Effects of ADT in Men with Prostate Cancer

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 currently accomplished either surgically by removal of the testes, or chemically by treatment with LHRH agonists or antagonists. LHRH agonists and antagonists 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), Eligard® (leuprolide acetate), Trelstar® (triptorelin pamoate), and Vantas® (histrelin), as well as the LHRH antagonist Firmagon® (degarelix).

In men, aromatase converts testosterone to estrogen. By reducing testosterone to castrate levels, ADT depletes up to 80% of a man's estrogen, resulting in multiple estrogen deficiency side effects. Estrogen deficiency side effects associated with ADT include accelerated and continuous bone loss, as well as high risk of fractures, adverse lipid changes which may lead to higher risk of cardiovascular diseases, hot flashes, gynecomastia, decreased libido, depression, and memory loss. Increased risk of 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 are 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 toremifene 80 mg, as well as preclinical and clinical information known about toremifene, toremifene has shown estrogenic activity both in bone, which reduces fractures, 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, toremifene has been shown to improve lipid profiles in men with prostate cancer on ADT. Toremifene has also been shown to block estrogen's action in the male breast, which may prevent and treat gynecomastia. As a consequence, we believe that toremifene 80 mg has the potential to treat the following estrogen deficiency related side effects of LHRH agonists: fractures, hot flashes, adverse lipid changes and gynecomastia. Importantly, as evidenced by our two Phase II clinical trials and our Phase III clinical trial, toremifene does not have a detrimental effect to the underlying prostate cancer growth or affect the anticancer mechanism of ADT.

Potential Market. In the United States, we believe that approximately 700,000 prostate cancer patients are currently being treated with ADT, and approximately 100,000 new patients are started on this therapy each year. Prostate cancer patients are being treated earlier and for longer periods with ADT and the estrogen deficiency related 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 estrogen deficiency related 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. No treatments have been approved by the FDA to reduce fractures or treat other estrogen deficiency side effects in men with prostate cancer on ADT.

Clinical Trials. In November 2003, we initiated a pivotal Phase III clinical trial of orally administered toremifene 80 mg dose in patients undergoing ADT for advanced, recurrent or metastatic prostate cancer. The primary endpoint of the trial was the reduction of new morphometric vertebral fractures measured by x-ray, and the secondary endpoints of the trial included bone mineral density, or 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 toremifene for 24 months. We conducted the trial in approximately 150 sites in the United States and Mexico. In December 2005, we completed a planned interim BMD analysis among the first 197 patients who completed one year of treatment. Patients treated with toremifene 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 ($p=0.009$).

The last patient completed the ADT Phase III clinical trial in November 2007. In February 2008, we announced that the results of the Phase III clinical trial showed that toremifene 80 mg reduced new morphometric vertebral fractures, met other key estrogen deficiency endpoints of BMD, lipid profiles and gynecomastia, and also demonstrated a reduction in hot flashes in a subset of patients. 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, toremifene 80 mg demonstrated a 50% reduction in new morphometric vertebral fractures. In an intent to treat analysis, which included all patients randomized into the trial and who received a minimum of one dose of study drug, toremifene 80 mg demonstrated a 54% reduction in new morphometric vertebral fractures. In prespecified subset analyses, in study patients who were greater than 80% treatment compliant, toremifene 80 mg reduced new morphometric vertebral fractures by 61%. When study patients who had greater than 7% bone loss at one year and new morphometric vertebral fractures were considered as treatment failures, toremifene 80 mg compared to placebo demonstrated a 56% reduction.

Patients treated with toremifene 80 mg compared to placebo demonstrated statistically significant increases in BMD in the lumbar spine, hip, and femur skeletal sites (each site demonstrating $p<0.0001$). Toremifene 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 toremifene 80 mg Phase III clinical trial experiencing six or more hot flashes per day at baseline and not being treated with megestrol acetate (Megace®), toremifene 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 toremifene 80 mg was durable for at least 12 months.

Toremifene 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 6.2%), back pain (treated 6.0%, 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 (2.6%) in the toremifene 80 mg treated group and 7 (1.1%) in the placebo group. The risk for VTE's was similar between the toremifene 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 greater than 80 years, history of VTEs, recent surgical procedure or immobilization). In men without major risk factors for VTE, there were 5 VTEs in the toremifene 80 mg treated group and 3 VTEs in the placebo group.

As part of our effort to complete the requirements for the submission of applications for regulatory approval of toremifene 80 mg, we have conducted a number of studies of toremifene in addition to our clinical trials, including a Thorough QT study, a bioequivalence study and a series of drug-drug interaction studies. The results of the Thorough QT study of 250 healthy male volunteers, with 5 parallel cohorts receiving 20 mg, 80 mg or 300 mg doses of toremifene, moxifloxacin, or placebo, showed that toremifene prolonged the QT interval in a dose dependent manner. The mean change in QTcB (a measurement of QT interval corrected by Bazett's formula) from baseline relative to placebo for toremifene 20 mg was 5.79 milliseconds, for toremifene 80 mg, it was 22.43 milliseconds, and for moxifloxacin, it was 8.83 milliseconds. Since we market FARESTON® in the United States under a license agreement with Orion, we notified the FDA of the Thorough QT study results and have proposed modifications to the FARESTON® label in the United States. FDA action on the proposed label changes is pending. The study results could lead to the inclusion of restrictions, limitations and/or warnings in the label of FARESTON or an approved product candidate, which may adversely affect the marketability of the product or limit the patients to whom the product is prescribed. Separately, Orion recommended label changes to the EMA. In January 2009, the EMA recommended that the FARESTON® label within the European Union reflect that toremifene should not be given to patients at risk of prolonged QT intervals or other certain heart problems. Our Thorough QT study was designed to better understand the risk of Torsades de Pointes, or Torsades, a rare and potentially fatal arrhythmia. The degree of QT interval prolongation is recognized as an imperfect surrogate marker for the risk of Torsades. Moreover, it is well established that not all medicines which prolong the QT interval will result in Torsades and Torsades can occur in the absence of QT prolongation. The post marketing pharmacovigilance database of approximately 480,000 patient years of use of toremifene at doses up to 240 mg in women, who are more sensitive to develop Torsades than are men, and the extensive clinical development programs in women and now in men, substantiate that there have been no reported cases of Torsades in patients taking toremifene. In our pivotal Phase III clinical trial, there was no increase in adverse events that have been associated with cardiac arrythmia in the toremifene group compared to placebo. The results of these completed studies were included as a part of the NDA submission to the FDA for our toremifene 80 mg product candidate to reduce fractures in men with prostate cancer on ADT and will be included as part of any future NDA submission for our toremifene 80 mg product candidate we make to the FDA if we determine to continue the development of toremifene 80 mg. In addition, the results of these completed studies will be used to update the label for FARESTON®. The study results could lead to the inclusion of restrictions, limitations and/or warnings in the label of FARESTON® or an approved toremifene 80 mg product candidate, which may adversely affect the marketability of the product or limit the patients to whom the product is prescribed.

NDA Filing; Clinical Development. In December 2008, we submitted a NDA for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT. In October 2009, we received a Complete Response Letter from the FDA regarding our NDA for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT, notifying us that the FDA would not approve our NDA in its present form as a result of certain clinical deficiencies identified in the Complete Response Letter. The FDA identified two deficiencies in the Complete Response Letter and recommended that the following information be provided to the FDA to address these clinical deficiencies: (i) results of a second adequate and well-controlled Phase III clinical trial demonstrating the safety and efficacy of toremifene 80 mg to reduce fractures in men with prostate cancer on ADT and (ii) results from an adequate and well-controlled clinical trial demonstrating that toremifene 80 mg treatment to reduce fractures in men with prostate cancer on ADT does

not have a detrimental effect on either time-to-disease progression or overall survival. We met with the FDA in December 2009 to better understand our options for addressing the deficiencies identified by the FDA in the Complete Response Letter. In April 2010, we submitted a proposed protocol to the FDA for a second pivotal Phase III clinical trial evaluating toremifene 80 mg to reduce fractures in men with prostate cancer on ADT to address in a single clinical trial the deficiencies identified by the FDA in the Complete Response Letter. Based on our discussions with the FDA to date, we believe that we have finalized the protocol for a second pivotal Phase III clinical trial. We are currently in discussions with the FDA about whether such second pivotal Phase III clinical trial can be conducted as a post-approval study. In some cases, the FDA may give conditional approval of an NDA for a product candidate on the NDA sponsor's agreement to conduct additional clinical trials to further assess the product's safety and effectiveness after NDA approval. If we determine to continue its development, any approval of our NDA for toremifene 80 mg by the FDA conditioned on our completing such additional Phase III clinical trial may require us to discontinue further marketing of the product if data from the clinical trial fails to demonstrate sufficient efficacy and safety in accordance with the agreed-upon protocol. However, pending our ongoing discussions with the FDA regarding whether such second Phase III clinical trial of toremifene 80 mg to address the deficiencies identified in the Complete Response Letter can be conducted as a post-approval study, we do not plan to continue any further clinical development of toremifene 80 mg. In the event that the FDA allows this clinical trial to be conducted as a post-approval study and we are able to secure sufficient funding for the study through new partnerships or collaborations or through other financing, we will reevaluate whether to continue the development of toremifene 80 mg. In the event the FDA does not permit such second pivotal Phase III clinical trial to be conducted as a post-approval study, we will likely determine to cease further development of our toremifene program.

Drug Discovery and Other Research and Development

Steroid hormone therapies, which include estrogen and testosterone, have been used to treat humans for many years. Steroid hormones by their nature have 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 as nonsteroidal small molecules that modulate estrogen receptors in a tissue selective way to treat breast cancer (toremifene and tamoxifen) or to treat postmenopausal osteoporosis (raloxifene) in women. We believe that the previous commercial and scientific success of SERMs indicates that it may be possible to design and develop classes of nonsteroidal small molecule drugs to modulate hormone receptors in addition to estrogen receptors.

We have an extensive preclinical pipeline generated from our own discovery program, including estrogen receptor beta agonists and other novel compounds that are currently in preclinical development for the potential treatment of metabolic diseases, ophthalmic diseases, cancer, psoriasis and/or pain.

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, inhibit cancer growth, or treat inflammatory conditions. Our in-house medicinal chemists and scientists provide us with significant discovery and development expertise. Using our capabilities in hormone receptor biology, cancer pharmacology and medicinal chemistry, we are able to target many hormone receptors or other cellular targets and generate compounds that are designed to address important unmet medical needs.

We design and synthesize new compounds based on computer, or *in silico,* models and crystal structures of a molecular target'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 that target the androgen receptor, such as Ostarine™, and the estrogen receptor alpha, such as Capesaris™. We continue to conduct research and development efforts focused on other androgen receptor agonists and antagonists, ER alpha agents, ER beta agents, SERM and SARM compounds, other selective hormone receptor modulator compounds and anticancer agents.

Our Strategy

Our objective is to discover, develop and commercialize small molecules that selectively target hormone pathways for the treatment of cancer and the side effects of anticancer therapy, cancer supportive care, and other serious medical conditions. Key elements of our strategy to achieve this objective are to:

Pursue Clinical Development and Commercialization of SARMs. As a result of the termination of our collaboration with Merck, we reacquired full rights to our SARM program, including Ostarine™. In December 2010, we held an End of Phase II meeting with the FDA to discuss our proposed Phase III clinical development of Ostarine™ for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer. We expect to initiate a pivotal Phase III clinical trial for this indication in the third quarter of 2011, following additional input from the FDA. We also intend to continue our pursuit of a strategic partnership or collaboration for the development and commercialization of SARMs, which includes Ostarine™ for the prevention and treatment of muscle wasting in patients with cancer, as well as other indications.

Pursue Clinical Development and Commercialization of Capesaris™. GTx is developing Capesaris™ as a first line treatment for advanced prostate cancer. In September 2010, we announced that in a Phase II, open label, pharmacokinetic and pharmacodynamic clinical trial in young healthy male volunteers, Capesaris™ suppressed serum total testosterone to castrate levels, increased serum SHBG, and reduced serum free testosterone, the form of testosterone which is available to prostate cancer cells for growth. In the second quarter of 2011, we plan to initiate a Phase IIb open label clinical trial evaluating Capesaris™ compared to Lupron® (leuprolide acetate), a LHRH agonist for first line treatment of men with advanced prostate cancer. We are also currently seeking a strategic partnership or collaboration for the development and commercialization of Capesaris™ for the treatment of advanced prostate cancer.

Continue Discussions Regarding the Regulatory Pathway for Toremifene 80 mg. In October 2009, we received a Complete Response Letter from the FDA regarding our NDA for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT, notifying us that the FDA would not approve our NDA in its present form as a result of certain clinical deficiencies identified in the Complete Response Letter. In 2010, with input from the FDA, we developed a protocol for a second pivotal Phase III clinical trial evaluating toremifene 80 mg to reduce fractures in men with prostate cancer on ADT which we believe will address in a single clinical trial the deficiencies identified by the FDA in the Complete Response Letter. In March 2011, we reacquired full rights to our toremifene program due to the termination of our collaboration and license agreement with Ipsen. Pending our ongoing discussions with the FDA regarding whether an additional single Phase III clinical trial of toremifene 80 mg to address the deficiencies identified in the Complete Response Letter can be conducted as a post-approval study, we do not plan to continue any further clinical development of toremifene 80 mg. In the event that the FDA allows this clinical trial to be conducted as a post-approval study and we are able to secure sufficient funding for the study through new partnerships or collaborations or through other financing, we will reevaluate whether to continue the development of toremifene 80 mg.

Build Upon Our Other Drug Discovery Capabilities to Sustain Our Small Molecule Product Candidate Pipeline. While our clinical development efforts to date have focused on selective hormone receptor modulator technologies, we have the capability to discover and develop additional drug candidates for other important disease targets. We intend to develop new molecules to treat diseases that affect large numbers of patients and are underserved by available alternatives or for which there are no current alternatives.

Increase Commercial Sales of FARESTON®. We market FARESTON® for the treatment of advanced metastatic breast cancer in postmenopausal women in the United States. Our strategy is to increase commercial sales of FARESTON®. However, sales of pharmaceuticals for breast cancer in the SERM class have declined in recent years as competitors have gained market share.

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. Our most significant license and collaboration relationships are as follows:

Orion Corporation

In March 2000, we entered into a license and supply agreement with Orion to develop and commercialize products containing toremifene. 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 in January 2005 with Orion which replaced the original license agreement. We paid Orion approximately $5.2 million under these 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 for all human indications worldwide, except breast cancer outside of the United States. We are required to pay Orion a portion of certain types of upfront and milestone income that we receive from third-party sublicensees, after we recover our clinical development costs, and a royalty in the low-teens 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 in the low-teens on sales by us, our affiliates and third-party sublicensees of other toremifene-based products, including toremifene 80 mg if approved for commercial sale. If a toremifene-based product is approved for commercial sale in the United States to reduce fractures in men with prostate cancer on ADT, we have agreed to achieve specified minimum sales requirements in the United States after commercialization or we must pay Orion royalties in the low-teens based on the portion of the minimum sales requirements that have not been met. In addition, we are required to pay up to $1.0 million if we are acquired before receiving marketing approval for the use of toremifene to reduce fractures in men with prostate cancer on ADT.

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 toremifene globally and FARESTON® in the United States. Orion has the right to terminate its supply obligations at its election at any time as a result of our failure to obtain regulatory approval of one of our toremifene product candidates in the United States prior to December 31, 2009, in which event we will have the right to enter into a contract manufacturing agreement with another supplier for toremifene-based products. However, any arrangements we make for an alternative supply would have to be made with a qualified alternative supplier with appropriate FDA approval in order for us to obtain our supply requirements for toremifene. 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 processes or the methods of use of toremifene for prostate cancer or the end of all marketing or regulatory exclusivity which we may obtain for toremifene-based products. The term of our issued method of use patents in United States related to toremifene 80 mg for the treatment of osteoporosis and the reduction of fractures of ADT in men with prostate cancer will expire in 2023. The term of our issued method of use patents outside of the United States related to toremifene 80 mg for the treatment of osteoporosis and the reduction of fractures of ADT in men with prostate cancer will expire in 2022. Orion may terminate the amended and restated license and supply agreement, on a country-by-country basis, as a result of our uncured material breach, including under certain circumstances if we decided not to commercially launch toremifene in any major country after we obtain regulatory approval in such country, or our bankruptcy. Following the termination of the amended and restated license and supply agreement by Orion for our material breach, we will grant a royalty-bearing license to Orion to enable Orion to continue the development and commercialization of toremifene-based products in the countries in which the agreement is terminated.

University of Tennessee Research Foundation

In July 2007, we and UTRF entered into a consolidated, amended and restated license agreement, or the SARM 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 the SARM License 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 the SARM License Agreement will continue, on a country-by-country basis, 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 SARM License Agreement for our uncured breach or upon our bankruptcy.

In September 2007, we and UTRF entered into an amended and restated license agreement, or the SERM License Agreement, to replace our previously existing exclusive worldwide license agreement for toremifene. Pursuant to the SERM License Agreement, we were granted exclusive worldwide rights to UTRF's method of use patents relating to SERMs, including toremifene 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 the SERM License Agreement will continue, on a country-by-country basis, 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 toremifene or until the expiration of the last valid claim of any licensed patent in such country. UTRF may terminate the SERM License Agreement for our uncured breach or upon our bankruptcy.

Under the SARM License Agreement and the SERM License Agreement, or together, the UTRF License Agreements, we paid UTRF a one-time, upfront fee of $290,000 per UTRF License Agreement as consideration for entering into the UTRF License Agreements. We are also obligated to pay UTRF annual license maintenance fees, low single digit royalties on net sales of products and mid single digit royalties on sublicense revenues. During the year ended December 31, 2007, we paid UTRF a sublicense royalty of approximately $1.9 million as a result of our previous collaboration with Merck. 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.

In December 2008, we and UTRF amended the UTRF License Agreements, or together, the License Amendments, to, among other things, clarify the treatment of certain payments that we may receive from our current and future sublicensees for purposes of determining sublicense fees payable to UTRF, including the treatment of payments made to us in exchange for the sale of our securities in connection with sublicensing arrangements. In consideration for the execution of the License Amendments, we paid UTRF an aggregate of $540,000.

Ipsen

In September 2006, we entered into a collaboration and license agreement with Ipsen, or the Ipsen Collaboration Agreement, pursuant to which we granted Ipsen exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein, and the Commonwealth of Independent States, collectively referred to as the European Territory, to develop and commercialize toremifene in all indications which we have 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 Ipsen Collaboration Agreement, Ipsen agreed to pay us €23.0 million as a license fee and expense reimbursement, of which €1.5 million was paid in equal installments over a three year period from the date of the Ipsen Collaboration Agreement. In October 2006, we received €21.5 million (approximately $27.1 million) from Ipsen as the initial payment for the license fee and expense reimbursement. In September 2009, 2008, and 2007, we received €500,000 (approximately $726,000, $711,000, and $688,000, respectively) from Ipsen for the three annual installment payments. In February 2008, we earned a milestone of €1.0 million (approximately $1.5 million) with the achievement of the primary endpoint in the toremifene 80 mg ADT Phase III clinical trial.

In March 2010, we amended the Ipsen Collaboration Agreement primarily to expand our collaboration for the development and commercialization of toremifene 80 mg to reduce fractures in men with prostate cancer on ADT and to potentially fund a second pivotal Phase III clinical trial of toremifene 80 mg. In accordance with the terms of this amended agreement, Ipsen agreed to pay us up to €42.0 million in clinical development milestones for the purpose of conducting a second pivotal Phase III clinical trial evaluating toremifene 80 mg to reduce fractures in men with prostate cancer on ADT. However, the amended agreement provided that if the projected third-party costs of such second pivotal Phase III clinical trial of toremifene 80 mg exceed €42.0 million by a certain percentage, then we and Ipsen agreed to discuss whether to initiate such trial or to renegotiate the terms of the our agreement.

In exchange for Ipsen's commitment to fund a second toremifene 80 mg ADT Phase III clinical trial, we granted Ipsen certain additional rights, including an expansion of the territory in which Ipsen had the right to develop and commercialize toremifene beyond the European Territory to include Australia and certain countries in North Africa, the Middle East and Asia (excluding Japan), collectively, the Ipsen Territory. In addition, Ipsen received the right to co-promote our toremifene 80 mg product candidate for the ADT indication in the United States or, at Ipsen's election in lieu of co-promotion, the right to receive a declining, tiered royalty on net sales of our toremifene 80 mg product candidate for the ADT indication in the United States, starting at approximately one-third of net sales. We also granted Ipsen the right of first negotiation, subject to certain conditions, with respect to development, marketing, sale and distribution in the Ipsen Territory of Capesaris™. Ipsen also agreed to pay us a royalty at a fixed percentage (12%) of aggregate net sales in the Ipsen Territory of our toremifene 80 mg product candidate for the ADT indication.

In March 2011, we reacquired full rights to our toremifene program following the termination by us and Ipsen of our collaboration and license agreement. In exchange for reacquiring all of Ipsen's rights under the collaboration agreement, we agreed to pay Ipsen a low single digit royalty on net sales of toremifene 80 mg in the United States if approved for commercial sale. As a result of the termination of the collaboration agreement, we will not receive any further payments or any royalties from Ipsen provided for under the collaboration agreement.

Merck & Co., Inc.

In December 2007, we entered into a global exclusive license and collaboration agreement, or the Merck Collaboration Agreement, governing our and Merck's joint research, development and commercialization of SARM compounds and related SARM products. In March 2010, following Merck's determination to discontinue internal development of Ostarine™ (previously designated by Merck as MK-2866), we and Merck mutually agreed to terminate our collaboration and, as a result, we reacquired full rights to our SARM program, including Ostarine™.

Under the Merck Collaboration Agreement, we granted Merck an exclusive worldwide license under our SARM-related patents and know-how. In connection with entering into the Merck Collaboration Agreement, Merck paid us an upfront licensing fee of $40.0 million and purchased approximately $30.0 million of our common stock. In addition, Merck 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 Merck Collaboration Agreement. We received $5.0 million from Merck in December 2010, 2009 and 2008 as the three annual payments of cost reimbursements for research and development activities.

Manufacturing

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.

We have agreed to purchase from Orion our worldwide requirements of toremifene in a finished tablet form at specified prices under a license and supply agreement. As such, we rely on Orion as the single source supplier of toremifene. 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 tablets 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 at its election at any time. There are a number of circumstances in which Orion is required to grant manufacturing rights to us, including following termination of its supply obligation, 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 would need to make arrangements for an alternative supply which would have to be made by a qualified alternative supplier with the appropriate FDA approval in order for us to obtain our supply requirements for toremifene. In addition, Orion may terminate its obligation to supply us with toremifene if we are in material breach of our supply agreement with Orion, or in connection with certain bankruptcy events involving us. If Orion elects to terminate its obligation to manufacture and supply us with toremifene, any arrangements we make for an alternative supply would have to be have to be made with a qualified alternative supplier with appropriate FDA approval in order for us to obtain our supply requirements for toremifene. In addition, although Orion's composition of matter patents have expired, and as such, we would not be prevented from manufacturing toremifene, there is no obligation on the part of Orion to transfer its manufacturing technology to us or to assist us in developing manufacturing capabilities to meet our supply needs.

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 for each step. Ostarine™ drug product is manufactured using conventional manufacturing technology without the use of novel excipients. Initially, we relied on third party vendors for the manufacture of Ostarine™ drug substance and drug product. During the term of our collaboration with Merck, Merck assumed primary manufacturing responsibilities for Ostarine™ and other SARM products developed under our collaboration. In connection with the termination of our collaboration, Merck returned to us all remaining inventory of Ostarine™ drug substance and drug product. We have reestablished relationships with third party vendors and will continue to rely on them for drug substance and drug product manufacturing.

There are no complicated chemistries or unusual equipment required in the manufacturing process for Capesaris™. The active ingredient in Capesaris™ is manufactured using a three-step synthetic process that uses commercially available starting materials for each step. Capesaris™ drug product is manufactured using conventional manufacturing technology without the use of novel excipients. We rely on third party vendors for the manufacture of Capesaris™ drug substance and drug product manufacturing.

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, 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. 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.

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 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. 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.

SARMs for the Treatment of Muscle Wasting in Patients with Cancer

There are currently no drugs that have been approved by the FDA for the prevention or treatment of muscle wasting in patients with cancer. Although there are two commercially available drugs, nandrolone and oxandrolone, both oral steroids, that are being prescribed off-label for the treatment of some types of weight loss in patients with chronic illnesses, chronic use of these drugs may result in bleeding liver cysts and liver cell tumors. 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 weight loss in patients with cancer. Oxandrolone has a black box warning for liver toxicity and has warnings and precautions related to increasing the risk for prostate cancer in men and virilization in women.

Testosterone products have been used off-label to treat secondary hypogonadism. Owing to their 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 loss. There are other SARM product candidates in development that may compete with our SARM product candidates if approved including SARMs in development from Ligand Pharmaceuticals Inc., GlaxoSmithKline, and Merck. Pfizer Inc., Eli Lilly & Co., and Amgen have myostatin inhibitors in development that may compete with Ostarine™ if approved for commercial sale. In addition, Cytokinetics, Inc. is developing a troponin activator with a muscle specific mechanism in Phase II studies with a focus on neurological muscle diseases (amyotrophic lateral sclerosis and myasthenia gravis). Moreover, there are other categories of drugs in development, including ghrelin receptor agonists and growth hormone secretagogues, that may have some muscle building activity. Other appetite stimulants such as megestrol acetate and dronabinol are also used off-label for weight loss and loss of appetite in patients with cancer.

Capesaris™ for First Line Treatment of Advanced Prostate Cancer

Androgen deprivation therapy, results in a castrate level of serum total testosterone by reducing LH secretion by the pituitary and is the primary treatment for advanced prostate cancer. Several major pharmaceutical companies market an ADT product and they have been very competitive in defending their business. Leuprolide (Lupron® marketed by Abbott Laboratories) and goserelin (Zoladex® marketed by Astra-Zeneca) are the leading molecules of ADT and both are LHRH agonists. Manufacturers have patented new formulations (Eligard® marked by Sanofi-Aventis and QLT, Inc.) or extended release formulations which have extended their brand's life (Lupron® marketed by Abbott Laboratories). Histerlin an implant marketed as Vantas® (Endo Pharmaceuticals) is a one year LHRH agonist implant. Triptorelin marketed as Trelstar® (Watson Pharmaceuticals) and marketed as Decapeptyl (Ipsen) is also a LHRH agonist. Degarelix marketed as Firmagon® (Ferring Pharmaceuticals) is a LHRH antagonist. All existing ADT are injectables and have potential estrogen deficiency side effects (hot flashes, bone loss and fractures, increase in body fat composition, loss of libido, impaired cognition and adverse lipid changes) and are viewed as having similar efficacy. There are no known late stage non-LHRH agonist and antagonist products in development for ADT. Most of the new prostate cancer agents in product pipelines that we are aware of are for castrate resistant prostate cancer that have failed ADT and would be used in combination with ADT, and we therefore do not consider these pipeline candidates to be potential competitors for Capesaris™.

Toremifene 80 mg to Reduce Fractures and Treat Other Estrogen Deficiency Side Effects of ADT in Men with Prostate Cancer

We have evaluated toremifene 80 mg for the reduction of fractures and treatment of other estrogen deficiency side effects of ADT. Although there are no products that have been approved by the FDA to reduce fractures or treat estrogen deficiency related side effects of ADT, we are aware of a number of drugs, including drugs marketed by Eli Lilly & Co. (Evista®), Merck (Fosamax®), Sanofi-Aventis and Warner Chilcott (Actonel®), Pfizer Inc. (Effexor®), Boehringer Ingelheim (Catapres®), Novartis (Zometa®) and generic megestrol acetate, that are prescribed to treat single side effects of ADT; that external beam radiation and tamoxifen are used to treat breast pain and enlargement, or gynecomastia. Xgeva™ (denosumab) a monoclonal antibody developed by Amgen is marketed in the United States for the prevention of skeletal related events in patients with bone metastases from solid tumors. Xgeva™ was also studied in a placebo controlled Phase III trial among men with castrate resistant Stage III prostate cancer with rapidly-rising PSA levels who had no bone metastases at baseline. Xgeva™ significantly improved median bone metastasis-free survival by 4.2 months. Denosumab is also marketed as Prolia™ in a different strength and dosing regimen and is approved in the United States, Europe and Australia for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. Additionally, Prolia™ is marketed in Europe for the treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures and may pursue other cancer specific indications, including prostate cancer, in the United States.

Sales and Marketing

We market FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of advanced metastatic breast cancer in postmenopausal women in the United States. 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.

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 Ostarine™ and our other SARMs, we have an exclusive license from UTRF under its issued patents and pending patent applications in the United States, Canada, Australia, Japan, China and other countries in Asia, before the European Patent Office designating Germany, Great Britain, Spain, France, Italy, and other European Union countries, as well as in certain other countries outside those regions, covering the composition of matter of the active pharmaceutical ingredient for pharmaceutical products, pharmaceutical compositions and methods of synthesizing the active pharmaceutical ingredients. We have also exclusively licensed from UTRF issued and pending patent applications in the United States, Canada, Australia, Japan, China and other countries in Asia, before the European Patent Office designating Germany, Great Britain, Spain, France, Italy and other European Union countries, as well as in certain other countries outside those regions, related to methods for building muscle mass and bone in patients, for treating bone related disorders, including bone frailty and osteoporosis, and for treating muscle wasting disorders, including cancer cachexia, using Ostarine™ and other SARMs. The patents we licensed from UTRF and issued in the United States for Ostarine™ expire in 2024 and the issued patents for our other SARMs in the United States will expire between 2021 and 2024. The patents we licensed from UTRF and issued outside of the United States for Ostarine™ expire in 2025, and with respect to other SARM compounds, expire between 2021 and 2023. We have pending patent applications for Ostarine™ and our other SARMs that will expire in the United States and is countries outside the United States between 2025 and 2027.

We have our own pending applications, but no issued patents, in the United States, Australia, Canada, before the European Patent office designating Germany, Great Britain, Spain, France, Italy and other European Union countries, Japan, and other jurisdictions internationally covering Capesaris™ (GTx-758) as the composition of matter of the active pharmaceutical ingredient products developed with this compound and for pharmaceutical compositions and/or methods of treating advanced prostate cancer, building muscle mass and bone in patients, and treating androgen-deprivation induced bone disorders in men having prostate cancer. If patents are issued from our pending patent applications covering Capesaris™, they will expire in late 2026 both in the United States and in those countries where the applications are pending outside of the United States.

For toremifene 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 for all uses in humans in the United States, and for all human uses outside the United States other than the treatment and prevention of breast cancer. However, Orion's patent for toremifene expired in the United States in September 2009 and foreign counterparts of this patent also have expired. As a result, we will need to rely primarily on the protection afforded by the method of use patents that either have been already issued or may later issue from our owned or licensed patent applications.

We have licensed from UTRF method of use patents and pending patent applications for specific disease indications and doses in the United States, and have licensed issued and pending patent applications in Canada, Australia, Japan, China, and other countries in Asia, and before the European Patent Office designating Germany, Great Britain, Spain, France, Italy and other European Union countries, as well as in certain other countries outside those regions, related to the use of toremifene 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 toremifene for this indication that we licensed from UTRF will expire in 2019. The method of use patents that we licensed from UTRF related to the use of toremifene for this indication and issued outside of the United States will expire between 2019 and 2020.

We have our own method of use patents and patent applications in the United States, Australia, and Canada, and pending patent applications in Japan, and before the European Patent Office designating Germany, Great Britain, Spain, France, Italy and other European Union countries, as well as pending patent applications in certain other countries outside those regions, related to the use of toremifene 80 mg for the treatment of osteoporosis and reduction of fractures in men with prostate cancer treated by ADT and other side effects from ADT such as bone loss and hot flashes. Our method of use patents issued in the United States related to the use of toremifene for the treatment of ADT-induced osteoporosis and fractures in men with prostate cancer will expire in 2023. Our method of use patents issued outside of the United States related to the use of toremifene 80 mg for the treatment of osteoporosis and fractures and other side effects of ADT in men with prostate cancer will expire in 2022. We own pending patent applications in the United States, Canada, Japan and other countries in Asia, and pending patent applications before the European Patent Office designating Germany, Great Britain, Spain, France, Italy and other European Union countries, as well as pending patent applications in certain other countries outside those regions, related to the method of use of toremifene 80 mg for the treatment of ADT-induced osteoporosis and fractures in men with prostate cancer that, if issued, would expire in 2022.

Even though patents have issued in respect of our owned and licensed pending method of use patent applications, since patents covering the composition of matter of toremifene have expired, 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 toremifene covered by our issued and pending method of use patent applications, and individual physicians would be permitted to prescribe generic versions of toremifene 60 mg for indications that are protected by our or our licensors' method of use patents and pending patent applications. Assuming toremifene receives appropriate marketing approval, if patents do not issue in particular countries on account of our pending method of use patent applications related to the use of toremifene 80 mg for the treatment of osteoporosis and fractures and other side effects of ADT in men with prostate cancer, competitors may be able to market and sell generic versions of toremifene tablets for these indications in that country.

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 us 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 a "complete response" letter at the end of the review period. A "complete response" letter will be issued to let a company know that the review period for a drug is complete and that the application is not yet ready for approval. The letter will describe specific deficiencies and, when possible, will outline recommended actions the applicant might take to get the application ready for approval.

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. For example, we are in discussions with FDA about whether an additional Phase III clinical study of toremifene 80 mg to address the deficiencies identified in the FDA's Complete Response Letter can be conducted as a post-marketing study. 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 authority gained pursuant to the Food and Drug Administration Amendments Act of 2007, or FDAAA, 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 regulatory tool for the FDA that became effective in March 2008, and the agency applies this tool on a case-by-case assessment as to whether a REMS is needed. Since the effective date, the FDA has not used its REMS enforcement authority for every product approval, but it has exercised this authority on a regular basis, and it is anticipated the agency will continue to do so going forward. 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. Whether a REMS would be imposed on a product and any resulting financial impact is 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, and any use of the drug for which marketing approval is sought could not violate another NDA holder's patent claims.

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 assuming the approval would not violate another NDA holder's patent claims. 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.

If a competitor submits an ANDA or 505(b)(2) NDA for a compound or use of any compound covered by another NDA holder's patent claims, the Hatch-Waxman Act requires, in some circumstances, the applicant 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 or have received 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. In March 2010, the United States Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act which includes changes to the coverage and reimbursement of drug products under government health care programs. The changes, implemented in 2010 and thereafter, include the following: (1) increasing drug rebates under state Medicaid programs for brand name prescription drugs and extending those rebates to Medicaid managed care; (2) extending discounted rates on drug products available under the Public Health Service 340 programs to additional hospitals and other providers; (3) assessing a fee on manufacturers and importers of brand name prescription drugs reimbursed under certain government programs, including Medicare and Medicaid; and (4) requiring drug manufacturers to provide a 50% discount on brand name prescription drugs sold to Medicare beneficiaries whose prescription drug costs cause the beneficiaries to be subject to the Medicare Part D coverage gap (i.e., the so-called "donut hole"). Adoption of other new legislation at the federal or state level could further limit reimbursement for pharmaceuticals.

The marketability of any products for which we receive or have received 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 advanced metastatic breast cancer, is eligible for coverage and reimbursement by most third-party payors.

Research and Development

Since our inception in 1997, we have been focused on drug discovery and development programs. Research and development expenses include, but are not limited to, 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 and medical affairs activities, quality assurance activities and license fees. Our research and development expenses were $28.5 million for the year ended December 31, 2010, $32.3 million for the year ended December 31, 2009, and $44.3 million for the year ended December 31, 2008.

Employees

As of December 31, 2010, we had 111 employees, 33 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 electronically with the U.S. Securities and Exchange Commission, or SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. We make available on our Web site at www.gtxinc.com, free of charge, copies of these reports as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Further, copies of these reports are located at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains a Web site that contains reports, proxy statements, and other information regarding our filings at www.sec.gov. 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.

Management

The following table sets forth information about our executive officers and other key medical, clinical and regulatory officers as of March 3, 2011.

Name	Age	Position(s)
Executive Officers		
Mitchell S. Steiner, M.D., F.A.C.S.	50	Chief Executive Officer and Vice Chairman of the Board of Directors
Marc S. Hanover	48	President, Chief Operating Officer and Director
James T. Dalton, Ph.D.	48	Vice President, Chief Scientific Officer
Ronald A. Morton, Jr., M.D., F.A.C.S.	52	Vice President, Chief Medical Officer
Henry P. Doggrell	62	Vice President, General Counsel and Secretary
Mark E. Mosteller	48	Vice President, Chief Financial Officer
Gregory A. Deener	49	Vice President, Sales and Marketing
Other Key Medical, Clinical and Regulatory Officers		
K. Gary Barnette, Ph.D.	43	Vice President, Clinical Research and Development Strategy
Shontelle Dodson, Pharm. D.	40	Vice President, Medical Affairs
Jeffrey G. Hesselberg	52	Vice President, Regulatory Affairs
Domingo Rodriguez, M.D.	49	Vice President, Clinical Operations

Executive Officers

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.

James T. Dalton, Ph.D., was appointed Vice President, Chief Scientific Officer on January 1, 2011, and prior to that he 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.

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 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 and Chief Operating Officer of Union Planters Mortgage. 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 by Ernst & Young LLP. Mr. Mosteller is a Certified Public Accountant and holds a B.S. in Accounting from the University of Tennessee.

Gregory A. Deener was appointed Vice President, Sales and Marketing on January 20, 2005, and prior to that he served as our Director of Marketing and Sales since February 2004. Mr. Deener has over 25 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.

Other Key Medical, Clinical and Regulatory Officers

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 to May 2007. From 1998 to 2001, Dr. Barnette was Assistant Director and then Director, Regulatory Affairs at Solvay Pharmaceuticals, Inc. From 1995 to 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.

Shontelle Dodson, Pharm.D., was appointed Vice President, Medical Affairs in 2008. Dr. Dodson has over 15 years of pharmaceutical experience, most recently at Pfizer, Inc., where she served as Senior Director and Group Leader, Global Medical, heading up the field-based medical organization. She also served as Director, Team Leader, US Medical, leading the Viagra® and Revatio® medical teams and the US field-based medical effort supporting the company's urology and respiratory medicines with total product sales exceeding $5 billion. Dr. Dodson holds a Doctor of Pharmacy degree from Mercer University Southern School of Pharmacy and completed a postdoctoral residency at the Department of Veterans Affairs Medical Center in Nashville.

Jeffrey G. Hesselberg was appointed Vice President, Regulatory Affairs in May 2007. He joined GTx from ICOS Corporation, where from 1996 to May 2007 he served as Manager, Associate Director, and then Director of Regulatory Affairs. 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.

Domingo Rodriguez, M.D., was appointed Vice President of Clinical Operations in May 2008. Prior to his appointment, Dr. Rodriguez was the Director of Clinical Operations since October 2005. Dr. Rodriguez joined GTx, Inc. in November 2004 as a Regional Medical Scientist. From 2001 to 2004, Dr. Rodríguez served as a Medical Director, Medical Science Liaison and District Sales Manager for ICOS Corporation. He began his career in 1987 with Bristol Myers Squibb and for almost 14 years served in various roles in medical affairs, sales and sales training and management. Dr. Rodriguez completed medical school in the Dominican Republic.

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 Condition and Need for Additional Financing

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

We have a limited operating history. As of December 31, 2010, we had an accumulated deficit of $352.9 million. Due to the recognition of the remaining $49.9 million of unamortized revenue from our exclusive license and collaboration agreement with Merck & Co., Inc., or Merck, we reported net income of $15.3 million for the year ended December 31, 2010. However, we have incurred losses in each year since our inception in 1997, including net losses of $46.3 million and $51.8 million in 2009 and 2008, respectively. We expect to incur significant operating losses in 2011 and for the foreseeable future as we continue our clinical development and research and development activities. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

In October 2009, we received a Complete Response Letter from the U.S. Food and Drug Administration, or FDA, regarding our New Drug Application, or NDA, for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT notifying us that the FDA would not approve our NDA in its present form as a result of certain clinical deficiencies identified in the Complete Response Letter. As a result, FDA approval of toremifene 80 mg, if it occurs, will be substantially delayed. In addition, significant additional clinical development is required in order to potentially obtain FDA approval of toremifene 80 mg, including a second pivotal Phase III clinical trial of toremifene 80 mg. Although we believe that we have finalized the protocol for a second pivotal Phase III clinical trial evaluating toremifene 80 mg to reduce fractures in men with prostate cancer on ADT to address in a single clinical trial the deficiencies identified by the FDA in the Complete Response Letter, we do not plan to continue any further clinical development of toremifene 80 mg, including the initiation of a second pivotal Phase III clinical trial, pending our ongoing discussions with the FDA regarding whether such second pivotal Phase III clinical trial can be conducted as a post-approval study. In the event the FDA does not permit such second pivotal Phase III clinical trial to be conducted as a post-approval study or if we are unable to enter into one or more new collaborations with third parties for toremifene 80 mg or otherwise obtain sufficient funding, we will likely determine to cease further development of our toremifene program and we will not receive any return on our investment in our toremifene 80 mg product candidate. There can be no assurance the FDA will approve the marketing of toremifene 80 mg conditioned on our conducting a post-approval study or that we will be successful in obtaining the funding sufficient to enable the continued development of toremifene 80 mg. Each of our other product candidates are in earlier-stage clinical development, and significant additional clinical development and financial resources will be required to obtain necessary regulatory approvals for our other product candidates, including Ostarine™ (GTx-024) and Capesaris™ (GTx-758) and to develop them into commercially viable products. Accordingly, we do not expect to obtain FDA or any other regulatory approvals to market any of our product candidates in the near future, if at all.

Because of the numerous risks and uncertainties associated with developing and commercializing small molecule drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. We have financed our operations and internal growth primarily through public offerings and private placement of our common stock, as well as payments from our former collaborators, including Merck and Ipsen Biopharm Limited, or Ipsen. In March 2010, we and Merck agreed to terminate our collaboration and, as a result, we will not receive any milestone payments or royalties for the development or sale of selective androgen receptor modulators, or SARMs, from Merck. Likewise, in March 2011, we and Ipsen agreed to terminate our collaboration and, as a result, we will not receive any milestone payments or royalties for the development or sale of toremifene, including any clinical development milestones or any other funding from Ipsen for the purpose of conducting any further clinical development of toremifene 80 mg. FARESTON® is currently our only commercial product and, until such time that we receive regulatory approval to market any of our product candidates, if ever, we expect that FARESTON® will account for all of our product revenue. For the year ended December 31, 2010, we recognized $3.8 million in net revenues from the sale of FARESTON®. If we and/or any potential future collaborators are unable to develop and commercialize any of our product candidates, if development is further delayed or eliminated, or if sales revenue from any product candidate that receives marketing approval is insufficient, we may never become profitable and we will not be successful.

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

We will need to raise substantial additional capital to:

- fund our operations and conduct 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, cash equivalents, and short-term investments, together with interest income and product revenue from the sale of FARESTON®, will be sufficient to meet our projected operating requirements for at least the next twelve months. We have based this estimate on our current business plan and assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect and we could need additional funding sooner than currently anticipated. We believe that our current cash resources, together with interest income and product revenue from the sale of FARESTON®, will be sufficient to enable us to initiate in 2011 our planned Phase III clinical trial of Ostarine™ for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer and to initiate and complete our planned Phase IIb clinical trial to evaluate Capesaris™ for first line treatment of advanced prostate cancer. To complete the Phase III clinical trial we expect to initiate in 2011 for Ostarine™, we may need to obtain additional funding. However to conduct any additional clinical trials for our product candidates, we will need to raise substantial additional capital through partnerships and/or collaborations or the sale of our securities. Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical trials and other research and development activities, including our currently-planned clinical trials of Ostarine™ and Capesaris™;
- the terms and timing of any potential future collaborative, licensing and other arrangements that we may establish;
- whether and to what extent we determine to continue the development of toremifene 80 mg;
- future clinical trial results;
- the cost and timing of regulatory filings and/or approvals to commercialize our product candidates and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- the amount and timing of any licensing fees, milestone payments and royalty payments from potential future collaborators, if any;
- the cost and timing of establishing medical education, sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we and/or any potential future 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 cost of defending any other litigation claims; 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.

We do not currently have any commitments for future external funding and until we can generate a sufficient amount of product revenue, which we may never do, we expect to finance future cash needs through public or private equity offerings, debt financings or collaboration and licensing arrangements, or a combination of the above, as well as through interest income earned on the investment of our cash balances and short-term investments and revenues from the sale of FARESTON®. In December 2009, we announced a reduction of approximately 26% of our workforce in order to reduce our operating expenses in connection with the receipt of the Complete Response Letter regarding our NDA for toremifene 80 mg and the associated delay in the potential regulatory approval of toremifene 80 mg. If we are unable to raise additional funds when we need them, we may need to further reduce our expenditures, perhaps significantly, to preserve our cash. The cost-cutting measures that we may take in the future may not be sufficient to enable us to meet our cash requirements, and they may negatively affect our business and growth prospects.

To the extent we raise additional funds by issuing equity securities, our stockholders may experience dilution, and 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. To the extent we raise additional funds through potential future collaboration and licensing arrangements, it may be necessary to relinquish rights to some of our technologies or product candidates, or grant licenses on terms that are not favorable to us. Our ability to raise additional funds and the terms upon which we are able to raise such funds may be adversely impacted by the uncertainty regarding our ability to fully finance our currently-planned clinical trial of Ostarine™ and additional clinical trials of Ostarine™ and Capesaris™ and/or current economic conditions, including the effects of the disruptions to and continuing volatility in the credit and financial markets in the United States and worldwide. As a result of these and other factors, we cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available when we need them, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs, including our SARM, selective ER alpha agonist, and toremifene programs, or conduct additional workforce or other expense reductions, any of which could have a material adverse effect on our business.

Risks Related to Development of Product Candidates

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

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

In clinical studies, the efficacy and/or safety results from the trial may be insufficient to support the submission or approval of a NDA with the FDA. For example, we received a Complete Response Letter in October 2009 from the FDA regarding our NDA for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT, notifying us that the FDA would not approve our NDA in its present form as a result of certain clinical deficiencies identified in the Complete Response Letter, which deficiencies may only be addressed by conducting an additional pivotal Phase III clinical trial of toremifene 80 mg. In addition, in May 2010, we announced that toremifene 20 mg failed to meet its primary efficacy endpoint in our Phase III clinical trial of toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia, or high grade PIN. As a result, we do not expect to conduct any additional clinical development of toremifene 20 mg for the high grade PIN indication or to submit a NDA to the FDA for this indication.

We or any potential future 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 potential future collaborators' ability to commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us or any potential future 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 any potential future 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 any potential future 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 any potential future 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 business and our financial condition.

If we or any potential future 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 any potential future 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.

Although the results from our completed Phase III clinical trial for toremifene 80 mg to reduce fractures and treat other estrogen deficiency side effects of ADT in men with prostate cancer showed that the drug was well tolerated and had a generally favorable safety profile, more subjects experienced a venous thromboembolic event, or VTE, such as a deep vein thrombosis, pulmonary embolism or heart attack, in the toremifene 80 mg treatment group, 17 (2.6%) compared to 7 (1.1%) in the placebo group. Even though the majority of VTEs recorded in the clinical trial occurred in men who were at high risk for a VTE (including: age greater than 80 years, history of VTEs, recent surgical procedure or immobilization) and data from the clinical trial showed that the number of men without any of these independent risk factors for VTEs in whom a VTE occurred during the clinical trial was 5 in the toremifene 80 mg treatment group versus 3 in the placebo group, the FDA will consider the overall safety profile from our clinical trials when making its determination whether to grant marketing approval and to require potential warnings in the label, if approval is granted.

We have conducted a number of studies of toremifene in addition to our clinical trials, including a Thorough QT study (toremifene 80 mg and toremifene 20 mg), a bioequivalence study (toremifene 80 mg), a series of drug-drug interaction studies (toremifene 80 mg and toremifene 20 mg), and a semen quality study (toremifene 20 mg) to assess the effect of toremifene. The results of the Thorough QT study of 250 healthy male volunteers, with 5 parallel cohorts receiving 20 mg, 80 mg or 300 mg doses of toremifene, moxifloxacin, or placebo, showed that toremifene prolonged the QT interval in a dose dependent manner. The mean change in QTcB (a measurement of QT interval corrected by Bazett's formula) from baseline relative to placebo for toremifene 20 mg was 5.79 milliseconds, for toremifene 80 mg, it was 22.43 milliseconds, and for moxifloxacin, it was 8.83 milliseconds. Since we market FARESTON® in the United States under a license agreement with Orion Corporation, or Orion, we notified the FDA of the Thorough QT study results and have proposed modifications to the FARESTON® label in the United States. FDA action on the proposed label changes is pending. Separately, Orion recommended label changes to the European Medicines Agency, or EMA. In January 2009, the EMA recommended that the FARESTON® label within the European Union reflect that toremifene should not be given to patients at risk of prolonged QT intervals or other certain heart problems. The results of these completed studies were included as a part of the NDA submission to the FDA for our toremifene 80 mg product candidate to reduce fractures in men with prostate cancer on ADT and will be included as part of any future NDA submission for our toremifene 80 mg product candidate we make to the FDA if we determine to continue the development of toremifene 80 mg. In addition, the results of these completed studies will be used to update the label for FARESTON®. The study results could lead to the inclusion of restrictions, limitations and/or warnings in the label of FARESTON® or an approved toremifene 80 mg product candidate, which may adversely affect the marketability of the product or limit the patients to whom the product is prescribed.

In addition, in our Phase II clinical trial for Ostarine™ for the treatment of muscle wasting in patients with cancer, 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.

Capesaris™ is a new chemical entity that is highly selective for estrogen receptor alpha. Although Capesaris™ has been well tolerated in clinical trials conducted to date, increases in the incidence of thromboembolic events or elevations in hepatic enzymes, which are known risk factors associated with approved non-selective estrogenic therapies, will be monitored and may be observed in future clinical studies.

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

- we or any potential future 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 we do not establish collaborations for our product candidates or otherwise raise substantial additional capital, we will likely need to alter our development and any commercialization plans.

Our strategy includes selectively partnering or collaborating with leading pharmaceutical and biotechnology companies to assist us in furthering development and potential commercialization of our product candidates. We face significant competition in seeking appropriate collaborators, and collaborations are complex and time consuming to negotiate and document. We may not be successful in entering into new collaborations with third parties on acceptable terms, or at all, including as a result of any collaboration discussions we chose to pursue for Ostarine™ and Capesaris™. In addition, we are unable to predict when, if ever, we will enter into any additional collaborative arrangements because of the numerous risks and uncertainties associated with establishing such arrangements. If we are unable to negotiate new collaborations, we may have to curtail the development of a particular product candidate, reduce, delay, or terminate its development or one or more of our other development programs, delay its potential commercialization or reduce the scope of our sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. For example, we will likely determine to cease further development of our toremifene program if we are unable to raise sufficient funding for the additional Phase III clinical trial of toremifene 80 mg through a new partnership, collaboration or financing, even if we determine there is a feasible regulatory pathway forward that does not require us to conduct an additional Phase III clinical trial of toremifene 80 mg prior to receiving regulatory approval. If we elect to increase our expenditures to fund development or commercialization activities on our own, we will need to raise substantial additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenues.

Any collaborative arrangements that we establish in the future may not be successful or we may otherwise not realize the anticipated benefits from these collaborations. In addition, any future collaboration 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.

We have in the past established and intend to continue to establish collaborations with third parties to develop and commercialize some of our current and future product candidates, and these collaborations may not be successful or we may otherwise not realize the anticipated benefits from these collaborations. For example, in March 2010, following Merck's determination to discontinue internal development of Ostarine™, we and Merck mutually agreed to terminate our collaboration and, as a result, we will not receive any milestone payments or royalties for the development or sale of SARMs from Merck. Likewise, in March 2011, we and Ipsen mutually agreed to terminate our collaboration and, as a result, we will not receive any milestone payments or royalties for the development or sale of toremifene from Ipsen. As of the date of this report, we have no ongoing collaborations for the development and commercialization of our product candidates. In the future, we may not be able to locate third-party collaborators to develop and market our product candidates, and we may lack the capital and resources necessary to develop our product candidates alone.

Dependence on collaborative arrangements subjects us to a number of risks, including:

- we may not be able to control the amount and timing of resources that our potential future collaborators may devote to our product candidates;
- potential future collaborations may experience financial difficulties or changes in business focus;
- we may be required to relinquish important rights such as marketing and distribution rights;
- should a collaborator fail to develop or commercialize one of our compounds or product candidates, we may not receive any future milestone payments and will not receive any royalties for 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, such as our former collaborations with Ipsen and Merck, which could delay the development and may increase the cost of developing our product candidates.

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, if any, and our ability to develop product candidates and commercialize any product candidates on a timely and competitive basis.

We have agreed to purchase from Orion our worldwide requirements of toremifene in a finished tablet form at specified prices under a license and supply agreement. Orion may terminate its supply obligations at its election at any time as a result of our failure to obtain regulatory approval of one of our toremifene product candidates in the United States prior to December 31, 2009. If Orion elects to terminate its obligation to manufacture and supply us with toremifene, any arrangements we make for an alternative supply would have to be made with a qualified alternative supplier with appropriate FDA approval in order for us to obtain our supply requirements for toremifene. In addition, although Orion's composition of matter patents have expired, and as such, we would not be prevented from manufacturing toremifene, there is no obligation on the part of Orion to transfer its manufacturing technology to us or to assist us in developing manufacturing capabilities to meet our supply needs. If we determine to continue the development of toremifene and our supply rights are terminated by Orion for any reason, a disruption in the supply of toremifene could delay the development of and impair our ability to commercialize toremifene.

We also rely on Orion to cooperate with us in the filing and maintenance of regulatory filings with respect to the manufacture of toremifene, and Orion may terminate its obligation to assist us in obtaining and maintaining regulatory approval of toremifene at its election at any time. 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 further delay or prevent regulatory approval of toremifene.

Historically, we have relied on third party vendors for the manufacture of Ostarine™ drug substance. However, Merck assumed primary manufacturing responsibilities for Ostarine™ under our exclusive license and collaboration agreement with Merck, which agreement was terminated in March 2010. In connection with the termination of the agreement with Merck, Merck returned to us all remaining inventory of Ostarine™ drug substance. If this supply of Ostarine™ becomes unusable or if the contract manufacturers that we are currently utilizing to meet our supply needs for Ostarine™ or our other SARM product candidates prove incapable or unwilling to continue to meet our supply needs, we could experience a further delay in conducting any additional clinical trials of Ostarine™ or other SARM product candidates. In addition, we rely on third party contractors for the manufacture of Capesaris™ drug substance. 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 our relationship with Orion for toremifene, or to do so at an acceptable cost, or other suppliers fail to meet our requirements for Capesaris™, or Ostarine™ or our other SARM product candidates for any reason, we would be required to obtain alternate suppliers. 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, which it may do at its election at any time.

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 potential future collaborators may develop may compete with other product candidates and products for access to manufacturing facilities. For example, the active pharmaceutical ingredient in our toremifene 80 mg product candidate is also the active pharmaceutical ingredient in FARESTON®. Orion also manufactures toremifene for third parties for sale outside the United States for the treatment of advanced metastatic breast cancer in postmenopausal women.

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

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

If we lose our licenses from the University of Tennessee Research Foundation, or UTRF, we may be unable to continue a substantial part of our business.

We have licensed intellectual property rights and technology from UTRF used in a substantial part of our business. These license agreements may be terminated by UTRF 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 a substantial part of our business and may result in a serious adverse effect on our financial condition, results of operations and any prospects for growth.

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 result in issued patents or result in patents with narrow, overbroad, or unenforceable claims, or claims that are not supported in regard to written description or enablement by the specification, 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 in the same class of products as our product candidates or 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, as well as the methods for treating patients in the product indications using these product candidates. We will be able to protect our product candidates and the methods for treating patients in the product indications using these product candidates from unauthorized use by third parties only to the extent that we or our exclusive licensors own or control such valid and enforceable patents or trade secrets.

Our rights to certain patents and patent applications relating to SARM compounds that we have licensed from 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.

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, disclosure 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 has expired in the United States and abroad. As a result, we will need to rely primarily on the protection afforded by method of use patents relating to the use of toremifene for the relevant prescribed indications that have been issued or may be issued from our owned or licensed patent applications. To date, many of our applications for method of use patents filed for toremifene outside of the United States are still pending and have not yielded issued patents.

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

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

Off-label sale or use of third-party toremifene products could decrease sales of any toremifene product candidates that we continue to develop and that are approved for commercial sale, 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 may continue to develop toremifene.

In all countries in which we hold or have licensed rights to patents or patent applications related to toremifene, the composition of matter patents we license from Orion have expired. As a result, we will need to rely primarily on the protection afforded by method of use patents. Our method of use patents may not protect toremifene from the risk of off-label sale or use of other toremifene products in place of any toremifene product candidates that we continue to develop and that are approved for commercial sale. 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 other toremifene products may adversely affect our ability to generate revenue from the sale of any toremifene product candidates that we continue to develop and that are approved for commercial sale.

Even in the event that patents are issued from our pending method of use patent applications, 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 method of use 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 or potential 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 toremifene for the indications for which we may continue to develop 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 toremifene in the countries outside of the United States where these applications are currently pending, we would not have as extensive patent coverage to prevent competitors from marketing and selling generic versions of toremifene at doses and in formulations equivalent to our toremifene product candidates for the indications covered by our pending method of use patent applications.

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 toremifene for human uses outside the United States.

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

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

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 any potential future 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 other amounts, or grant a cross license to our patents to another patent holder; or
- be required to redesign the formulation of a product candidate so that it does not infringe, which may not be possible or could require substantial funds and time.

Risks Related to Regulatory Approval of Our Product Candidates

If we or any potential future collaborators are not able to obtain required regulatory approvals, we or such 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 any collaborator from commercializing the product candidate. We have not received regulatory approval to market any of our product candidates in any jurisdiction, and we do not expect to obtain FDA or any other regulatory approvals to market any of our product candidates in the near future, if at all. 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 FDA announced in 2008 that, due to staffing and resource limitations, it has given its managers discretion to miss certain timing goals for completing reviews of NDAs set forth under the Prescription Drug User Fee Act, or PDUFA. Although the FDA has since publicly expressed a recommitment to meeting PDUFA deadlines, it remains unclear whether and to what extent the FDA will adhere to PDUFA deadlines in the future. If the FDA were to miss a PDUFA timing goal for one of our product candidates, the development and commercialization of the product candidate could be delayed. In addition, the Food and Drug Administration Amendments Act of 2007, or FDAAA, 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 potential future 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, in October 2009, we received a Complete Response Letter from the FDA regarding our NDA for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT notifying us that the FDA would not approve our NDA in its present form as a result of certain clinical deficiencies identified in the Complete Response Letter. As a result, FDA approval of toremifene 80 mg, if it occurs, will be substantially delayed. 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 submit an application to the FDA for marketing approval of a product candidate, it may not result in marketing approval from the FDA.

We do not expect to receive regulatory approval for the commercial sale of any of our product candidates that are in development, in the near future, if at all. The inability to obtain FDA approval or approval from comparable authorities in other countries for our product candidates would prevent us or any potential future collaborators from commercializing these product candidates in the United States or other countries. See the section entitled "Business — Government Regulation" under Part 1, Item 1 of this Annual Report on Form 10-K 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 any potential future collaborators may develop will depend upon the market and the degree of market acceptance among physicians, patients, healthcare payors and the medical community.

Any products that we and/or any potential future 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;
- whether the products we commercialize remain a preferred course of treatment;
- 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.

We have conducted a number of studies of toremifene in addition to our clinical trials, including a Thorough QT study (toremifene 80 mg and toremifene 20 mg), a bioequivalence study (toremifene 80 mg), a series of drug-drug interaction studies (toremifene 80 mg and toremifene 20 mg), and a semen quality study (toremifene 20 mg) to assess the effect of toremifene. The results of the Thorough QT study of 250 healthy male volunteers, with 5 parallel cohorts receiving 20 mg, 80 mg or 300 mg doses of toremifene, moxifloxacin, or placebo, showed that toremifene prolonged the QT interval in a dose dependent manner. The mean change in QTcB (a measurement of QT interval corrected by Bazett's formula) from baseline relative to placebo for toremifene 20 mg was 5.79 milliseconds, for toremifene 80 mg, it was 22.43 milliseconds, and for moxifloxacin, it was 8.83 milliseconds. Since we market FARESTON® in the United States under a license agreement with Orion, we notified the FDA of the Thorough QT study results and have proposed modifications to the FARESTON® label in the United States. FDA action on the proposed label changes is pending. Separately, Orion recommended label changes to the EMA. In January 2009, the EMA recommended that the FARESTON® label within the European Union reflect that toremifene should not be given to patients at risk of prolonged QT intervals or other certain heart problems. The results of these completed studies were included as a part of the NDA submission to the FDA for our toremifene 80 mg product candidate to reduce fractures in men with prostate cancer on ADT and will be included as part of any future NDA submission we make to the FDA for toremifene 80 mg if we determine to continue the development of toremifene 80 mg. In addition, the results of these completed studies will be used to update the label for FARESTON®. The study results could lead to the inclusion of restrictions, limitations and/or warnings in the label of FARESTON® or an approved toremifene 80 mg product candidate, which may adversely affect the marketability of the product or limit the patients to whom the product is prescribed.

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

FARESTON® is currently our only marketed product. FARESTON® is indicated for the treatment of advanced metastatic breast cancer in postmenopausal women. FARESTON® competes against tamoxifen, fulvestrant, and several aromatase inhibitors, including anastrozole, letrozole, and exemestane, for hormonal treatment of breast cancer. Sales of pharmaceuticals for breast cancer in the SERM class have declined in recent years as competitors have gained market share, and we believe this trend will continue. Further, the branded competitors have greater resources and generic competitors are preferred by insurers. 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:

- 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 95% of our product sales of FARESTON® for the year ended December 31, 2010;

- any restrictions, limitations, and/or warnings added to the FARESTON® label as a result of our studies of toremifene, including a Thorough QT study and drug interaction studies, or otherwise;
- 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 introduction of generic toremifene products that compete with FARESTON® for the treatment of breast cancer; and
- the loss of Orion, upon which we rely as a single source, as our supplier of FARESTON®.

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, and in any event have only limited company personnel to undertake such activities, and we therefore need 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 build our own sales and marketing capabilities and there are risks involved with entering into arrangements with third parties to perform these services, which could delay the commercialization of any of our product candidates if approved for commercial sale. 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 and/or any potential future collaborators are unable to obtain reimbursement or experience a reduction in reimbursement from third-party payors for products we sell, our revenues and prospects for profitability will suffer.

Sales of products developed by us and/or any potential future collaborators are dependent on the availability and extent of reimbursement from third-party payors. Changes in the reimbursement policies of these third-party payors that reduce reimbursements for FARESTON® and any other products that we and/or any potential future collaborators may develop and sell could negatively impact our future operating and financial results.

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 established comprehensive Medicare coverage and reimbursement of prescription drugs under Medicare Part D. The prescription drug program established by this legislation may have the effect of reducing the prices that we or any potential future collaborators are able to charge for products we and/or any potential future 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 any potential future collaborators may develop or to lower the amount that they pay.

In March 2010, the United States Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act. This health care reform legislation will increase the number of individuals who receive health insurance coverage and will close a gap in drug coverage under Medicare Part D as established in 2003. However, the newly-enacted legislation also implements cost containment measures that could adversely affect our revenues. These measures include increased drug rebates under Medicaid starting in 2010 for brand name prescription drugs, such as FARESTON®, and extension of these rebates to Medicaid managed care, which would reduce the amount of net reimbursement received for FARESTON® or any other products that we and/or any potential future collaborators may develop and sell. Also effective for 2010, the legislation extends 340B discounted pricing on outpatient drugs to children's hospitals, critical access hospitals, and rural health centers, which extension reduces the amount of reimbursement received for drugs purchased by these new 340B-covered entities.

Additional provisions of the health care reform legislation, which become effective later in 2011, may negatively affect our revenues and prospects for profitability in the future. Along with other pharmaceutical manufacturers and importers of brand name prescription drugs, we will be assessed a fee based on our proportionate share of sales of brand name prescription drugs to certain government programs, including Medicare and Medicaid. As part of the health care reform legislation's provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the "donut hole"), we will also be required to provide a 50% discount on brand name prescription drugs, including FARESTON®, sold to beneficiaries who fall within the donut hole.

Economic pressure on state budgets may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for drugs. State Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization for use of drugs where supplemental rebates are not provided. Private health insurers and managed care plans are likely to continue challenging the prices charged for medical products and services, and many of these third-party payors may 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 any potential future collaborators may develop or sell. These cost-control initiatives could decrease the price we might establish for products that we or any potential future collaborators may develop or sell, which would result in lower product revenues or royalties payable to us.

Similar cost containment initiatives exist in countries outside of the United States, particularly in the countries of the European Union, where the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to twelve months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or any potential future 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 a potential future 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 any potential future collaborators may develop or sell. Cost-control initiatives could decrease the price we might establish for products that we or any potential future collaborators may develop or sell, which would result in lower product revenues or royalties payable to us.

Another development that could affect the pricing of drugs would be if the Secretary of Health and Human Services allowed 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 from countries where the drugs are sold at a lower price than in the United States. If the circumstances were met and the Secretary exercised the discretion to allow for the direct reimportation of drugs, it could decrease the price we or any potential future collaborators receive for any products that we and/or any potential future collaborators may develop, negatively affecting our revenues and prospects for profitability.

Health care reform measures could hinder or prevent our product candidates' commercial success.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting health care reform, as evidenced by the recent enactment in the United States of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act. It is likely that federal and state legislatures within the United States and foreign governments will continue to consider changes to existing health care legislation. These changes adopted by governments may adversely impact our business by lowering the price of health care products in the United States and elsewhere.

We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations or existing laws, regulations or decisions, related to health care availability, method of delivery or payment for health care products and services, or sales, marketing and pricing practices could negatively impact our business, operations and financial condition.

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 our commercial sale of FARESTON® and 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 $20 million annual aggregate limit. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

If our competitors are better able to develop and market products than any products that we and/or any potential future 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 any potential future collaborators may develop. Competition could result in reduced sales and pricing pressure on our product candidates, if approved, which in turn would reduce our ability to generate meaningful revenue and have a negative impact on our results of operations. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before us and impair any 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 in our pipeline, 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 any ability to market and sell any products that we and/or any potential future collaborators may develop.

With respect to our SARM program, there are other SARM product candidates in development that may compete with our SARM product candidates, if approved for commercial sale, including SARMs in development from Ligand Pharmaceuticals Inc., GlaxoSmithKline, and Merck. Pfizer Inc., Eli Lilly & Co., and Amgen have myostatin inhibitors in development that may compete with Ostarine™ if approved for commercial sale. In addition, Cytokinetics, Inc. is developing a troponin activator with a muscle specific mechanism in Phase II studies, with a focus on neurological muscle diseases (amyotrophic lateral sclerosis and myasthenia gravis). Moreover, there are other categories of drugs in development, including ghrelin receptor agonists and growth hormone secretagogues that may have some muscle building activity. Other appetite stimulants such as megestrol acetate and dronabinol are also used off-label for weight loss and loss of appetite in patients with cancer.

We are developing Capesaris™ for first line treatment of advanced prostate cancer. Currently, there are several products approved to reduce testosterone levels in men with advanced prostate cancer that may compete with Capesaris™ if approved for commercial sale, including those marketed by Abbott Laboratories (Lupron®), Sanofi-Aventis (Eligard®), AstraZeneca (Zoladex®), Ferring Pharmaceuticals (Firmagon®), Endo Pharmaceuticals (Vantas®) and Watson Pharmaceuticals (Trelstar®).

We have evaluated toremifene 80 mg for the reduction of fractures and treatment of other estrogen deficiency side effects of ADT. Although there are no products that have been approved by the FDA to reduce fractures or treat estrogen deficiency related side effects of ADT, we are aware of a number of drugs, including drugs marketed by Eli Lilly & Co. (Evista®), Merck (Fosamax®), Sanofi-Aventis and Warner Chilcott (Actonel®), Pfizer Inc. (Effexor®), Boehringer Ingelheim (Catapres®), Novartis (Zometa®) and generic megestrol acetate, that are prescribed to treat single side effects of ADT; that external beam radiation and tamoxifen are used to treat breast pain and enlargement, or gynecomastia. Xgeva™ (denosumab), a monoclonal antibody developed by Amgen, is marketed in the United States for the prevention of skeletal related events in patients with bone metastases from solid tumors. Xgeva™ was also studied in a placebo controlled Phase III trial among men with castrate resistant Stage III prostate cancer with rapidly-rising PSA levels who had no bone metastases at baseline. Xgeva™ significantly improved median bone metastasis-free survival by 4.2 months. Denosumab is also marketed as Prolia™ in a different strength and dosing regimen and is approved in the United States, Europe and Australia for the treatment of postmenopausal women with osteoporosis at high risk for fracture (defined as a history of osteoporotic fracture, or multiple risk factors for fracture); or patients who have failed or are intolerant to other available osteoporosis therapy. Additionally Prolia™ is marketed in Europe for the treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures and is under regulatory review for cancer specific indications including prostate cancer.

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 $22.5 million of insurance covering Dr. Steiner.

In December 2009, we announced a reduction of approximately 26% of our workforce in order to reduce our operating expenses in connection with the receipt of the Complete Response Letter regarding our NDA for toremifene 80 mg and the associated delay in the potential regulatory approval of toremifene 80 mg. This and any future workforce reductions may negatively affect our ability to retain or attract talented employees.

We will need to hire additional employees in order to commercialize our product candidates in the future. 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 commercialize our product candidates in the future, we will need to expand the number of our managerial, operational, financial and other employees and competition exists for qualified personnel in the biotechnology field.

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:

- delays in the initiation or completion of our currently-planned clinical trials of Ostarine™ and Capesaris™, or adverse results in any of our initiated clinical trials;
- our ability to enter into new collaborative arrangements with respect to our product candidates;
- the terms and timing of any future collaborative, licensing or other arrangements that we may establish;
- the timing of achievement of, or failure to achieve, our and any potential future 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 or adverse events during 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, including regulatory actions requiring or leading to restrictions, limitations and/or warnings in the label of FARESTON® or an approved product candidate;
- the commercial success of any product approved by the FDA or its foreign counterparts;
- introductions or announcements of technological innovations or new products by us, our potential future collaborators, or our competitors, and the timing of these introductions or announcements;
- market conditions for equity investments in general, or the biotechnology or pharmaceutical industries in particular;
- regulatory developments in the United States and foreign countries;
- changes in the structure or reimbursement policies of health care payment systems;
- any intellectual property infringement lawsuit involving us;
- 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. Recently, the financial markets have faced almost unprecedented turmoil, resulting in a decline in investor confidence and concerns about the proper functioning of the securities markets, which decline in general investor confidence has resulted in depressed stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. 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 executive officers, directors and largest stockholders have the ability to control all matters submitted to stockholders for approval.

As of January 31, 2011, our executive officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 70.1% of our outstanding common stock, and our executive officers and directors alone beneficially owned approximately 45.1% of our outstanding common stock. As a result, these stockholders, acting together, may or will have the ability 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.

If there are substantial sales of our common stock, the market price of our common stock could drop substantially, even if our business is doing well.

For the 12-month period ended December 31, 2010, the average daily trading volume of our common stock on the NASDAQ Global Market was 222,731 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, 2010, we had 51,719,187 shares of common stock outstanding.

Moreover, J.R. Hyde, III, and Oracle Investment Management, Inc., 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. If any of these large stockholders were to sell large blocks of shares in a short period of time, the market price of our common stock could drop substantially.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We sublease approximately 53,000 square feet of laboratory and office space located at 3 North Dunlap Street, Memphis, Tennessee from the University of Tennessee Research Foundation ("UTRF"). The sublease expires on December 31, 2012, unless sooner terminated in accordance with the terms of this sublease. We have an option to extend this sublease for an additional two years.

We sublease approximately 31,000 square feet of office space located at 175 Toyota Plaza, Memphis, Tennessee, under an operating lease which expires on April 30, 2015. In July 2008, we amended the sublease to add approximately 22,000 square feet of additional office space through April 30, 2015. In February 2011, we amended the sublease agreement to eliminate the additional office space, effective January 1, 2011.

ITEM 3. LEGAL PROCEEDINGS

We are not currently involved in any material legal proceedings.

ITEM 4. (REMOVED AND RESERVED)

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. The following table presents, for the periods indicated, the high and low intraday sales prices per share of our common stock as reported on The NASDAQ Global Market.

	2010		2009	
	High	Low	High	Low
First Quarter	$ 4.47	$ 3.21	$ 18.00	$ 8.06
Second Quarter	4.30	1.90	11.24	8.07
Third Quarter	3.60	2.76	13.59	7.72
Fourth Quarter	3.95	2.45	12.70	3.22

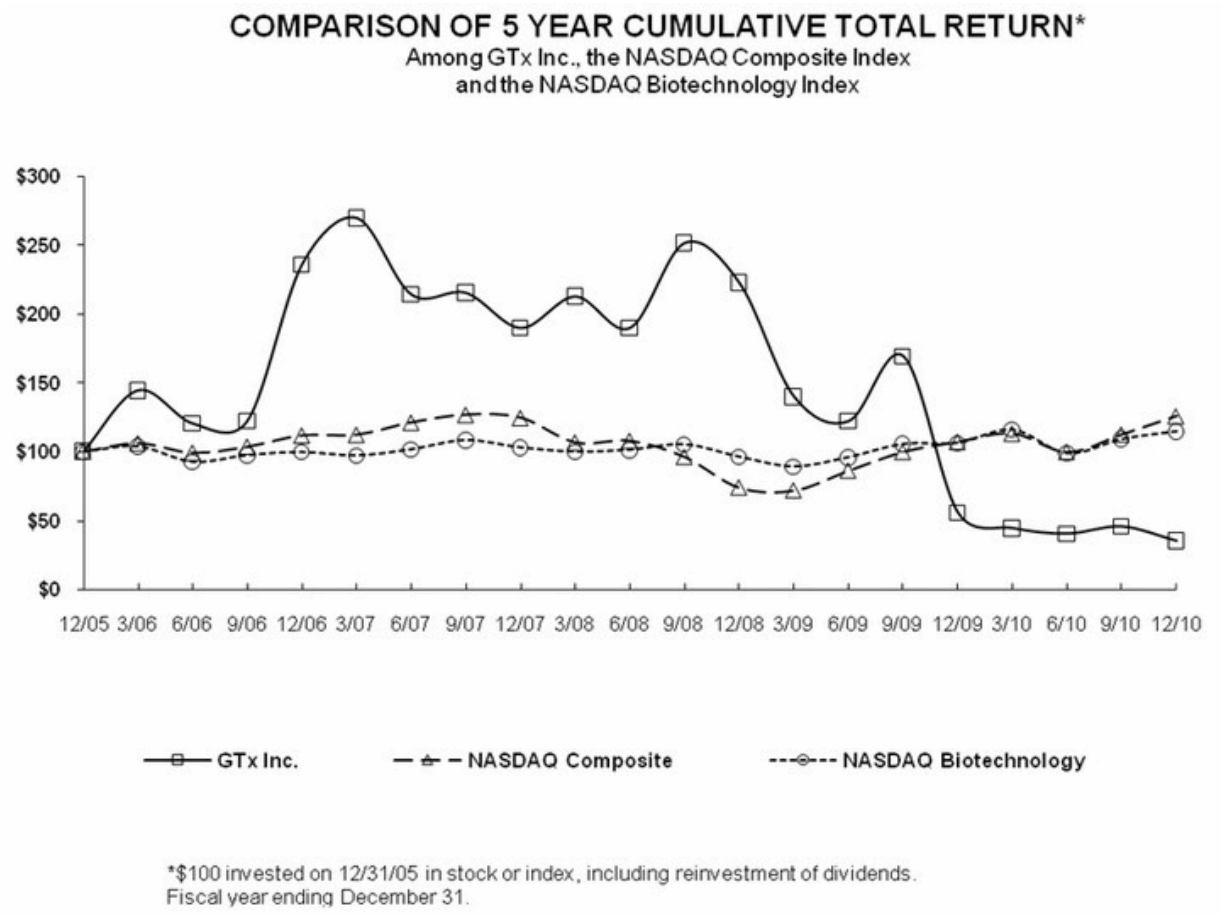
On March 3, 2011, the closing price of our common stock as reported on The NASDAQ Global Market was $2.37 per share and there were approximately 73 holders of record of our common stock.

Performance Graph[1]

The rules of the SEC require that we include in our annual report to stockholders 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 Stock Market) 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 December 31, 2005 on The NASDAQ Global Market for: (1) our common stock; (2) The NASDAQ Composite Index and (3) The NASDAQ Biotechnology Index. All values assume reinvestment of the full amounts of all dividends. No dividends have been declared on our common stock. The closing sale price of our common stock on December 31, 2010 as reported on The NASDAQ Global Market was $2.65.

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.



1 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 Securities Exchange Act of 1934 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, 2010, 2009 and 2008, and the balance sheet data as of December 31, 2010 and 2009, 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, 2007 and 2006, and the consolidated balance sheet data as of December 31, 2008, 2007 and 2006, 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,				
	2010	2009	2008	2007	2006
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenues:					
Product sales, net	$ 3,827	$ 3,289	$ 1,088	$ 1,076	$ 1,357
Collaboration revenue	56,786	11,441	12,440	6,050	6,148
Total revenues	60,613	14,730	13,528	7,126	7,505
Cost and expenses:					
Cost of product sales	768	1,290	649	621	773
Research and development expenses	28,495	32,344	44,259	38,508	33,897
General and administrative expenses	17,419	27,778	23,140	13,667	11,114
Total costs and expenses	46,682	61,412	68,048	52,796	45,784
Net income (loss) from operations	13,931	(46,682)	(54,520)	(45,670)	(38,279)
Other income, net	1,363	188	2,740	5,311	2,769
Net income (loss) before income taxes	15,924	(46,494)	(51,780)	(40,359)	(35,510)
Income tax benefit	—	238	—	—	—
Net income (loss)	$ 15,294	$ (46,256)	$ (51,780)	$ (40,359)	$ (35,510)
Net income (loss) per share:					
Basic and diluted	$ 0.39	$ (1.27)	$ (1.43)	$ (1.16)	$ (1.14)

Foreign currency transaction gains and losses and interest expense have been reclassified to other income, net from general and administrative expenses in the statement of operations for the years ended December 31, 2009, 2008, 2007 and 2006.

	As of December 31,				
	2010	2009	2008	2007	2006
			(in thousands)		
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 58,631	$ 49,044	$ 97,667	$ 109,988	$ 119,550
Working capital	55,055	34,723	79,047	132,932	111,363
Total assets	64,250	57,721	108,109	159,730	129,255
Accumulated deficit	(352,880)	(368,174)	(321,918)	(270,138)	(229,779)
Total stockholders' equity (deficit)	51,727	(8,750)	32,018	78,917	97,049

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 contains 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 Part I, Item 1A "Risk Factors" and elsewhere in this Annual Report on Form 10-K. See "Special Note Regarding Forward-Looking Statements" 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 for the treatment of cancer and the side effects of anticancer therapy, cancer supportive care, and other serious medical conditions.

We are developing selective androgen receptor modulators, or SARMs, a new class of drugs with the potential to prevent and treat muscle wasting in patients with cancer, and other musculoskeletal wasting or muscle loss conditions, including chronic sarcopenia (age related muscle loss). In December 2010, we held an End of Phase II meeting with the U.S. Food and Drug Administration, or FDA, to discuss our proposed Phase III clinical development of Ostarine™ (GTx-024) for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer. We expect to initiate a pivotal Phase III clinical trial for this indication in the third quarter of 2011, following additional input from the FDA. We also intend to continue our pursuit of a strategic partnership or collaboration for the development and commercialization of SARMs, which includes Ostarine™ for the prevention and treatment of muscle wasting in patients with cancer, as well as other indications.

Additionally, we are developing Capesaris™ (GTx-758), a selective estrogen receptor, or ER, alpha agonist for first line treatment of advanced prostate cancer. In September 2010, we announced that in a Phase II, open label, pharmacokinetic and pharmacodynamic clinical trial in young healthy male volunteers, Capesaris™ suppressed serum total testosterone to castrate levels, increased serum SHBG, and reduced serum free testosterone, the form of testosterone which is available to prostate cancer cells for growth. Capesaris™ was well tolerated and no serious adverse events were reported in the study. We met with the FDA in February 2011 and confirmed that the primary endpoint acceptable for approval for this indication is total testosterone levels (achieve and maintain serum total testosterone levels less than 50ng/dL). In the second quarter of 2011, we plan to initiate a Phase IIb open label clinical trial evaluating Capesaris™ compared to Lupron® (leuprolide acetate), a luteinizing hormone releasing hormone, or LHRH, agonist for first line treatment in men with advanced prostate cancer. We are also currently seeking a strategic partnership or collaboration for the development and commercialization of Capesaris™ for the treatment of advanced prostate cancer.

In December 2008, we submitted a New Drug Application, or NDA, for toremifene 80 mg, a selective estrogen receptor modulator, or SERM, to reduce fractures in men with prostate cancer on androgen deprivation therapy, or ADT, to the FDA. In October 2009, we received a Complete Response Letter from the FDA regarding our NDA for toremifene 80 mg notifying us that the FDA would not approve our NDA in its present form as a result of certain clinical deficiencies identified in the Complete Response Letter. In April 2010, we submitted a proposed protocol to the FDA for a second pivotal Phase III clinical trial evaluating toremifene 80 mg to reduce fractures in men with prostate cancer on ADT to address in a single clinical trial the deficiencies identified by the FDA in the Complete Response Letter. Based on our discussions with the FDA to date, we believe that we have finalized the protocol for a second pivotal Phase III clinical trial (which we previously referred to as the TREAT 2 trial).

In March 2011, we reacquired full rights to our toremifene program following the termination by us and Ipsen Biopharm Limited, or Ipsen, of our collaboration and license agreement, which was entered into in September 2006 and amended in March 2010. In exchange for reacquiring all of Ipsen's rights under the collaboration agreement, we agreed to pay Ipsen a low single digit royalty on net sales of toremifene 80 mg in the United States if approved for commercial sale. Pending our ongoing discussions with the FDA regarding whether an additional single Phase III clinical trial of toremifene 80 mg to address the deficiencies identified in the Complete Response Letter can be conducted as a post-approval study, we do not plan to continue any further clinical development of toremifene 80 mg. In the event that the FDA allows this clinical trial to be conducted as a post-approval study and we are able to secure sufficient funding for the study through new partnerships or collaborations or through other financing, we will reevaluate whether to continue the development of toremifene 80 mg.

In May 2010, we announced that toremifene 20 mg failed to meet the primary efficacy endpoint in a completed Phase III clinical trial evaluating toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia, or high grade PIN. We do not expect to conduct additional clinical trials evaluating toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN or to submit a NDA to the FDA for this indication.

We market FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of advanced metastatic breast cancer in postmenopausal women in the United States.

Our net income for the year ended December 31, 2010 was $15.3 million. Our net income resulted from the recognition of the remaining $49.9 million of deferred revenue due to the termination of our exclusive license and collaboration agreement for our SARM program with Merck, the final payment from Merck of $5.0 million of cost reimbursement for research and development activities that was received from Merck in December 2010, and FARESTON® net product sales of $3.8 million. Additionally, our net income included grants totaling $1.2 million that were awarded to us by the United States Government under the Qualifying Therapeutic Discovery Project Program, which was established under the Patient Protection and Affordable Care Act. We were granted $244,000 for each of five applications submitted for our cancer and cancer supportive care research and development programs. Although we reported net income for the year ended December 31, 2010, we expect to incur significant operating losses in 2011 and for the foreseeable future as we continue our clinical development and research and development activities. Due to the termination of our license and collaboration with Ipsen in March 2011, we expect to recognize as collaboration revenue all of the remaining $8.1 million unamortized revenue that was deferred as of December 31, 2010 during the first quarter of 2011.

We estimate that our current cash, cash equivalents, and short-term investments, together with interest income and product revenue from the sale of FARESTON®, will be sufficient to meet our projected operating requirements for at least the next twelve months. We have based this estimate on our current business plan and assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect and we could need additional funding sooner than currently anticipated. We believe that our current cash resources, together with interest income and product revenue from the sale of FARESTON®, will be sufficient to enable us to initiate in 2011 our planned Phase III clinical trial of Ostarine™ for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer and to initiate and complete our planned Phase IIb clinical trial to evaluate Capesaris™ for first line treatment of advanced prostate cancer. To complete the Phase III clinical trial we expect to initiate in 2011 for Ostarine™, we may need to obtain additional funding. However to conduct any additional clinical trials for our product candidates, we will need to raise additional capital through partnerships and/or collaborations or the sale of our securities. We do not expect to obtain FDA or any other regulatory approvals to market any of our product candidates in the near future.

Research and Development

Since our inception in 1997, we have been focused on drug discovery and development programs. Research and development expenses include, but are not limited to, 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 tlrials, regulatory affairs activities, quality assurance activities and license fees.

We expect our research and development expenses for fiscal year 2011 to be relatively consistent with fiscal year 2010 and to be primarily focused on the following:

- the continued clinical development of Ostarine™;
- the continued clinical development of Capesaris™; and
- the continued preclinical development of other potential product candidates.

There is a risk that any drug discovery and development program may not produce revenue. Moreover, because of uncertainties inherent in drug discovery and development, including those factors described in Part I, 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. Even if the FDA grants marketing approval, the FDA may impose restrictions, limitations and/or warnings in the label of an approved product candidate, which may adversely affect the marketability of the product or limit the patients to whom the product is prescribed. In some cases, the FDA may give conditional approval of an NDA for a product candidate on the NDA sponsor's agreement to conduct additional clinical trials to further assess the product's safety and effectiveness after NDA approval. Any approval of an NDA by the FDA conditioned on completing additional clinical trials may require the sponsor to discontinue further marketing of the product if data from the clinical trial fails to demonstrate sufficient efficacy and safety in accordance with the agreed-upon protocol for the clinical trial.

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 due to the numerous risks and uncertainties associated with developing and commercializing drugs, including the uncertainty of:

- our ability to progress product candidates into preclinical and clinical trials;
- the scope, rate of progress and cost of our clinical trials and other research and development activities, including our currently-planned clinical trials of Ostarine™ and Capesaris™;
- the terms and timing of any potential future collaborative, licensing and other arrangements that we may establish;
- whether and to what extent we determine to continue the development of toremifene 80 mg;
- future clinical trials;
- the cost and timing of regulatory filings and/or approvals to commercialize our product candidates and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- the amount and timing of any licensing fees, milestone payments and royalty payments from potential future collaborators, if any;
- the cost and timing of establishing medical education, sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we and/or any potential future 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, and the cost of defending any other litigation claims.

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 development and commercialization efforts 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.

Sales and Marketing

We market FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of advanced metastatic breast cancer in postmenopausal women in the United States. 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.

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. General and administrative expenses also include facility costs, insurance costs, professional fees for legal, accounting, public relations, and marketing services, and FARESTON® selling and distribution expenses. We expect our general and administrative expenses for fiscal year 2011 to be relatively consistent with fiscal year 2010.

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, share-based compensation, 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.

Collaboration revenue consists of non-refundable upfront payments, license fees, reimbursements for research and development activities, and milestone payments associated with our collaboration and license agreements and is based on the performance requirements of the specific agreements. We analyze our 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. For arrangements for which we are not able to identify evidence of fair value for the undelivered elements, we will recognize any consideration for a single unit of accounting in the same manner as the revenue is recognized for the final deliverable, which is 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 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 product candidates and technology, such as initiation of clinical trials, achievement of specified clinical trial endpoints, filing for approval with regulatory agencies and approvals by regulatory agencies.

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 estimated the performance obligation period to be ten years for the development of toremifene under our former collaboration agreement with Ipsen. However, due to the termination of our license and collaboration with Ipsen in March 2011, we expect to recognize as collaboration revenue all of the remaining $8.1 million unamortized revenue that was deferred as of December 31, 2010 during the first quarter of 2011. We estimated the performance obligation period to be ten years for our former collaboration agreement with Merck. However, due to the termination of our license and collaboration agreement with Merck in March 2010, we recognized as collaboration revenue in the first quarter of 2010 all of the remaining $49.9 million of unamortized revenue that was deferred as of December 31, 2009, as well as the final payment of $5.0 million for cost reimbursement for research and development activities that we received from Merck in December 2010.

We recognize revenue from product sales of FARESTON® less deductions for estimated sales discounts and sales returns. We recognize revenue from product sales when persuasive evidence of an arrangement exists, title passes, the price is fixed or determinable, and collectability is reasonably assured. 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. We consider historical product return trend information that we continue to update each period. We estimate the number of months of product on hand and the amount of product 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 95% of our product sales of FARESTON® for the year ended December 31, 2010. Based on this information, and other factors, we estimate an accrual for product returns. At December 31, 2010 and 2009, our accrual for product returns was $802,000 and $494,000, respectively. In the second quarter of 2010, we increased the price of FARESTON®. While we do not expect a material increase in the volume of product returns in future periods as a result of the price increase, the price increase resulted in an increase in the product returns accrual since certain product returns are accepted at or near the current sales price of FARESTON®.

Research and Development Expenses

Research and development expenses include, but are not limited to, our expenses for personnel, supplies, and facilities associated with research activities, screening and identification of product candidates, formulation and synthesis activities, manufacturing, preclinical studies, toxicology studies, clinical trials, regulatory affairs activities, quality assurance activities and license fees. We expense these costs in the period in which they are incurred. We estimate our liabilities for research and development expenses in order to match the recognition of expenses to the period in which the actual services are received. As such, accrued liabilities related to third party research and development activities are recognized based upon our estimate of services received and degree of completion of the services in accordance with the specific third party contract.

Share-Based Compensation

We have stock option and equity incentive plans that provide for the purchase of our common stock by certain of our employees and non-employee directors. We recognize compensation expense for our share-based payments based on the fair value of the awards on the grant date and recognize the expense over the period during which an employee or non-employee director is required to provide service in exchange for the award.

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. We estimate the expected stock price volatility based on the historical volatility of our common stock. 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. The amount of share-based compensation expense recognized is reduced ratably over the vesting period by an estimate of the percentage of options granted that are expected to be forfeited or canceled before becoming fully vested. 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, 2010 was $4.9 million, of which approximately $2.3 million and approximately $2.5 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, 2009 and 2008 was $5.4 million and $3.7 million, 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 $187,000, $178,000 and $178,000 for the years ended December 31, 2010, 2009 and 2008, respectively. At December 31, 2010, the total compensation cost related to non-vested awards not yet recognized was approximately $10.3 million with a weighted average expense recognition period of 2.94 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. Accordingly, at December 31, 2010 and 2009, net of the valuation allowance, the net deferred tax assets were reduced to zero.

Intangible Assets

We amortize our purchased intangible assets with finite lives over their estimated economic lives. 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 is recognized when estimated future cash flows is less than the carrying amount. The cash flow estimates are based on management's best estimates, using appropriate and customary assumptions and projections at the time.

During the second quarter of 2010, we determined that, based on the results of the Phase III clinical trial evaluating toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, we do not expect to conduct additional clinical trials or submit a NDA to the FDA for toremifene 20 mg for this indication. Based upon this determination, a triggering event occurred requiring us to perform an impairment review of the toremifene 20 mg intangible assets. After analyzing future cash flows and estimates of fair market value from a market participant perspective, we determined that an impairment existed and recorded an impairment charge of $1.7 million during the second quarter of 2010, which was included in research and development expenses in the statement of operations for the year ended December 31, 2010.

At December 31, 2010, our purchased intangible assets consisted of 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 the amended and restated license agreement related to our SARM program. The remaining Orion license fee, which relates entirely to our toremifene 80 mg program, is being amortized on a straight-line basis over the term of the agreement which we estimate to be 16 years. The remaining UTRF license fee related to our SARM program is being amortized on a straight-line basis over the term of the agreement with UTRF, which we estimate to be approximately 14 years.

Recent Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2009-13, *Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements (a consensus of the FASB Emerging Issues Task Force)* ("ASU No. 2009-13"). ASU No. 2009-13 amends revenue recognition guidance related to multiple deliverable arrangements to provide new guidance concerning the determination of whether an arrangement involving multiple deliverables contains more than one unit of accounting and the manner in which arrangement consideration should be allocated to such deliverables. The amended guidance is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010 and may be applied prospectively or retroactively. We do not expect the adoption of ASU No. 2009-13 to have a material impact on our financial position or results of operations.

In April 2010, the FASB issued Accounting Standards Update No. 2010-17, *Revenue Recognition (Topic 605): Milestone Method of Revenue Recognition (a consensus of the FASB Emerging Issues Task Force)* ("ASU No. 2010-17"). ASU No. 2010-17 allows an entity to make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. Additionally, ASU No. 2010-17 provides guidance in identifying milestones and determining whether the milestones are substantive. The amended guidance is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010 and may be applied prospectively or retroactively. We do not expect the adoption of ASU No. 2010-17 to have a material impact on our financial position or results of operations.

Recent Health Care Legislation

The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act were signed into law in March of 2010, but certain provisions applied retroactively as of January 1, 2010. The legislation, among other things: increased drug rebates under Medicaid; applied those rebates to Medicaid managed care enrollees for the first time; and expanded 340B discounted drug pricing to more categories of providers. In particular, as a result of the new legislation, minimum percentage Medicaid drug rebates on FARESTON® increased from 15.1% to 23.1% of our average manufacturer price. These changes did not have a significant impact on our results of operations for the year ended December 31, 2010.

Results of Operations

Comparison of Years Ended December 31, 2010 and December 31, 2009

Revenues. Revenues for the year ended December 31, 2010 were $60.6 million as compared to $14.7 million for the same period of 2009. Revenues for the year ended December 31, 2010 included net sales of FARESTON® marketed for the treatment of advanced metastatic breast cancer in postmenopausal women and collaboration income from Ipsen and Merck. During the years ended December 31, 2010 and 2009, FARESTON® net product sales were $3.8 million and $3.3 million, respectively, while cost of products sales were $768,000 and $1.3 million, respectively. FARESTON® net product sales for the year ended December 31, 2010 increased from the same period in the prior year due primarily to an increase in the sales price of FARESTON® taken during the second quarter of 2010 and, to a lesser extent, an approximately 16% increase in sales volume. These increases were partially offset by an increase in the provision for product returns due to an increase in sales price and increases in governmental rebates. Cost of product sales decreased from the prior year due to a reduction in the royalty payable to Orion on our net sales of FARESTON® in the third quarter of 2009. Collaboration income was $56.8 million for the year ended December 31, 2010, which consisted of approximately $1.9 million from Ipsen and $54.9 million from Merck. As a result of the termination of our license and collaboration agreement with Merck in March 2010, we recognized as collaboration revenue the remaining $49.9 million of unamortized deferred revenue in the first quarter of 2010, as well as the final payment of $5.0 million of cost reimbursement that was received from Merck in December 2010. For the year ended December 31, 2009, collaboration income was $11.4 million, of which $5.8 million and $5.6 million was from the amortization of deferred revenue from Ipsen and Merck, respectively. Due to the termination of our license and collaboration with Ipsen in March 2011, we expect to recognize as collaboration revenue all of the remaining $8.1 million unamortized revenue that was deferred as of December 31, 2010 during the first quarter of 2011.

Research and Development Expenses. Research and development expenses decreased 12% to $28.5 million for the year ended December 31, 2010 from $32.3 million for the year ended December 31, 2009. The decrease in research and development expenses during the year ended December 31, 2010 compared to the year ended December 31, 2009 was due primarily to the completion of the toremifene 20 mg Phase III clinical trial in early 2010, the completion of two Phase I clinical trials for Capesaris™ during 2009, and a decrease in discovery research and development activities in 2010. The decrease was partially offset by a Phase II clinical trial for Capesaris ™ conducted in 2010 and increased spending on Ostarine™ development. Additionally, research and development expenses for the year ended December 31, 2010 included an impairment charge of $1.7 million related to our toremifene 20 mg intangible assets. This amount is included in "Toremifene 20 mg" in the table below.

The following table identifies the research and development expenses for each of our clinical product candidates, as well as research and development expenses pertaining to our other research and development efforts, for each of the periods presented. "Other research and development" expenses in the table below represent the cost of personnel, supplies and facilities associated with preclinical and discovery research and development activities. Research and development spending for past periods is not indicative of spending in future periods.

Product Candidate/ Proposed Indication	Program	Years Ended December 31, 2010	2009	Increase/ (Decrease)
		(in thousands)		
Ostarine™				
Prevention and treatment of muscle wasting in patients with cancer	**SARM**	$ 3,207	$ 679	$ 2,528
Capesaris™				
First line treatment of advanced prostate cancer	**Selective ER alpha agonist**	8,647	10,074	(1,427)
Toremifene 80 mg				
To reduce fractures in men with prostate cancer on ADT	**SERM**	4,282	3,377	905
Toremifene 20 mg				
Prevention of prostate cancer in high risk men with high grade PIN	**SERM**	5,072	5,881	(809)
Other research and development		7,287	12,333	(5,046)
Total research and development expenses		$ 28,495	$ 32,344	$ (3,849)

General and Administrative Expenses. General and administrative expenses decreased 37% to $17.4 million for the year ended December 31, 2010 from $27.8 million for the year ended December 31, 2009. This decrease was primarily due to decreased personnel related expenses of $5.8 million resulting from the reduction in our workforce in December 2009, reduced marketing expenses of $2.7 million, and reduced medical education expenses of $693,000, in each case, as a result of our not receiving regulatory approval of our toremifene 80 mg product candidate.

Other Income, Net. Other income, net increased to $1.4 million for the year ended December 31, 2010 from $188,000 for the year ended December 31, 2009. For the year ended December 31, 2010, other income, net included income from grants totaling $1.2 million awarded to us by the United States Government under the Qualifying Therapeutic Discovery Project Program, which was established under Patient Protection and Affordable Care Act. We were granted $244,000 for each of five applications submitted for our cancer and cancer supportive care research and development programs.

Comparison of Years Ended December 31, 2009 and December 31, 2008

Revenues. Revenues for the year ended December 31, 2009 were $14.7 million as compared to $13.5 million for the same period of 2008. Revenues for the year ended December 31, 2009 included net sales of FARESTON® marketed for the treatment of advanced metastatic breast cancer in postmenopausal women and collaboration income from Ipsen and Merck. During the years ended December 31, 2009 and 2008, FARESTON® net product sales were $3.3 million and $1.1 million, respectively, while cost of products sales were $1.3 million and $649,000, respectively. FARESTON® net product sales for the year ended December 31, 2009 increased from the same period in the prior year as a result of a price increase instituted in the fourth quarter of 2008, partially offset by a decrease of approximately 22% in sales volume of FARESTON® as compared to the year ended December 31, 2008. The increase in cost of product sales was due to an increase in royalty expense which is based on our net sales of FARESTON®. Collaboration income was $11.4 million for the year ended December 31, 2009, which consisted of approximately $5.8 million and $5.6 million from the amortization of deferred revenue from Ipsen and Merck, respectively. For the year ended December 31, 2008, collaboration income was $12.4 million, of which $5.9 million and $5.1 million was from the amortization of deferred revenue from Ipsen and Merck, respectively, and approximately $1.5 million was from an earned milestone from Ipsen with the achievement of the primary endpoint in the toremifene 80 mg Phase III clinical trial.

Research and Development Expenses. Research and development expenses decreased 27% to $32.3 million for the year ended December 31, 2009 from $44.3 million for the year ended December 31, 2008. The decrease in research and development expenses during the year ended December 31, 2009 compared to the year ended December 31, 2008 was due primarily to the completion of the toremifene 80 mg Phase III clinical trial, a decreased number of subject visits in the toremifene 20 mg Phase III clinical trial due to a portion of the subjects having completed the trial prior to or during the year ended December 31, 2009, and the completion of the Ostarine™ Phase II clinical trial during 2008. Research and development expenses for the year ended December 31, 2008 included payment of a $1.2 million fee to the FDA for the submission of the NDA for toremifene 80 mg and a payment to UTRF of $540,000 for the execution of amendments to our existing SARM and SERM license agreements. These amounts are included in "Toremifene 80 mg" and "Other research and development", respectively, for the year ended December 31, 2008 in the table below. Research and development expenses were also lower in the year ended December 31, 2009 as a result of our decision to not pay cash bonuses to employees for 2009. Research and development expenses included employee bonus expense of $967,000 for the year ended December 31, 2008.

The decrease in research and development expenses in the year ended December 31, 2009 was partially offset by increased research and development spending on our Phase I clinical trials for Capesaris™ and by approximately $290,000 of severance costs incurred related to our workforce reduction that occurred in December 2009. Additionally, toremifene 80 mg tablets purchased at a cost of approximately $941,000 were recorded as research and development expense in the fourth quarter due to the receipt of the Complete Response Letter regarding our NDA for toremifene 80 mg and the associated delay in the potential regulatory approval of toremifene 80 mg to reduce fractures in men with prostate cancer on ADT. This expense is included in "Toremifene 80 mg" in the table below.

The following table identifies the research and development expenses for each of our clinical product candidates, as well as research and development expenses pertaining to our other research and development efforts, for each of the periods presented. "Other research and development" expenses in the table below represent the cost of personnel, supplies and facilities associated with preclinical and discovery research and development activities. Research and development spending for past periods is not indicative of spending in future periods.

Product Candidate/ Proposed Indication	Program	Years Ended December 31, 2009	2008	Increase/ (Decrease)
		(in thousands)		
Ostarine™				
Prevention and treatment of muscle wasting in patients with cancer	**SARM**	$ 679	$ 5,973	$ (5,294)
Capesaris™				
First line treatment of advanced prostate cancer	**Selective ER alpha agonist**	10,074	3,786	6,288
Toremifene 80 mg				
To reduce fractures in men with prostate cancer on ADT	**SERM**	3,377	11,724	(8,347)
Toremifene 20 mg				
Prevention of prostate cancer in high risk men with high grade PIN	**SERM**	5,881	9,338	(3,457)
Other research and development		12,333	13,438	(1,105)
Total research and development expenses		$ 32,344	$ 44,259	$ (11,915)

General and Administrative Expenses. General and administrative expenses increased 20% to $27.8 million for the year ended December 31, 2009 from $23.1 million for the year ended December 31, 2008. The increase of approximately $4.6 million was primarily the result of increased personnel and personnel related expenses of approximately $5.3 million, severance costs and legal fees of $656,000 related to the workforce reduction that occurred in December 2009, and an increase of approximately $630,000 in intellectual property and other legal expenses. These increases were slightly offset by a decrease in marketing expenses of approximately $950,000 due to lower spending on marketing expositions and public relation activities in 2009. General and administrative expenses were also lower in the year ended December 31, 2009 as compared to the prior year as a result of our decision to not pay cash bonuses to employees for 2009. General and administrative expenses for the year ended December 31, 2008 included employee bonus expense of approximately $1.3 million.

Other Income, Net. Other income, net decreased to $188,000 for the year ended December 31, 2009 from $2.7 million for the year ended December 31, 2008. The decrease of approximately $2.5 million was attributable to lower average interest rates and lower average cash balances during the year ended December 31, 2009, as compared to the prior year.

Liquidity and Capital Resources

Through December 31, 2010, we have financed our operations and internal growth primarily through public offerings and private placements of our common stock, as well as payments from our former collaborators. 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, 2010, we had an accumulated deficit of $352.9 million, which resulted primarily from:

- our research and development activities associated with:
  - the preclinical and clinical development of our SARM compounds, including Ostarine™ for the prevention and treatment of muscle wasting in patients with cancer;
  - the preclinical and clinical development of Capesaris™ for first line treatment of advanced prostate cancer;

- the development of toremifene 80 mg to reduce fractures and treat other estrogen deficiency side effects of ADT in men with prostate cancer, including two Phase II clinical trials, a pivotal Phase III clinical trial, and the preparation and submission of a NDA to the FDA;
- the development of toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, including our Phase IIb clinical trial and a Phase III clinical trial;
- the preclinical development of other product candidates;

- 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, which was converted to common stock in conjunction with our initial public offering.

Although we reported net income for the year ending December 31, 2010, it was primarily the result of the termination of our collaboration with Merck and the recognition in the first quarter of $49.9 million in deferred revenue from the collaboration. However, while recognition of this revenue resulted in net income for 2010, we expect to incur significant operating losses in 2011 and for the foreseeable future as we continue our clinical development and research and development activities. Due to the termination of our license and collaboration with Ipsen in March 2011, we expect to recognize as collaboration revenue all of the remaining $8.1 million unamortized revenue that was deferred as of December 31, 2010 during the first quarter of 2011. We do not expect to obtain FDA or any other regulatory approvals to market any of our product candidates in the near future.

At December 31, 2010, we had cash, cash equivalents and short-term investments of $58.6 million, compared to $49.0 million at December 31, 2009 and $97.7 million at December 31, 2008. As of December 31, 2010, our cash and cash equivalents consisted of bank deposits, certificates of deposit with original maturities of 90 days or less, and money market mutual funds which are required to comply with Rule 2a-7 under the Investment Company Act of 1940. Our short-term investments consisted of investments in certificates of deposit with original maturities greater than three months and less than one year. On November 1, 2010, we completed an underwritten public offering of 14,285,715 shares of our common stock at a price to the public of $2.80 per share. Net cash proceeds from the public offering were approximately $37.7 million after deducting underwriting discounts and commissions and other offering expenses. We also granted the underwriter a 30-day option to purchase up to an additional 2,142,857 shares of common stock to cover over-allotments, if any. On November 24, 2010, the underwriter exercised its option and purchased an additional 1,000,000 shares of our common stock at a price of $2.80 per share. Net cash proceeds from the exercise of the over-allotment option were approximately $2.6 million after deducting underwriting discounts and commissions and other offering expenses.

In September 2006, we entered into a collaboration and license agreement with Ipsen, under which Ipsen paid us €21.5 million (approximately $27.1 million) as a license fee and expense reimbursement and paid us €1.5 million in equal installments over a three year period from the date of the agreement. In September of 2009, 2008, and 2007, we received €500,000 (approximately $726,000, $711,000, and $688,000, respectively) from Ipsen for the three annual installment payments. In February 2008, we earned a milestone of €1.0 million (approximately $1.5 million) with the achievement of the primary endpoint in the toremifene 80 mg Phase III clinical trial. As a result of the termination of our collaboration with Ipsen in March of 2011, we will not receive any future milestone payments, royalties or reimbursement of clinical development expenses for the development or sale of toremifene from Ipsen provided for under our former collaboration with Ipsen.

In December 2007, we entered into an exclusive license and collaboration agreement with Merck, or the Merck Collaboration Agreement, which was terminated in March 2010. In connection with entering into this agreement, we received an upfront licensing fee of $40.0 million in January 2008, and Merck purchased approximately $30.0 million of our common stock in December 2007. Merck also paid 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 received the three annual payments of $5 million from Merck in December 2010, 2009, and 2008, respectively. As a result of the termination of our collaboration with Merck, we will not receive any milestone payments or royalties for the development or sale of SARMs from Merck provided for under our former collaboration with Merck. As of the date of this report, we had no ongoing collaborations for the development and commercialization of our product candidates, and we do not currently have any commitments for future external funding.

Net cash used in operating activities was $30.5 million, $46.0 million and $2.9 million for the years ended December 31, 2010, 2009 and 2008, respectively. The use of cash in all periods resulted primarily from funding our operations. In 2010, this was reduced by $5.0 million received from Merck related to the third and final cost reimbursement payment in conjunction with our exclusive license and collaboration agreement and grants totaling $1.2 million received from the United States government under the Qualifying Therapeutic Discovery Project Program. In 2009, the cash used in operating activities was partially offset by approximately $726,000 related to the third and final annual license fee and expense reimbursement installment payment from Ipsen in conjunction with our collaboration and license agreement, $5.0 million from Merck related to the second annual installment cost reimbursement payment in conjunction with our exclusive license and collaboration agreement, and approximately $2.3 million in distributions from our investment in Bank of America Corporation's Columbia Strategic Cash Portfolio. In 2008, the cash used in operating activities was substantially offset by the receipt of $40.0 million in conjunction with our exclusive license and collaboration agreement with Merck, approximately $1.5 million from Ipsen due to the achievement of the primary endpoint in the toremifene 80 mg Phase III clinical trial, approximately $711,000 related to the second annual license fee and expense reimbursement installment payment from Ipsen in conjunction with our collaboration and license agreement, $5.0 million from Merck related to the first annual installment payment in conjunction with our exclusive license and collaboration agreement, and approximately $7.1 million in distributions from our investment in Bank of America Corporation's Columbia Strategic Cash Portfolio.

Net cash provided by investing activities for the year ended December 31, 2010 was $8.3 million and resulted from the maturities of short-term investments of $16.9 million, offset by the purchase of short-term investments of $8.6 million and the purchase of information technology equipment and research and development equipment of approximately $95,000. Net cash used in investing activities for the year ended December 31, 2009 was $9.4 million and was for the purchase of short-term investments in certificates of deposit of approximately $11.3 million and the purchase of information technology equipment, research and development equipment, and software totaling approximately $600,000. This was reduced by the maturities of certificates of deposit of approximately $2.5 million. Net cash used in investing activities for the year ended December 31, 2008 was $2.9 million and was primarily for the purchase of furniture and fixtures, leasehold improvements, office equipment, software and information technology equipment related to the addition of office space. Additionally, investing activities in 2008 included the purchase of research and development equipment.

Net cash provided by financing activities was $40.2 million, $131,000 and $1.2 million for the years ended December 31, 2010, 2009 and 2008, respectively. Net cash provided by financing activities for the year ended December 31, 2010 reflected proceeds from our underwritten public offering of common stock in November 2010 and proceeds from the exercise of employee stock options. These proceeds were reduced by payments on our capital lease and financed equipment obligations. Net cash provided by financing activities for the years ended December 31, 2009 and 2008 was provided primarily from proceeds from the exercises of employee stock options.

We estimate that our current cash, cash equivalents, and short-term investments, together with interest income and product revenue from the sale of FARESTON®, will be sufficient to meet our projected operating requirements for at least the next twelve months. We have based this estimate on our current business plan and assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect and we could need additional funding sooner than currently anticipated. We believe that our current cash resources, together with interest income and product revenue from the sale of FARESTON®, will be sufficient to enable us to initiate in 2011 our planned Phase III clinical trial of Ostarine™ for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer and to initiate and complete our planned Phase IIb clinical trial to evaluate Capesaris™ for first line treatment of advanced prostate cancer. To complete the Phase III clinical trial we expect to initiate in 2011 for Ostarine™, we may need to obtain additional funding. However to conduct any additional clinical trials for our product candidates, we will need to raise additional capital through partnerships and/or collaborations or the sale of our securities.

Our estimate of the period of time through which our financial resources will be adequate to support our projected operating requirements is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed under Part II, Item 1A "Risk Factors" section of this Annual Report on Form 10-K. Because of the numerous risks and uncertainties associated with the development and potential 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 and commercialization activities, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures associated with our anticipated future clinical trials, other research and development activities, and potential commercialization activities. Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical trials and other research and development activities, including our currently-planned clinical trials of Ostarine™ and Capesaris™;
- the terms and timing of any potential future collaborative, licensing and other arrangements that we may establish;
- whether and to what extent we determine to continue the development of toremifene 80 mg;
- future clinical trial results;
- the cost and timing of regulatory filings and/or approvals to commercialize our product candidates and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- the amount and timing of any licensing fees, milestone payments and royalty payments from potential future collaborators, if any;
- the cost and timing of establishing medical education, sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we and/or any potential future 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 cost of defending any other litigation claims; 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.

We do not currently have any commitments for future external funding and until we can generate a sufficient amount of product revenue, which we may never do, we expect to finance future cash needs through public or private equity offerings, debt financings or collaboration and licensing arrangements, or a combination of the above, as well as through interest income earned on the investment of our cash balances and short-term investments and revenues from the sale of FARESTON®. In December 2009, we announced a reduction of approximately 26% of our workforce in order to reduce our operating expenses in connection with the receipt of the Complete Response Letter regarding our NDA for toremifene 80 mg and the associated delay in the potential regulatory approval of toremifene 80 mg. If we are unable to raise additional funds when we need them, we may need to further reduce our expenditures, perhaps significantly, to preserve our cash. The cost-cutting measures that we may take in the future may not be sufficient to enable us to meet our cash requirements, and they may negatively affect our business and growth prospects. To the extent we raise additional funds by issuing equity securities, our stockholders may experience dilution, and 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. To the extent we raise additional funds through potential future collaboration and licensing arrangements, it may be necessary to

relinquish rights to some of our technologies or product candidates, or grant licenses on terms that are not favorable to us. Our ability to raise additional funds and the terms upon which we are able to raise such funds may be adversely impacted by the uncertainty regarding our ability to fully finance our currently-planned clinical trial of Ostarine™ and additional clinical trials of Ostarine™ and Capesaris™ and/or current economic conditions, including the effects of the disruptions to and continuing volatility in the credit and financial markets in the United States and worldwide. As a result of these and other factors, we cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available when we need them, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs, including our SARM, selective ER alpha agonist, and toremifene programs, or conduct additional workforce or other expense reductions, any of which could have a material adverse effect on our business.

At December 31, 2010, 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	$ 24	$ 7	$ 17	$ —	$ —
Operating lease obligations	4,085	1,451	2,449	185	—
Equipment financing obligation	168	84	84	—	—
Purchase obligations	7	7	—	—	—
Total	$ 4,284	$ 1,549	$ 2,550	$ 185	$ —

Our long-term commitments under the operating leases shown above consist of payments relating to a sublease for laboratory and office space at 3 North Dunlap Street, Memphis, Tennessee and a sublease for office space at 175 Toyota Plaza, Memphis, Tennessee. Our sublease agreement for the premises located at 3 North Dunlap Street expires on December 31, 2012, with an option to extend for two additional years. The sublease for the premises at 175 Toyota Plaza expires on April 30, 2015 and includes escalating rental payments. In July 2008, we amended this sublease agreement to add additional office space. In February 2011, we amended the sublease agreement to eliminate the additional office space, effective January 1, 2011. 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 and investments in certificates of deposit. 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 an immaterial decrease in our interest income for the year ended December 31, 2010.

We operate primarily in the United States. However, our clinical trial sites may be located in foreign countries which could require us to make payments for certain clinical trial services in foreign currencies. Our exposure to foreign currency rate fluctuations will increase if we initiate future clinical trials outside the United States and to the extent we are able to commercialize toremifene 80 mg because we are obligated to pay Orion Corporation, our supplier of toremifene, in Euros. However, we do not expect that our total exposure to changes in foreign currencies will be material to our operating results in 2011. 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, 2010 using the criteria for effective internal control over financial reporting as described in "Internal Control — Integrated Framework," issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, we concluded that, as of December 31, 2010, 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 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 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not applicable.

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 2011 Annual Meeting of Stockholders with the U.S. Securities and Exchange Commission pursuant to Regulation 14A (the "2011 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 2011 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 and Certain Corporate Governance Matters" appearing in the 2011 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 2010 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.

(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 "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, 175 Toyota Plaza, Suite 700, Memphis, Tennessee 38103. 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 location 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 2011 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 2011 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 2011 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 2011 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 2011 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 2011 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 2011 Proxy Statement under the section entitled "Additional Information About the Board of Directors and Certain Corporate Governance Matters — 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 2011 Proxy Statement under the section entitled "Proposal No. 3 — 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)
10.1*	Genotherapeutics, Inc. 1999 Stock Option Plan, as amended through December 10, 2009, and Form of Stock Option Agreement(5)
10.2*	GTx, Inc. 2000 Stock Option Plan, as amended through December 10, 2009, and Form of Stock Option Agreement(5)
10.3*	GTx, Inc. 2001 Stock Option Plan, as amended through November 3, 2009, and Form of Stock Option Agreement(5)
10.4*	GTx, Inc. 2002 Stock Option Plan, as amended through November 3, 2009, and Form of Stock Option Agreement(5)
10.5*	GTx, Inc. 2004 Equity Incentive Plan and Form of Stock Option Agreement(3)
10.6*	GTx, Inc. 2004 Equity Incentive Plan, as amended effective April 30, 2008(6)
10.8*	Amended and Restated Employment Agreement dated November 10, 2008, between Registrant and Mitchell S. Steiner, M.D.(7)
10.9*	Amended and Restated Employment Agreement dated November 10, 2008, between Registrant and Marc S. Hanover(7)
10.10*	Amended and Restated Employment Agreement dated November 10, 2008, between Registrant and Mark E. Mosteller(7)
10.11*	Amended and Restated Employment Agreement dated November 10, 2008, between Registrant and Henry P. Doggrell(7)
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)
10.24†	Purchase Agreement dated December 13, 2004, between Registrant and Orion Corporation(10)
10.25†	Amended and Restated License and Supply Agreement effective January 1, 2005, between Registrant and Orion Corporation(11)
10.26	Sublease Agreement dated April 1, 2005, as amended, between Registrant and TriStar Enterprises, Inc.(12)
10.27*	Amended and Restated Employment Agreement dated November 10, 2008 between Registrant and James T. Dalton(7)
10.28*	2010 Compensation Information for Registrant's Executive Officers (5)
10.30*	GTx, Inc. 2004 Non-Employee Directors' Stock Option Plan and Form of Stock Option Agreement(3)
10.31*	Amended and Restated GTx, Inc. 2004 Non-Employee Directors' Stock Option Plan, effective April 26, 2006(13)
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(14)
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(15)
10.34*	Form of Stock Option Agreement under the Amended and Restated GTx, Inc. 2004 Non-Employee Directors' Stock Option Plan(16)
10.35†	Partial Assignment Agreement among Registrant, Orion Corporation and Ipsen Limited dated September 7, 2006(17)
10.36†	Collaboration and License Agreement between Registrant and Ipsen Limited dated September 7, 2006(18)
10.38*	Amended and Restated Employment Agreement dated November 10, 2008, between Registrant and Ronald A. Morton, Jr., M.D.(7)
10.40†	Consolidated, Amended, and Restated License Agreement dated July 24, 2007, between Registrant and University of Tennessee Research Foundation(8)
10.41†	Amended and Restated License Agreement dated September 24, 2007, between Registrant and University of Tennessee Research Foundation(8)
10.44*	Amended and Restated Employment Agreement, dated November 10, 2008, between Registrant and Gregory A. Deener(7)
10.46	Sublease Agreement, dated December 17, 2007 by and between the Registrant and ESS SUSA Holdings, LLC(19)

Number	Description
10.47	First Amendment, dated December 29, 2008, to the Consolidated, Amended and Restated License Agreement dated July 24, 2007 between the Registrant and University of Tennessee Research Foundation(7)
10.48	First Amendment, dated December 29, 2008, to the Amended and Restated License Agreement dated September 24, 2007 between the Registrant and University of Tennessee Research Foundation(7)
10.49*	Directors' Deferred Compensation Plan, as amended effective November 4, 2008(7)
10.50*	Non-Employee Director Compensation Policy of GTx, Inc., effective January 1, 2009(7)
10.51*	Amended and Restated GTx, Inc. 2004 Non-Employee Directors' Stock Option Plan, as amended effective November 4, 2008(7)
10.52*	GTx, Inc. 2004 Equity Incentive Plan, as amended effective November 4, 2008 and Form of Stock Option Agreement(7)
10.53*	Amended and Restated GTx, Inc. Executive Bonus Compensation Plan, effective November 4, 2008(7)
10.54	First Amendment, dated July 21, 2008, to the Sublease and Parking Sublicense Agreements dated December 17, 2007 by and between the Registrant and ESS SUSA Holdings, LLC(7)
10.55	Sublease Agreement dated October 1, 2009 between Registrant and University of Tennessee Research Foundation(5)
10.56†	First Amendment to the Collaboration and License Agreement of 7 September 2006 between the Registrant and Ipsen Biopharm Limited dated March 22, 2010(20)
10.57+	Second Amendment to Sublease and Parking Sublicense Agreements dated January 1, 2011 by and between the Registrant and ESS SUSA Holdings, LLC
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)(21)
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)(21)

† Confidential treatment has been granted with respect to certain portions of this exhibit. This exhibit omits the information subject to this confidentiality request. Omitted portions have been filed separately with the SEC.

* Indicates a management contract or compensation plan or arrangement.

+ Filed herewith

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

(2) Filed as 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 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 Annual Report on Form 10-K (File No. 000-50549), filed with the SEC on March 15, 2010, and incorporated herein by reference.

(6) 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 May 6, 2008, 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 3, 2009, and incorporated herein by reference.

(8) 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.

(9) 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.

(10) 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.

(11) 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.

(12) 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.

(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 April 27, 2006, and incorporated herein by reference.

(14) 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.

(15) 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.

(16) 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.

(17) 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.

(18) 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.

(19) 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 11, 2008, and incorporated herein by reference.

(20) 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 May 4, 2010, and incorporated herein by reference.

(21) 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 8, 2011

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 8, 2011
/s/ Mitchell S. Steiner Mitchell S. Steiner, M.D., F.A.C.S.	Chief Executive Officer, Vice Chairman and Director (Principal Executive Officer)	March 8, 2011
/s/ Mark E. Mosteller Mark E. Mosteller, CPA	Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 8, 2011
/s/ Marc S. Hanover Marc S. Hanover	Director	March 8, 2011
/s/ Michael G. Carter Michael G. Carter, M. D.	Director	March 8, 2011
/s/ Barrington J. A. Furr Barrington J. A. Furr	Director	March 8, 2011

		Date
/s/ J. Kenneth Glass J. Kenneth Glass	Director	March 8, 2011
/s/ Robert W. Karr Robert W. Karr, M.D.	Director	March 8, 2011
/s/ John H. Pontius John H. Pontius	Director	March 8, 2011
/s/ Kenneth S. Robinson Rev. Kenneth S. Robinson, M.D.	Director	March 8, 2011
/s/ Timothy R. G. Sear Timothy R. G. Sear	Director	March 8, 2011

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, 2010 using the criteria for effective internal control over financial reporting as described in "Internal Control — Integrated Framework," issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, we concluded that, as of December 31, 2010, 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 and Chief Financial Officer

Memphis, Tennessee
March 8, 2011

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, 2010, 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, 2010, 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 of GTx, Inc. as of December 31, 2010 and 2009, and the related statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2010 and our report dated March 8, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Memphis, Tennessee
March 8, 2011

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, 2010 and 2009, and the related statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2010. 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, 2010 and 2009, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2010, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), GTx, Inc.'s internal control over financial reporting as of December 31, 2010, 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 8, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Memphis, Tennessee
March 8, 2011

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

	December 31, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 58,181	$ 40,219
Short-term investments	450	8,825
Accounts receivable, net	683	406
Inventory	171	116
Receivable from collaboration partners	—	189
Prepaid expenses and other current assets	875	920
Total current assets	60,360	50,675
Property and equipment, net	2,040	3,291
Intangible and other assets, net	1,850	3,755
Total assets	$ 64,250	$ 57,721
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 848	$ 1,268
Accrued expenses and other current liabilities	3,112	4,730
Deferred revenue — current portion	1,345	9,954
Total current liabilities	5,305	15,952
Deferred revenue, less current portion	6,721	49,898
Other long-term liabilities	497	621
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock, $0.001 par value: 60,000,000 shares authorized; 51,719,187 shares issued and outstanding at December 31, 2010 and 36,420,901 shares issued and outstanding at December 31, 2009	52	36
Additional paid-in capital	404,555	359,388
Accumulated deficit	(352,880)	(368,174)
Total stockholders' equity (deficit)	51,727	(8,750)
Total liabilities and stockholders' equity (deficit)	$ 64,250	$ 57,721

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,		
	2010	**2009**	**2008**
Revenues:			
Product sales, net	$ 3,827	$ 3,289	$ 1,088
Collaboration revenue	56,786	11,441	12,440
Total revenues	60,613	14,730	13,528
Costs and expenses:			
Cost of product sales	768	1,290	649
Research and development expenses	28,495	32,344	44,259
General and administrative expenses	17,419	27,778	23,140
Total costs and expenses	46,682	61,412	68,048
Income (loss) from operations	13,931	(46,682)	(54,520)
Other income, net	1,363	188	2,740
Income (loss) before income taxes	15,294	(46,494)	(51,780)
Income tax benefit	—	238	—
Net income (loss)	$ 15,294	$ (46,256)	$ (51,780)
Net income (loss) per share:			
Basic and diluted	$ 0.39	$ (1.27)	$ (1.43)
Weighted average shares used in computing net income (loss) per share:			
Basic and diluted	38,874,721	36,415,379	36,301,558

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

GTx, Inc.
STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
For the Years Ended December 31, 2010, 2009 and 2008
(in thousands, except share and per share data)

	Stockholders' Equity (Deficit)				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balances at January 1, 2008	36,216,263	$ 36	$ 349,019	$ (270,138)	$ 78,917
Exercise of employee stock options	176,180	—	1,167	—	1,167
Directors' deferred compensation	—	—	178	—	178
Share-based compensation	—	—	3,536	—	3,536
Net loss and comprehensive loss	—	—	—	(51,780)	(51,780)
Balances at December 31, 2008	36,392,443	36	353,900	(321,918)	32,018
Exercise of employee stock options	18,434	—	136	—	136
Directors' deferred compensation	—	—	178	—	178
Issuance of common stock under deferred compensation arrangements	10,024	—	—	—	—
Share-based compensation	—	—	5,174	—	5,174
Net loss and comprehensive loss	—	—	—	(46,256)	(46,256)
Balances at December 31, 2009	36,420,901	36	359,388	(368,174)	(8,750)
Issuance of common stock, net of offering costs	15,285,715	15	40,273	—	40,288
Issuance of common stock under deferred compensation arrangements	8,321	—	—	—	—
Exercise of employee stock options	4,250	—	9	—	9
Directors' deferred compensation	—	1	186	—	187
Share-based compensation	—	—	4,699	—	4,699
Net loss and comprehensive loss	—	—	—	15,294	15,294
Balances at December 31, 2010	51,719,187	$ 52	$ 404,555	$ (352,880)	$ 51,727

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

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

	Years Ended December 31,		
	2010	**2009**	**2008**
Cash flows from operating activities:			
Net income (loss)	$ 15,294	$ (46,256)	$ (51,780)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation and amortization	1,573	1,785	1,562
Share-based compensation	4,699	5,174	3,536
Directors' deferred compensation	187	178	178
Deferred revenue amortization	(51,786)	(11,441)	(10,957)
Impairment of intangible assets	1,687	—	—
Write off of property and equipment	—	114	—
Foreign currency transaction loss	—	—	34
Changes in assets and liabilities:			
Short-term investments, trading	—	2,157	7,653
Accounts receivable, net	(277)	81	(370)
Inventory	(55)	(24)	(14)
Receivable from collaboration partners	189	588	40,610
Prepaid expenses and other assets	36	85	383
Accounts payable	(420)	(1,553)	1,207
Accrued expenses and other long-term liabilities	(1,654)	(1,956)	33
Deferred revenue	—	5,071	5,000
Net cash used in operating activities	(30,527)	(45,997)	(2,925)
Cash flows from investing activities:			
Purchase of property and equipment	(95)	(600)	(2,905)
Purchase of short-term investments, held to maturity	(8,569)	(11,275)	—
Proceeds from maturities of short-term investments, held to maturity	16,944	2,450	—
Net cash provided by (used in) investing activities	8,280	(9,425)	(2,905)
Cash flows from financing activities:			
Proceeds from issuance of common stock	40,288	—	—
Proceeds from exercise of employee stock options	9	136	1,167
Payments on capital lease and financed equipment obligations	(88)	(5)	(5)
Net cash provided by financing activities	40,209	131	1,162
Net increase (decrease) in cash and cash equivalents	17,962	(55,291)	(4,668)
Cash and cash equivalents, beginning of year	40,219	95,510	100,178
Cash and cash equivalents, end of year	$ 58,181	$ 40,219	$ 95,510
Supplemental schedule of non-cash investing and financing activities:			
Equipment purchased under debt or capital lease	$ —	$ 268	$ —

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 for the treatment of cancer and the side effects of anticancer therapy, cancer supportive care, and other serious medical conditions. GTx operates in one business segment.

The Company is developing selective androgen receptor modulators ("SARMs"), a new class of drugs with the potential to prevent and treat muscle wasting in patients with cancer and other musculoskeletal wasting or muscle loss conditions including chronic sarcopenia (age related muscle loss). In March 2010, the Company reacquired full rights to its SARM program, including Ostarine™ (GTx-024), following the termination by the Company and Merck & Co., Inc. ("Merck") of their exclusive license and collaboration agreement for SARM compounds and related SARM products. See Note 8, *Collaboration and License Agreements*, for further discussion.

Additionally, the Company is developing Capesaris™ (GTx-758), a selective estrogen receptor alpha agonist, for first line treatment of advanced prostate cancer. In September 2010, the Company announced that in a Phase II, open label, pharmacokinetic/pharmacodynamic clinical trial, Capesaris™ suppressed serum total testosterone to castrate levels, increased serum sex hormone binding globulin, and reduced serum free testosterone in young healthy male volunteers.

In December 2008, the Company submitted a New Drug Application ("NDA") for toremifene 80 mg, a selective estrogen receptor modulator ("SERM"), to reduce fractures in men with prostate cancer on androgen deprivation therapy ("ADT") to the U.S. Food and Drug Administration ("FDA"). In October 2009, the Company received a Complete Response Letter from the FDA regarding its NDA for toremifene 80 mg notifying the Company that the FDA would not approve the Company's NDA in its present form as a result of certain clinical deficiencies identified in the Complete Response Letter. In April 2010, the Company submitted to the FDA a proposed protocol for a second pivotal Phase III clinical trial evaluating toremifene 80 mg to reduce fractures in men with prostate cancer on ADT to address in a single clinical trial the deficiencies identified by the FDA in the Complete Response Letter. Based on the Company's discussions with the FDA to date, the Company believes that it has finalized the protocol for a second pivotal Phase III clinical trial. In March 2011, the Company reacquired full rights to its toremifene program following the termination by the Company and Ipsen Biopharm Limited, or Ipsen, of the collaboration and license agreement, which was entered into in September 2006 and amended in March 2010. Pending the Company's ongoing discussions with the FDA regarding whether an additional single Phase III clinical trial of toremifene 80 mg to address the deficiencies identified in the Complete Response Letter can be conducted as a post-approval study, it does not plan to continue any further clinical development of toremifene 80 mg. In the event that the FDA allows this clinical trial to be conducted as a post-approval study and the Company is able to secure sufficient funding for the study through new partnerships or collaborations or through other financing, it will reevaluate whether to continue the development of toremifene 80 mg. See Note 13, *Subsequent Events*, for further discussion.

In May 2010, the Company announced that toremifene 20 mg failed to meet the primary efficacy endpoint in a completed Phase III clinical trial evaluating toremifene 20 mg for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia ("high grade PIN"). The Company does not expect to conduct additional clinical trials evaluating toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN or to submit a NDA to the FDA for this indication.

The Company markets FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of advanced metastatic breast cancer in postmenopausal women in the United States.

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

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

At December 31, 2010 and 2009, short-term investments consisted of certificates of deposit with original maturities of greater than three months and less than one year. As the Company has the positive intent and ability to hold the certificates of deposit until maturity, these investments have been classified as held to maturity investments and are stated at cost, which approximates fair value.

Accounts Receivable

Accounts receivable are recorded net of allowances for cash discounts for prompt payment. The Company makes judgments as to its ability to collect outstanding receivables and will provide allowances for the portion of receivables if and when collection becomes doubtful. The Company has not recorded reserves related to the collectability of its accounts receivable for the years ended December 31, 2010 and 2009.

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. The Company analyzes its current inventory levels and will write down inventory if it has become un-saleable or has a cost basis in excess of its expected net realizable value. To date, there have been no inventory write-downs.

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 7 years
Furniture and fixtures	5 years
Computer equipment and software	3 years

Intangible Assets

The Company amortizes its purchased intangible assets with finite lives over their estimated economic lives. The Company's purchased intangible assets, license fees, represent the value of each license acquired by the Company pursuant to the agreements described in Note 6, *Intangible Assets*. The license fees are being amortized on a straight-line basis over the respective terms of the agreements.

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

Impairment of Long-Lived Assets

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 is recognized when estimated future cash flows are less than the carrying amount. The cash flow estimates are based on management's best estimates, using appropriate and customary assumptions and projections at the time. See Note 6, *Intangible Assets*, for further discussion.

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. The method of determining the fair value for the Company's short-term investments is discussed under *Short-term Investments* in this Note 2.

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 mutual funds. Bank deposits may at times be in excess of FDIC insurance limits. The Company's short-term investments consist of investments in certificates of deposit with original maturities of greater than 3 months and less than 1 year as discussed under *Short-term Investments* in this Note 2.

Three wholesale drug distributors individually comprised 18%, 47% and 30%, respectively, of the Company's accounts receivable as of December 31, 2010. These same three distributors represented 19%, 43% and 33%, respectively, of the Company's product sales for the year ended December 31, 2010.

Revenue Recognition

The Company recognizes revenue from product sales of FARESTON® less deductions for estimated sales discounts and sales returns. Revenue from product sales is recognized when persuasive evidence of an arrangement exists, title passes, the price is fixed or determinable, and collectability is reasonably assured. 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, 2010 and 2009, the Company's accrual for product returns was $802 and $494, respectively.

Collaboration revenue consists of non-refundable upfront payments, license fees, reimbursements for research and development activities, and milestone payments associated with the Company's collaboration and license agreements. Revenues from licensing agreements are recognized based on the performance requirements of the specific agreements. 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. For these arrangements for which the Company is not able to identify evidence of fair value for the undelivered elements, the Company will recognize any consideration for a single unit of accounting in the same manner as revenue is recognized for the final deliverable, which is ratable over the performance period. The performance period is estimated at the inception of each agreement and is reevaluated at each reporting period. 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 product candidates and technology, such as initiation of clinical trials, achievement of specified clinical trial endpoints, filing for approval with regulatory agencies and approvals by regulatory agencies. Due to the termination of the Company's license and collaboration agreement with Merck in March 2010, the Company recognized collaboration revenue of $54,856 in the first quarter of 2010 as the agreement was terminated and the Company has no further performance obligations. See Note 8, *Collaboration and License Agreements*, for further discussion.

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

Research and Development Expenses

Research and development expenses include, but are not limited to, the Company's expenses for personnel, supplies, and facilities associated with research activities, screening and identification of product candidates, formulation and synthesis activities, manufacturing, preclinical studies, toxicology studies, clinical trials, regulatory affairs activities, quality assurance activities and license fees. The Company expenses these costs in the period in which they are incurred. The Company estimates its liabilities for research and development expenses in order to match the recognition of expenses to the period in which the actual services are received. As such, accrued liabilities related to third party research and development activities are recognized based upon the Company's estimate of services received and degree of completion of the services in accordance with the specific third party contract.

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.

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, 2010 and 2009, net of the valuation allowance, the net deferred tax assets were reduced to zero. See Note 9, *Income Taxes*, for further discussion.

Stock Options

The Company has stock option and equity incentive plans that provide for the purchase or acquisition of the Company's common stock by certain of the Company's employees and directors. The Company recognizes compensation expense for its share-based payments based on the fair value of the awards over the period during which an employee or director is required to provide service in exchange for the award. See Note 3, *Share-Based Compensation*, for further discussion.

Other Income, Net

Other income, net consists of interest earned on the Company's cash, cash equivalents and short-term investments, interest expense, foreign currency transaction gains and losses, and other non-operating income or expense.

For the year ended December 31, 2010, other income, net included income from grants totaling $1,220 awarded to the Company by the United States Government under the Qualifying Therapeutic Discovery Project Program, which was established under the Patient Protection and Affordable Care Act. The Company was granted $244 for each of five applications submitted for the Company's cancer and cancer supportive care research and development programs.

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

Reclassification

The foreign currency transaction gains and losses and interest expense in prior periods have been reclassified to other income, net from general and administrative expenses in the statement of operations.

Basic and Diluted Net Income (Loss) Per Share

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

The following table sets forth the computation of the Company's basic and diluted net income (loss) per share for the years ended December 31, 2010, 2009 and 2008:

	Years Ended December 31,		
	2010	2009	2008
Basic and diluted net income (loss) per share			
Numerator:			
Net income (loss)	$ 15,294	$ (46,256)	$ (51,780)
Denominator:			
Weighted average shares used in computing basic and diluted net income (loss) per share	38,874,721	36,415,379	36,301,558
Basic and diluted net income (loss) per share	$ 0.39	$ (1.27)	$ (1.43)

Weighted average options outstanding to purchase shares of common stock of 4,473,576, 3,597,716, and 2,638,760 were excluded from the calculation of diluted net income (loss) per share for the years ended December 31, 2010, 2009 and 2008, respectively, as inclusion of the options would have had an anti-dilutive effect on the net income (loss) per share for the periods. At December 31, 2010, the Company had outstanding 51,719,187 shares of common stock.

Comprehensive Loss

For all periods presented, there were no differences between net loss and comprehensive loss.

3. Share-Based Compensation

Share-based payments include stock option grants under the Company's stock option and equity incentive plans and deferred compensation arrangements for the Company's non-employee directors.

The Company grants to employees and non-employee directors options to purchase common stock under various plans at prices equal to the fair market value of the stock on the dates the options are granted as determined in accordance with the terms of the applicable plan. The options have a term of ten years from the grant date and vest over three years from the grant date for director options and over periods of up to five years from the grant date for employee options. Employees generally have three months after the employment relationship ends to exercise all vested options except in the case of voluntary retirement, disability or death, where exercise periods are generally longer. The Company issues new shares of common stock upon the exercise of options. The Company estimates the fair value of certain stock option awards as of the date of the grant by applying the Black-Scholes-Merton option pricing valuation model. The application of this valuation model involves assumptions that are judgmental and highly sensitive in the determination of compensation expense.

The 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 amount of share-based compensation expense recognized is reduced ratably over the vesting period by an estimate of the percentage of options granted that are expected to be forfeited or canceled before becoming fully vested.

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

The following table summarizes share-based compensation expense included within the statements of operations for each of the three years in the period ended December 31, 2010:

	Years Ended December 31,		
	2010	2009	2008
Research and development expenses	$ 2,340	$ 2,143	$ 1,682
General and administrative expenses	2,546	3,209	2,032
Total share-based compensation	$ 4,886	$ 5,352	$ 3,714

Share-based compensation expense recorded in the statement of operations as general and administrative expense for the years ended December 31, 2010, 2009 and 2008 included share-based compensation expense related to deferred compensation arrangements for the Company's non-employee directors of $187, $178 and $178, respectively. See Note 10, *Directors' Deferred Compensation Plan*, for further discussion of deferred compensation arrangements for the Company's non-employee directors.

For the years ended December 31, 2010, 2009 and 2008, the weighted average grant date fair value per share of options granted was $2.62, $8.45 and $8.54, respectively. The weighted average for key assumptions used in determining the grant date fair value of options granted in 2010, 2009 and 2008, and a summary of the methodology applied to develop each assumption were as follows:

	Years Ended December 31,		
	2010	2009	2008
Expected price volatility	64.6%	55.0%	51.6%
Risk-free interest rate	3.36%	2.04%	3.5%
Weighted average expected life in years	6.5years	6.9years	6.9years
Dividend yield	0%	0%	0%

Expected Price Volatility — This is a measure of the amount by which a price has fluctuated or is expected to fluctuate. The Company based its determination of expected volatility on its historical stock price volatility. An increase in the expected price volatility will increase compensation expense.

Risk-Free Interest Rate — This is determined using U.S. Treasury rates where the term is consistent with the expected life of the stock options. 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. The Company has utilized this method due to the lack of historical option exercise information related to the Company's stock option and equity incentive 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.

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

The following is a summary of stock option transactions for all of the Company's stock option and equity incentive plans for the three year period ended December 31, 2010:

	Number of Shares	Weighted Average Exercise Price Per Share
Options outstanding at January 1, 2008	1,879,652	11.27
Options granted	1,013,000	15.19
Options forfeited	(42,496)	14.07
Options exercised	(176,180)	6.62
Options outstanding at December 31, 2008	2,673,976	13.01
Options granted	1,118,150	15.07
Options forfeited or expired	(408,821)	14.52
Options exercised	(18,434)	7.37
Options outstanding at December 31, 2009	3,364,871	13.55
Options granted	1,320,500	4.14
Options forfeited or expired	(250,626)	10.68
Options exercised	(4,250)	2.24
Options outstanding at December 31, 2010	4,430,495	10.91
Options vested and expected to vest at December 31, 2010	4,280,224	10.94

The following table summarizes information about stock options outstanding at December 31, 2010:

	Options Outstanding			Options Exercisable	
Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$2.80 – $6.24	1,546,463	7.77	$ 4.55	303,463	$ 6.24
$6.78 – $14.50	1,481,915	5.36	11.44	714,265	9.54
$14.77 – $20.40	1,402,117	7.28	17.38	215,773	18.30
	4,430,495	6.81	10.91	1,233,501	10.26

At December 31, 2010, the Company's outstanding options had a weighted average remaining contractual term of 6.8 years and had no intrinsic value. Of the Company's outstanding options, 1,233,501 options were exercisable and had a weighted average remaining contractual term of 3.8 years and had no intrinsic value. Additionally, the Company's vested and expected to vest options had a weighted average remaining contractual term of 6.8 years and had no intrinsic value. Options to purchase 4,250 shares were exercised during the year ended December 31, 2010. The total intrinsic value of options exercised during the years ended December 31, 2010, 2009 and 2008 was $6, $99 and $1,626, respectively. At December 31, 2010, the total compensation cost related to non-vested options not yet recognized was $10,327, with a weighted average expense recognition period of 2.94 years. Shares available for future issuance under the Company's stock option and equity incentive plans were 2,475,478 at December 31, 2010.

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

4. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
	2010	2009
Laboratory and office equipment	$ 4,183	$ 4,328
Computer equipment and software	2,612	3,076
Furniture and fixtures	1,361	1,355
Leasehold improvements	1,024	1,024
	9,180	9,783
Less: accumulated depreciation	(7,140)	(6,492)
	$ 2,040	$ 3,291

Depreciation and amortization expense for the years ended December 31, 2010, 2009 and 2008 was $1,346, $1,447 and $1,225, respectively. Of these amounts, $543, $619 and $528, respectively, were included in research and development expenses in the statements of operations.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2010	2009
Sales and marketing	$ 1,330	$ 819
General and administrative	803	1,029
Research and development	379	1,749
Employee compensation	326	605
Clinical trials	189	446
Current portion of capital lease and financed equipment liabilities	85	82
	$ 3,112	$ 4,730

6. Intangible Assets, Net

Intangible assets, net consisted of the following:

	December 31,	
	2010	2009
License fees	$ 2,703	$ 5,339
Less: accumulated amortization	(862)	(1,584)
	$ 1,841	$ 3,755

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 paid a license fee to Orion of $4,826. In accordance with the terms of the Consolidated, Amended, and Restated License Agreement ("SARM License Agreement") and the Amended and Restated License Agreement ("SERM License Agreement") 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 agreement.

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

During the second quarter of 2010, the Company determined that, based on the results of the Phase III clinical trial evaluating toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, it does not expect to conduct additional clinical trials or submit a NDA to the FDA for toremifene 20 mg for this indication. Based upon this determination, a triggering event occurred requiring the Company to perform an impairment review of the toremifene 20 mg intangible assets. After analyzing future cash flows and estimates of fair market value from a market participant perspective, the Company determined that an impairment existed and recorded an impairment charge of $1,687 during the second quarter of 2010. The impaired intangible assets consisted of the unamortized portions of capitalized license fees paid to Orion and UTRF related to the Company's toremifene 20 mg program. Of the $1,687 impairment charge, $1,515 related to unamortized license fees paid to Orion under the Orion License and Supply Agreement for the Company's exclusive license from Orion to develop and commercialize toremifene-based products, as approximately half of the original payment to Orion of $4,826 was allocated to the Company's toremifene 20 mg program. The remaining impairment charge of $172 related to the SERM License Agreement with UTRF, as the capitalized amount for this license agreement pertained solely to the Company's toremifene 20 mg program. The impairment charge was included in research and development expenses in the statement of operations for the year ended December 31, 2010.

The Company's intangible assets, net at December 31, 2010 consisted of $1,619 under the Orion License and Supply Agreement, which related entirely to the Company's toremifene 80 mg program, and $222 related to the SARM License Agreement. These intangible assets are being amortized on a straight-line basis over the respective terms of the agreements, which the Company estimates to be approximately 16 years and 14 years, respectively. Amortization expense for the years ended December 31, 2010, 2009 and 2008 was $227, $338 and $337, respectively. See Note 13, *Subsequent Events*, regarding the Company's collaboration with Ipsen and the status of the Company's toremifene 80 mg program.

Estimated future amortization expense for purchased intangible assets at December 31, 2010 is as follows:

Years Ending December 31,	
2011	$ 149
2012	149
2013	149
2014	149
2015	149
Thereafter	1,096
Total	$ 1,841

7. Common and Preferred Stock

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

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, *Collaboration and License Agreements*, for further discussion.

On November 1, 2010, the Company completed an underwritten public offering of 14,285,715 shares of its common stock at a price to the public of $2.80 per share. Net cash proceeds from the public offering were $37,656 after deducting underwriting discounts and commissions and other offering expenses. The Company also granted the underwriter a 30-day option to purchase up to an additional 2,142,857 shares of common stock to cover over-allotments, if any. On November 24, 2010, the underwriter exercised its option and purchased an additional 1,000,000 shares of the Company's common stock at a price of $2.80 per share. Net cash proceeds from the exercise of the over-allotment option were $2,632 after deducting underwriting discounts and commissions and other offering expenses.

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

8. Collaboration and License Agreements

Orion Corporation License and Supply Agreement

In March 2000, the Company entered into a license and supply agreement with Orion to develop and commercialize products containing toremifene. The Company's rights under the original license agreement were limited to specific disease fields pertaining to prostate cancer. In December 2004, the Company entered into an agreement with Orion to purchase specified FARESTON® related assets which Orion had re-acquired from another licensee. The Company also entered into the Orion License and Supply Agreement, effective January 2005, with Orion which replaced the original license agreement and provided the Company an exclusive license from Orion to develop and commercialize toremifene-based products for all human indications worldwide, except breast cancer outside of the United States. Additionally, the Orion License and Supply Agreement requires that Orion will manufacture and supply all of the Company's and the Company's sublicensees' needs for clinical trial and commercial grade material for toremifene-based products developed and marketed in the United States and abroad, including toremifene globally and FARESTON® in the United States. Orion may terminate its supply obligations at its election at any time as a result of the Company's failure to obtain regulatory approval of one of its toremifene product candidates in the United States prior to December 31, 2009, in which event the Company will have the right to enter into a contract manufacturing agreement with another supplier for toremifene-based products. 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 lasts, on a country-by-country basis, until the later of expiration of the Company's own patents claiming the processes or the methods of use of toremifene for prostate cancer or the end of all marketing or regulatory exclusivity which the Company may obtain for toremifene-based products. The term of the Company's issued and pending method of use patents pertaining to toremifene for prostate cancer extend from 2019 to 2025. Orion may terminate the Orion License and Supply Agreement, on a country-by-country basis, as a result of the Company's uncured material breach, including under certain circumstances if the Company decided not to commercially launch toremifene in any major country after the Company obtains regulatory approval in such country, or the Company's bankruptcy.

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 pay a royalty in the low-teens to Orion for toremifene-based products for breast cancer in the United States, and to pay a royalty in the low-teens to Orion for toremifene-based products to treat high grade PIN and prevent prostate cancer and reduce fractures in men with prostate cancer on ADT.

If a toremifene-based product is approved for commercial sale in the United States to treat high grade PIN and prevent prostate cancer or reduce fractures in men with prostate cancer on ADT, the Company has agreed to achieve specified minimum sales requirements in the United States after commercialization or it must pay Orion royalties in the low-teens based on the portion of the minimum sales requirements that have not been met. 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 toremifene to treat high grade PIN and prevent prostate cancer and reduce fractures in men with prostate cancer on ADT.

Ipsen Collaboration and License Agreement

In September 2006, the Company entered into a collaboration and license agreement with Ipsen (the "Ipsen Collaboration Agreement") pursuant to which the Company granted Ipsen exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein, and the Commonwealth of Independent States (the "European Territory") to develop and commercialize 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 Ipsen Collaboration Agreement, Ipsen paid the Company €23,000 as a license fee and expense reimbursement, of which €1,500 was paid in equal installments over a three year period from the date of the Ipsen Collaboration 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 2009, 2008 and 2007, the Company received €500 (approximately $726, $711 and $688, respectively) from Ipsen for the three annual installment payments. In February 2008, the Company earned a milestone of €1,000 (approximately $1,482) with the achievement of the primary endpoint in the toremifene 80 mg ADT Phase III clinical trial. This amount was recognized as collaboration revenue in the first quarter of 2008.

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

Under the original Ipsen Collaboration Agreement, the Company recorded deferred revenue of $29,330 related to the Ipsen upfront license fee and expense reimbursement which is being amortized into revenue on a straight-line basis over an estimated ten year development period for toremifene in the Ipsen Territory. The Company recognized as collaboration revenue $1,930, $5,777 and $5,852 for the years ended December 31, 2010, 2009 and 2008, respectively, from the amortization of the Ipsen deferred revenue.

In March 2011, the Company reacquired full rights to its toremifene program following the termination by the Company and Ipsen of the collaboration and license agreement, as amended (the "Amended Ipsen Collaboration Agreement"). See Note 13, *Subsequent Events*, for further discussion.

Merck & Co., Inc. Collaboration and License Agreement

In December 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 for all potential indications of interest. In March 2010, the Company reacquired full rights to its SARM program, including Ostarine™, following the termination by the Company and Merck of the Merck Collaboration Agreement.

Under the Merck Collaboration Agreement, the Company granted Merck an exclusive worldwide license under its SARM-related patents and know-how. The Company conducted preclinical research of SARM compounds and products, and Merck was primarily responsible under the terms of the agreement for conducting and funding development and commercialization of products developed under the Merck Collaboration Agreement. Merck paid the Company an upfront licensing fee of $40,000 and purchased approximately $30,000 of the Company's common stock. In addition, Merck 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 received $5,000 from Merck in December 2008, 2009 and 2010 as the first, second, and third annual payments of cost reimbursements for research and development activities.

The Company deferred the recognition of the upfront licensing fee of $40,000 and the $10,800 in equity premium received that represented 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 were being recognized as collaboration revenue over the period of the Company's performance obligation, which the Company estimated to be ten years. The $5,000 of cost reimbursements received in both December 2008 and December 2009 were being recognized as collaboration revenue over the remaining period of the Company's performance obligation. In March 2010, the Company reacquired full rights to the Company's SARM program following the termination by the Company and Merck of the Merck Collaboration Agreement. In the first quarter of 2010, the Company recognized as collaboration revenue all of the remaining $49,856 unamortized revenue that was deferred as of December 31, 2009, as well as the final $5,000 research and development activities cost reimbursement due under the terms of the Merck Collaboration Agreement in December 2010 for which the Company had no further performance obligations. The Company recognized as collaboration revenue $54,856, $5,664 and $5,106 for the years ended December 31, 2010, 2009 and 2008, respectively, from the amortization of the Merck deferred revenue. The final $5,000 payment for research and development activities cost reimbursement was received from Merck in December 2010.

University of Tennessee Research Foundation License Agreements

The Company and UTRF are parties to a consolidated, amended and restated license agreement (the "SARM License Agreement") pursuant to which 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. Additionally, the Company and UTRF have entered into an amended and restated license agreement (the "SERM License Agreement") pursuant to which the Company was granted exclusive worldwide rights to UTRF's method of use patents relating to SERMs, including toremifene for chemoprevention of prostate cancer as well as future related SERM technologies that may be developed by certain scientists at the University of Tennessee. Under the SARM License Agreement and the SERM License Agreement, the Company is obligated to pay UTRF annual license maintenance fees, low single digit royalties on net sales of products and mid single-digit royalties on sublicense revenues.

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

Unless terminated earlier, the term of the SARM License Agreement will continue, on a country-by-country basis, 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 SARM License Agreement for the Company's uncured breach or upon its bankruptcy. Unless terminated earlier, the term of the SERM License Agreement will continue, on a country-by-country basis, in a particular country for the longer of 20 years from the effective date of the Company's previously existing exclusive worldwide license agreement with UTRF for toremifene or until the expiration of the last valid claim of any licensed patent in such country. UTRF may terminate the SERM License Agreement for the Company's uncured breach or upon its bankruptcy.

9. Income Taxes

The Company has incurred net losses since inception and, consequently, has 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.

The principal components of the Company's net deferred income tax assets and liabilities consisted of the following:

	December 31,	
	2010	**2009**
Deferred income tax assets:		
Net federal and state operating loss carryforwards	$ 87,766	$ 75,280
Research and development credits	9,776	8,893
Deferred revenue	3,215	22,984
Share-based compensation	7,332	5,188
Depreciation and amortization	776	121
Other	624	901
Total deferred tax assets	109,489	113,367
Valuation allowance	(109,489)	(113,367)
Net deferred tax assets and liabilities	$ —	$ —

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 decreased by $3,878 in 2010 and increased by $17,979 and $22,765 in 2009 and 2008, respectively.

At December 31, 2010, the Company had net federal operating loss carryforwards of approximately $226,597, which expire from 2018 to 2030 if not utilized. The Company had state operating loss carryforwards of approximately $214,886, which expire from 2013 to 2025 if not utilized. The Company also had research and development credits of approximately $9,776, which expire from 2020 to 2030 if not utilized.

Both of the net federal and state operating loss carryforwards include approximately $1,900 of deductions related to the exercise of stock options. This amount represents an excess tax benefit and has not been included in the gross deferred tax asset reflected for net federal and state operating loss carryforwards. If utilized, the benefits from these deductions will be recorded as an adjustment to additional paid in capital.

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

The Company will recognize 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. As of December 31, 2010, the Company had no unrecognized tax benefits. Utilization of the Company's net operating loss 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. The Company has not yet performed a Section 382 change in control study in order to determine if there is a limitation of its net operating loss carryforwards. Until this study is performed, the Company cannot be certain of the use of these loss carryforwards. Additionally, the Company has not yet conducted an in depth study of its research and development credits. This study may result in an increase or decrease to the Company's research and development credits. Until studies are conducted of the Company's net operating loss carryforwards and research and development credits, no amounts are being presented as an uncertain tax position under FIN 48. The Company's net deferred tax assets have been fully offset by a valuation allowance. Therefore, future changes to the Company's unrecognized tax benefits would be offset by an adjustment to the valuation allowance and there would be no impact on the Company's balance sheet, statement of operations, or cash flows. The Company does not expect its unrecognized tax benefits to change significantly over the next 12 months.

The Company is currently open to audit under the statute of limitations by the Internal Revenue Service and the appropriate state income taxing authorities for all years due to the net loss carryforwards from those years. The Company is currently not under examination by the Internal Revenue Service or any other taxing authorities. The Company has not recorded any interest and penalties on any unrecognized tax benefits since its inception.

For the year ended December 31, 2009, the Company recognized a federal income tax benefit of $238 due to the adoption of a provision in the Housing and Economic Recovery Act of 2008 that allowed the Company to claim refunds for portions of its pre-2006 research and development tax credits.

10. Directors' Deferred Compensation Plan

Non-employee directors may 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 account, or a combination of both. Stock 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 accounts under the Directors' Deferred Compensation Plan are credited with interest or the value of any cash and stock dividends, respectively. 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, 2010, 2009 and 2008, the Company incurred non-employee director fee expense of $279, $298 and $241, respectively, of which $187, $178 and $178 was deferred into stock accounts and will be paid in common stock following separation from service as a director. At December 31, 2010, 110,128 shares of the Company's common stock had been credited to individual director stock accounts under the Directors' Deferred Compensation Plan, and no amounts had been credited to individual director cash accounts under the Directors' Deferred Compensation Plan.

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 $16.5 for employees under age 50 and $22 for employees 50 and older in calendar year 2010. 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 $433, $551 and $395 in 2010, 2009 and 2008, respectively.

12. Commitments and Contingencies

Operating Lease Commitments

The Company leases laboratory facilities and office space pursuant to a sublease, which is accounted for as an operating lease. The sublease expires on December 31, 2012, with an option to extend the sublease for an additional two years. The Company subleases additional office space under a sublease that is accounted for as an operating lease. This sublease has escalating rent payments and expires on April 30, 2015. In July 2008, the Company amended this sublease agreement to add additional office space. In February 2011, the Company amended the sublease agreement to eliminate the additional office space, effective January 1, 2011. Total rent expense under these real estate leases was approximately $1,508, $1,458 and $1,302 for the years ended December 31, 2010, 2009 and 2008, respectively.

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

As of December 31, 2010, annual minimum payments under operating lease arrangements were as follows:

2011	$ 1,451
2012	1,358
2013	538
2014	553
2015	185
Total	$ 4,085

Equipment Financing and Capital Lease Obligations

As of December 31, 2010 and 2009, the Company had approximately $268 of property and equipment that was financed or acquired through a capital lease. Amortization expense for these assets under capital lease is included in depreciation expense, with accumulated amortization of $128 and $24 at December 31, 2010 and 2009, respectively.

As of December 31, 2010, the annual minimum payments under these financing and capital lease arrangements were as follows:

2011	$ 92
2012	92
2013	7
2014	2
Total	$ 193

Purchase Commitments

The Company had outstanding contractual purchase obligations of $7 and $40 at December 31, 2010 and 2009, 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, 2010 and 2009, respectively.

13. Subsequent Events

The Company has evaluated all events or transactions that occurred after December 31, 2010 up through the date the financial statements were issued.

Ipsen Collaboration and License Agreement

In March 2011, the Company reacquired full rights to the Company's toremifene program following the termination by the Company and Ipsen of the Ipsen Collaboration Agreement. In exchange for reacquiring all of Ipsen's rights under the Ipsen Collaboration Agreement, the Company agreed to pay Ipsen a low single digit royalty on net sales of toremifene 80 mg in the United States if approved for commercial sale. In the first quarter of 2011, the Company expects to recognize as collaboration revenue all of the remaining $8,066 unamortized revenue that was deferred as of December 31, 2010. Additionally, upon the termination of the Ipsen Collaboration Agreement, the Company evaluated its intangible asset related to toremifene 80 mg, which had a net book value of $1,619 at December 31, 2010, for impairment and determined that no impairment existed. See Note 6, *Intangible Assets, Net*, for information related to the Company's intangible asset related to toremifene 80 mg.

There were no other material recognizable or nonrecognizable subsequent events during the period evaluated.

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

14. Quarterly Financial Data (Unaudited)

The following is a summary of the quarterly results of operations for the years ended December 31, 2010 and 2009:

	2010 Quarters Ended			
	March 31	June 30	September 30	December 31
Revenues:				
Product sales, net	$ 799	$ 599	$ 960	$ 1,469
Collaboration revenue	55,778	336	336	336
Total revenues	56,577	935	1,296	1,805
Costs and expenses:				
Cost of product sales	151	134	216	267
Research and development expenses	7,650	9,477	5,593	5,775
General and administrative expenses	4,509	4,325	4,066	4,519
Total costs and expenses	12,310	13,936	9,875	10,561
Income (loss) from operations	44,267	(13,001)	(8,579)	(8,756)
Other income, net	72	60	4	1,227
Net income (loss)	$ 44,339	$ (12,941)	$ (8,575)	$ (7,529)
Net income (loss) per share:				
Basic and diluted	$ 1.22	$ (0.36)	$ (0.24)	$ (0.16)

	2009 Quarters Ended			
	March 31	June 30	September 30	December 31
Revenues:				
Product sales, net	$ 759	$ 949	$ 719	$ 862
Collaboration revenue	2,872	2,873	2,881	2,815
Total revenues	3,631	3,822	3,600	3,677
Costs and expenses:				
Cost of product sales	348	431	344	167
Research and development expenses	8,312	7,746	8,123	8,163
General and administrative expenses	6,511	6,981	8,002	6,284
Total costs and expenses	15,171	15,158	16,469	14,614
Loss from operations	(11,540)	(11,336)	(12,869)	(10,937)
Other income, net	45	76	49	18
Loss before income taxes	(11,495)	(11,260)	(12,820)	(10,919)
Income tax benefit	194	—	—	44
Net loss	$ (11,301)	$ (11,260)	$ (12,820)	$ (10,875)
Net loss per share:				
Basic and diluted	$ (0.31)	$ (0.31)	$ (0.35)	$ (0.30)

Exhibit 10.57

SECOND AMENDMENT TO
SUBLEASE AND PARKING SUBLICENSE AGREEMENTS

This Second Amendment to Sublease and Parking Sublicense Agreements (this "**Second Amendment**") is made and entered into as of January 1, 2011 (the "**Second Amendment Effective Date**") by and between ESS SUSA HOLDINGS, LLC, a Delaware limited liability company, ("**Landlord**") and GTx, Inc., a Delaware corporation, ("**Tenant**").

WHEREAS, Landlord and Tenant entered into that certain Sublease Agreement (the "**Sublease**") as of December 17, 2007, regarding the subleasing of certain Premises in the Building, and that certain Parking Sublicense Agreement (the "**Sublicense**", and collectively with the Sublease, as amended from time to time, the "**Agreements**") as of December 17, 2007, as amended by that certain First Amendment to Sublease and Parking Sublicense Agreements dated as of July 21, 2008 (the "**First Amendment**"), regarding the sublicensing of the right to use certain parking spaces in the Parking Facility, as such terms are defined, and on such additional terms and conditions set forth, in the Agreements; and

WHEREAS, Landlord and Tenant wish to discontinue Tenant's leasing of the fourth floor space of the Building, Tenant's right of first refusal to lease the third floor space of the Building, and Tenant's early termination rights in the seventh and eighth floor space of the Building, on certain terms and conditions, all as more particularly set forth herein.

NOW THEREFORE, in consideration of the premises and the mutual covenants of the parties, more particularly hereinafter set forth, the adequacy and sufficiency of which are hereby acknowledged, it is agreed as follows:

1. Termination Fee. On or before thirty (30) days after the full execution and delivery of this Second Amendment, provided Landlord has delivered to Tenant an invoice for the Termination Payment defined below, and in consideration of the terms and conditions of this Second Amendment, Tenant shall pay to Landlord the sum of One Hundred Twenty-Five Thousand and No/100 Dollars ($125,000.00) (the "**Termination Payment**").

2. Termination of Certain Rights and Obligations of Tenant.

(a) Expansion Rights in 3rd Floor. In consideration of the terms and conditions of this Second Amendment, Tenant and Landlord relinquish and terminate the ROFR in the third floor space of the Building.

(b) Leasing of 4th Floor. As of the Second Amendment Effective Date of this Second Amendment, but subject to the timely payment of the Termination Payment, Tenant shall have no further right of occupancy of the fourth floor space of the Building; Landlord agrees that Tenant shall have no further obligations in connection with the fourth floor space, whether in the payment of Base Rent therefor, the licensing of parking spaces in connection therewith, or otherwise. Landlord agrees to credit against March and April 2011 rent due from Tenant for the 7th and 8th floor space the amount of Fifty Thousand One Hundred Sixty-Six and 66/100 Dollars ($50,166.66), which represents the total amount of January and February 2011 rent payments previously received by Landlord for the 4th floor space from Tenant.

The terms and conditions of Section 1(b) and 1(e) of the First Amendment shall be deleted in their entirety and replaced with the following, respectively:

(b) "**Premises**": Seventh and Eighth Floors of the Building

(e) "**Rentable Area of Premises**": approximately 30,748 comprised of 21,500 square feet on the seventh floor and 9,248 square feet on the eighth floor.

The terms and conditions of Section 2 and the second sentence of Section 4 of the First Amendment shall be deleted in their entirety and are of no further force or effect.

(c) Early Termination Rights for 7th and 8th Floors. In consideration of the terms and conditions of this Second Amendment, Tenant relinquishes and releases its options to cancel the Sublease as of the early termination dates set forth in Section 4 of the Sublease. Accordingly, the Termination Date shall remain April 30, 2015 without option to terminate prior thereto.

Tenant agrees to execute a Memorandum of Sublease consistent with this Second Amendment upon request of Landlord.

3. Counterparts. This Second Amendment may be executed in one or more counterparts, each of which shall be deemed an original and all of which, taken together, shall constitute one and the same instrument.

4. Ratification. The Agreements remain in full force and effect, as expressly amended by this Second Amendment. Capitalized terms utilized but not defined in this Second Amendment shall have the meanings ascribed to such terms in the Agreements.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties have made and entered into this Second Amendment as of the first set forth above.

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/ Mark E. Mosteller
Name: Mark E. Mosteller
Title: Vice President and Chief Financial Officer

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 Statements (Form S-8 Nos. 333-149661 and 333-165507) pertaining to the GTx, Inc. 2004 Equity Incentive Plan and the Amended and Restated 2004 Non-Employee Directors' Stock Option Plan;

of our reports dated March 8, 2011, 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, 2010.

/s/ Ernst & Young LLP
Memphis, Tennessee
March 8, 2011

EXHIBIT 31.1

CHIEF EXECUTIVE OFFICER CERTIFICATION

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 8, 2011

/s/ Mitchell S. Steiner

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

EXHIBIT 31.2

CHIEF FINANCIAL OFFICER CERTIFICATION

I, Mark E. Mosteller, certify that:

1. I have reviewed this 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 8, 2011

/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, 2010, 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 8, 2011

/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, 2010, 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 8, 2011

/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.