# 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, 2012

OR

o TRANSITION REPORT PURSUANT	TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHA	NGE 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)

175 Toyota Plaza
7<sup>th</sup> Floor
Memphis, Tennessee 38103

(Address of principal executive offices)

# (901) 523-9700

(Registrant's telephone number, including area code)

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

Title of Each Class Name of Each Exchange on Which Registered

Common Stock, par value \$0.001 per share The NASDAQ Stock Market, LLC

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

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

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

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

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  $\boxtimes$  No o

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

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 o Non-accelerated filer o Accelerated filer ⊠

(Do not check if a smaller reporting company)

Smaller reporting company o

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

The aggregate market value of common stock held by non-affiliates of the registrant based on the closing sales price of the registrant's common stock on June 29, 2012 as reported on The NASDAQ Global Market was \$94,929,673.

There were 62,891,791 shares of registrant's common s	stock issued and outstanding as of	February 26, 2013.	

# 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 2013 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

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#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- the anticipated progress of our research, development and clinical programs, including whether our ongoing or planned clinical trials will achieve similar results to clinical trials that we have previously concluded;
- the timing, scope and anticipated initiation, enrollment and completion of our ongoing and planned clinical trials and any other 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 for the treatment of cancer, 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). Our lead SARM product candidate, enobosarm (also known as Ostarine® or GTx-024), has to date been evaluated in eight completed clinical trials enrolling approximately 600 subjects, including in a Phase Ib and two Phase II efficacy studies. Enobosarm is the generic name given to the compound by the USAN Council and the World Health Organization and is the first compound to receive the SARM stem in its name, recognizing enobosarm as the first in this new class of compounds.

We are conducting the POWER 1 and POWER 2 (Prevention and treatment Of muscle Wasting in patients with cancER) pivotal Phase III clinical trials evaluating enobosarm for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer. We are conducting these trials in clinical sites in the United States, Europe, Russia and South America. Each of the pivotal Phase III placebo-controlled, double-blind clinical trials was fully enrolled during the fourth quarter of 2012, with approximately 325 patients in each clinical trial. In each of these clinical trials, patients with Stage III or IV non-small cell lung cancer have been randomized to placebo or enobosarm 3 mg at the time they began first line chemotherapy. The trials are evaluating as co-primary endpoints the effect of enobosarm versus placebo on total lean body mass (muscle) assessed by dual x-ray absorptiometry, or DXA, and on physical function assessed by the Stair Climb Test at three months. Durability of effect is being assessed as a secondary endpoint at five months. In October 2012, after a prespecified safety review in subjects currently enrolled in these two clinical trials, the independent Data Safety Monitoring Board determined that the trials could continue as planned. In January 2013, the United States Food and Drug Administration, or FDA, designated enobosarm for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer as a fast track development program. Fast track status is a process designed by the FDA to facilitate the development and expedite the review of new drug candidates that are intended to treat serious diseases and have the potential to fill an unmet medical need. We currently expect topline data from these pivotal Phase III clinical trials during the third quarter of 2013. Subject to obtaining positive data from these pivotal Phase III clinical trials and marketing organization to commercialize enobosarm in the United States and/or entering into strategi

Additionally, we are developing Capesaris® (GTx-758), an oral nonsteroidal selective estrogen receptor (ER) alpha agonist, for secondary hormonal therapy in men with metastatic castration resistant prostate cancer, or CRPC, and, potentially, as a primary treatment for advanced prostate cancer used in combination with androgen deprivation therapy, or ADT. We believe Capesaris® has the potential to reduce free testosterone without also causing certain estrogen deficiency side effects, such as bone loss, hot flashes and insulin resistance, which are common with current androgen deprivation therapies for prostate cancer. We also believe that Capesaris® may be effective, in combination with ADT, as a primary treatment of advanced prostate cancer by reducing free testosterone to levels lower than those attainable with ADT alone and potentially reducing the estrogen deficiency side effects caused by the use of ADT.

In May 2012, we announced that the FDA had removed its full clinical hold on our Investigational New Drug, or IND, application for Capesaris®. The full clinical hold was placed on our three then ongoing Phase II clinical trials evaluating Capesaris® to treat men with advanced prostate cancer in February 2012 and resulted in the discontinuation of these trials. The full clinical hold followed our reports to the FDA of venous thromboembolic events (blood clots), or VTEs, in subjects treated with Capesaris® at the doses being studied in those trials (1000 mg and higher per day). Based upon feedback from the FDA in connection with the removal of the full clinical hold, we initiated in the third quarter of 2012 a Phase II clinical trial to evaluate the safety and efficacy of lower doses of Capesaris® as secondary hormonal therapy in men with CRPC.

Capesaris® has previously demonstrated the ability to increase the production of a protein called sex hormone binding globulin, or SHBG, in men with advanced prostate cancer and reduce free testosterone. By reducing free testosterone, we believe serum prostate specific antigen, or PSA, will be reduced in men with CRPC. The primary endpoint of the current Phase II open-label clinical trial is the proportion of subjects with a 350% decline from baseline in serum PSA by day 90. Other key endpoints include serum SHBG levels, total and free testosterone levels, and progression free survival in the study subjects. In addition, the clinical study will evaluate the ability of Capesaris® to treat certain estrogen deficiency side effects associated with luteinizing hormone releasing hormone, or LHRH, agonists such as hot flashes, bone loss, and insulin resistance. The clinical trial requires subjects to continue receiving their ADT treatment, which will allow us to assess the safety and tolerability of Capesaris® in these subjects, including the incidence of VTEs. The trial design provides for 75 total subjects, with three sequential dosing arms. The first 25 subjects in the Phase II clinical trial are being enrolled in the Capesaris® 125 mg dosing arm. Assuming that an acceptable incidence of VTEs has been observed when the last subject enrolled in the Capesaris® 125 mg dose arm has completed one 30 day cycle of therapy, enrollment of the final 25 subjects when the last subject enrolled in the 250 mg dose arm has completed one 30 day cycle of therapy, assuming an acceptable incidence of VTEs has been observed in both of the lower dosage arms.

We have an extensive preclinical pipeline generated from our own discovery program, including inhibitors of steroid biosynthetic enzymes, anticancer therapies (receptor tyrosine kinase and tubulin inhibitors), estrogen receptor beta agonists, and other novel compounds that are currently in preclinical development for the potential treatment of cancer, metabolic diseases, ophthalmic diseases, psoriasis and/or pain.

Effective September 30, 2012, we sold our rights and certain assets related to FARESTON® to Strakan International S.á r.l., an affliliate of ProStrakan Group plc, or ProStrakan, for a purchase price of approximately \$21.7 million in cash and recognized a gain on the sale of \$18.8 million. Through September 30, 2012, we sold FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of metastatic breast cancer in postmenopausal women, in the United States

# 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 acts as the primary androgen in the prostate, sebaceous glands and hair follicles, and may cause unwanted effects like benign prostatic hyperplasia, or BPH, 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 hot flashes and 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 anabolic/androgenic 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 BPH, development or worsening of acne, 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 and hair 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 and erectile dysfunction; (9) androgen receptor positive breast cancer; and (10) 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.

Capesaris®, a selective estrogen receptor alpha agonist, has previously demonstrated the ability to increase serum concentrations of SHBG, an important serum protein that tightly binds to testosterone and regulates serum concentrations of unbound (free) testosterone. Free testosterone is the functionally active form of the hormone and the only form that is capable of passively diffusing into prostate cancer cells or is available to target tissues for androgen action. We believe that Capesaris® may have the ability to treat men with advanced prostate cancer and men with metastatic CRPC by lowering serum free testosterone concentrations and lowering the incidences of hot flashes, insulin resistance, bone loss or other side effects related to LHRH agonists and antagonists.

#### **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
Enobosarm (Ostarine®; GTx-024) Prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer	SARM	Phase III	Fully enrolled and conducting the POWER 1 and POWER 2 pivotal Phase III clinical trials for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer. Topline data from these pivotal Phase III clinical trials expected during the third quarter of 2013.
Capesaris® (GTx-758) Secondary hormonal therapy in men with metastatic CRPC	Selective estrogen receptor alpha agonist	Phase II	Initiated a Phase II clinical trial in the third quarter of 2012 for secondary hormonal therapy in men with metastatic CRPC.

#### **SARMs**

SARMs are 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).

# Enobosarm 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, poor 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 improve 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.

Enobosarm is an oral nonsteroidal SARM which means that it is similar to testosterone in activating androgen receptors in muscle, thereby potentially promoting lean body mass (muscle) and improving physical function, while avoiding other effects which have been observed with testosterone such as hair growth, stimulation of sebaceous glands, the cause of acne, or enhanced growth of the prostate, which may exacerbate BPH or stimulate prostate cancer.

**Potential Market.** Lung cancer accounts for more deaths than any other cancer in both men and women. Worldwide, there are an estimated 1.5 million new cases and approximately 1.3 million deaths annually. In the United States, there are approximately 225,000 new cases and 160,000 deaths attributed to lung cancer each year. Approximately 85% of all newly diagnosed lung cancers are non-small cell lung cancer. Up to 50% of non-small cell lung cancer patients have severe muscle wasting at diagnosis with the majority developing severe wasting throughout the course of their disease. Body functional limitations, such as the inability to walk up or down steps without rest, or the inability to lift 10 pounds, are present in almost 90% of lung cancer survivors.

There are currently no drugs approved by the FDA for the prevention or treatment of muscle wasting in patients with non-small cell lung 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 that are sometimes prescribed off-label for the treatment of weight loss in cancer patients, chronic use of these drugs may result in liver toxicity or other adverse events and has limited their use. Appetite stimulants such as Megace® (megestrol acetate) and dronabinol are also used off-label for weight loss and loss of appetite in patients with cancer. Additionally, there are other companies developing drugs for the treatment of muscle wasting, appetite stimulation and cachexia. These compounds may compete with enobosarm if approved for commercial sale.

*Clinical Trials.* Enobosarm has been evaluated in eight completed clinical trials enrolling approximately 600 subjects, and is currently being evaluated in two pivotal Phase III clinical trials.

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 enobosarm 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 enobosarm had dose dependent increases in the primary endpoint of total lean body mass. Treatment with enobosarm also resulted in a dose dependent improvement in functional performance, a secondary endpoint, measured by stair climb. Enobosarm had a favorable safety profile, with no serious adverse events reported. Enobosarm 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, serum LH, or hair growth.

In July 2007, we initiated a Phase IIb randomized, double blind, placebo-controlled clinical trial evaluating enobosarm 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. Our pivotal Phase III clinical trials currently being conducted with enobosarm are based on the data in the subset of subjects in this Phase IIb study with non-small cell lung cancer.

In 2009, enobosarm was evaluated in a 12 week, randomized Phase Ib clinical trial comparing enobosarm 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, enobosarm 3 mg significantly increased total lean body mass. Enobosarm treatment also resulted in increased leg muscle strength. Enobosarm treatment did not cause virilization, as there was no change in sebaceous gland volume, rate of sebum excretion, or hair follicle gene expression.

We held End of Phase II meetings with the FDA prior to initiating our Phase III clinical development of enobosarm for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer. Based upon data from our Phase II clinical trials and with feedback from the FDA, we designed the POWER 1 and POWER 2 (Prevention and treatment Of muscle Wasting in cancER) pivotal Phase III clinical trials evaluating enobosarm for this indication. We also met with representatives of the Medicines and Healthcare Products Regulatory Agency (United Kingdom) and Medical Products Agency (Sweden), who confirmed that the design of the POWER 1 and POWER 2 clinical trials should be sufficient for the European Medicines Agency to support registration in Europe. Each of the pivotal Phase III placebo-controlled, double-blind clinical trials was fully enrolled during the fourth quarter of 2012, with approximately 325 patients in each clinical trial. In each of these clinical trials, patients with Stage III or IV non-small cell lung cancer have been randomized to placebo or enobosarm 3 mg at the time they began first line chemotherapy. The trials are evaluating as co-primary endpoints the effect of enobosarm versus placebo on total lean body mass (muscle) assessed by DXA and on physical function assessed by the Stair Climb Test at three months. Durability of effect is being assessed as a secondary endpoint at five months. In October 2012, after a pre-specified safety review in subjects currently enrolled in these two clinical trials, the independent Data Safety Monitoring Board determined that the trials could continue as planned. In January 2013, the FDA designated enobosarm for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer as a fast track development program. Fast track status is a process designed by the FDA to facilitate the development and expedite the review of new drug candidates that are intended to treat serious diseases and have the potential to

# Selective ER Alpha Agonist

# Capesaris® for the Treatment of Metastatic Hormone Sensitive Prostate Cancer and Castration Resistant Prostate Cancer

**Scientific Overview.** 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. 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. We believe Capesaris® has the potential to reduce free testosterone without also causing certain estrogen deficiency side effects, such as bone loss, hot flashes and insulin resistance, which are common with current androgen deprivation therapies for prostate cancer.

**Potential Market.** We are developing Capesaris® for secondary hormonal therapy in men with CRPC, and, potentially, as a primary treatment for advanced prostate cancer used in combination with ADT. We believe that Capesaris® may be effective, in combination with ADT, as a primary treatment of advanced prostate cancer by reducing free testosterone, the unbound biologically active form of testosterone, to levels lower than those attainable with ADT alone and potentially reducing the estrogen deficiency side effects caused by the use of ADT.

In the United States alone, we believe there are approximately 80,000 men who have developed resistance to LHRH therapies and therefore have CRPC but who have not received chemotherapy. We believe there are approximately 36,000 men diagnosed each year with metastatic hormone sensitive prostate cancer. Zytiga® is currently the only drug approved for the treatment of metastatic CRPC in patients who have not yet received chemotherapy, although several other drugs are in clinical development for this indication. We believe new hormonal therapies in development, if approved, will be used prior to chemotherapy as physicians and patients look for treatment options capable of delaying cancer progression and possibly prolonging survival prior to chemotherapy.

In the United States, there are currently approximately 750,000 men with nonmetastatic hormone sensitive prostate cancer and approximately 60,000 new cases are diagnosed each year. For metastatic hormone sensitive prostate cancer, ADT is the most common treatment. There are no approved androgen deprivation therapies designed to significantly minimize estrogen deficiency side effects, including bone loss, fractures, insulin resistance and hot flashes. For many men on ADT, physicians are currently prescribing certain drugs, some of them on an off-label basis, to help ameliorate some of the specific estrogen deficiency related side effects of ADT. These drugs include the use of estrogen patches and compounds, as well as, off-label use of bisphosphonates for osteoporosis and Megace® (megestrol acetate) for hot flashes.

Our ability to develop Capesaris® as an effective secondary hormonal therapy for men with metastatic CRPC or potentially, as a primary treatment for advanced prostate cancer used in combination with ADT, is dependent on our ability to find an appropriate dose that is both effective and safe for these patient populations.

Clinical Trials. In 2009, we evaluated Capesaris® in healthy male volunteers in two Phase I clinical trials, including a ten day multiple ascending dose study in 61 subjects where Capesaris® 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 (levels of serum total testosterone less than 50ng/dL), increased serum SHBG, and reduced serum free testosterone, the form of testosterone which is available to prostate cancer cells for growth. 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. In May 2011, we completed a Phase I clinical trial of Capesaris® using a tablet formulation in older healthy male volunteers. In this trial, reductions in testosterone to medical castration levels, increases in SHBG and decreases in free testosterone were observed in Capesaris® doses given orally each day.

We designed two Phase II clinical trials to identify an appropriate dose of Capesaris® to achieve and maintain medical castration (less than 50ng/dL) from day 28 to day 364 in men with advanced prostate cancer. In June 2011, we initiated the Phase II maintenance dose finding clinical trial

evaluating Capesaris® 1000 mg and 2000 mg once-a-day doses compared to Lupron Depot® (leuprolide acetate for depot suspension) in 164 men with advanced prostate cancer. We also initiated the Phase II loading dose finding clinical trial evaluating 1000 mg and 1500 mg doses twice-a-day to medically castrate men by day 28 in 104 men with advanced prostate cancer. After day 28, castrate patients were to continue treatment on one of two once-a-day doses of Capesaris®, 2000 mg or 1000 mg, until day 360. We were also conducting a second line hormonal therapy Phase II clinical trial evaluating Capesaris® 2000 mg once-a-day dose in 25 men with CRPC. The objective of this trial was to determine the ability of Capesaris® to reduce serum PSA and the duration of this PSA reduction in men with CRPC who are currently receiving ADT. On February 21, 2012, we announced that the FDA had placed a full clinical hold on our IND application for Capesaris®, effective February 17, 2012, causing us to stop all three of these clinical trials. The full clinical hold followed our reports to the FDA of VTEs (blood clots) in subjects treated with Capesaris® at the doses being studied in the trials (1000 mg and higher per day). There were two deaths in subjects treated with Capesaris® and two deaths in subjects treated with Lupron Depot®. As a result of the full clinical hold, we suspended further enrollment into these three trials and notified clinical sites to discontinue treatment of subjects with Capesaris®.

In May 2012, we announced that the FDA had removed its full clinical hold on our IND for Capesaris®. Based upon feedback from the FDA in connection with the removal of the full clinical hold, we initiated in the third quarter of 2012 a Phase II clinical trial to evaluate the safety and efficacy of three lower doses of Capesaris® as secondary hormonal therapy in men with metastatic CRPC.

Capesaris® has previously demonstrated the ability to increase the production of SHBG in men with advanced prostate cancer and reduce free testosterone. By reducing free testosterone, we believe serum PSA will be reduced in men with CRPC. The primary endpoint of the current Phase II open-label clinical trial is the proportion of subjects with a ³ 50% decline from baseline in serum PSA by day 90. Other key endpoints include serum SHBG levels, total and free testosterone and progression free survival in the study subjects. In addition, the clinical study will evaluate the ability of Capesaris® to treat certain estrogen deficiency side effects associated with LHRH agonists such as hot flashes, bone loss, and insulin resistance. The clinical trial requires subjects to continue receiving their ADT treatment, which will allow us to assess the safety and tolerability of Capesaris® in these subjects, including the incidence of VTEs. The trial design provides for 75 total subjects, with three sequential dosing arms. The first 25 subjects in the Phase II clinical trial are being enrolled in the Capesaris® 125 mg dosing arm. Assuming that an acceptable incidence of VTEs has been observed when the last subject enrolled in the Capesaris® 125 mg dose arm has completed one 30 day cycle of therapy, enrollment of the next 25 subjects when the last subject enrolled in the 250 mg dose arm has completed one 30 day cycle of therapy, assuming an acceptable incidence of VTEs has been observed in both of the lower dosage arms.

# Other Research and Development and Drug Discovery

We 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 enobosarm, 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, SARM compounds, other selective hormone receptor modulator compounds and anticancer agents. Further, we also focus research and development efforts on identifying new indications for our current product candidates. For

example, we believe that enobosarm may have the ability to halt the progression of cancer in women with androgen receptor positive breast cancer.

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. Our enobosarm product candidate was discovered by GTx scientists working in collaboration with certain academic institutions and our Capesaris® product candidate was discovered and developed by GTx scientists.

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 have an extensive preclinical pipeline generated from our own discovery program, including inhibitors of steroid biosynthetic enzymes, (aldoketoreductase 1C3 inhibitors), anticancer therapies (receptor tyrosine kinase and tubulin inhibitors), estrogen receptor beta agonists, and other novel compounds that are currently in preclinical development for the potential treatment of cancer, metabolic diseases, ophthalmic diseases, psoriasis and/or pain.

# **FARESTON®**

Effective September 30, 2012, we sold our rights and certain assets related to FARESTON® to ProStrakan for a purchase price of approximately \$21.7 million in cash and recognized a gain on the sale of \$18.8 million. Through September 30, 2012, we sold FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of metastatic breast cancer in postmenopausal women, in the United States. As a result of our sale of FARESTON®, we currently have no products approved for commercial sale.

In connection with the sale of our rights and certain assets related to FARESTON® to ProStrakan, we and Orion Corporation, or Orion, agreed to terminate the Amended and Restated License and Supply Agreement, dated January 1, 2005, as amended, we previously entered into with Orion as well as certain other related agreements between us and Orion. Pursuant to the license and supply agreement with Orion, we obtained an exclusive license from Orion to develop and commercialize toremifene-based products for all human indications worldwide, except breast cancer outside the United States, and Orion agreed to manufacture and supply all of our 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. The termination of these agreements was effective September 30, 2012.

#### **Our Strategy**

Our objective is to discover, develop and commercialize small molecules for the treatment of cancer, 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 Enobosarm.** Based upon data from our Phase II clinical trials and feedback from the FDA, we are conducting two pivotal Phase III clinical trials evaluating enobosarm for the prevention and treatment of muscle wasting in patients with

advanced non-small cell lung cancer. Subject to obtaining positive data from these pivotal Phase III clinical trials, we will consider either building a specialized sales and marketing organization to commercialize enobosarm in the United States and/or entering into strategic partnerships or collaborations for the development and commercialization of this product candidate. Additionally, we are planning to develop enobosarm for indications other than the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer.

*Pursue Clinical Development and Commercialization of Capesaris*®. Assuming the receipt of positive data from our ongoing Phase II clinical trial to evaluate the safety and efficacy of lower doses of Capesaris® as secondary hormonal therapy in men with metastatic CRPC, we plan to initiate additional clinical trials in order to seek marketing authorization for this product candidate.

**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 discovered additional molecules with the potential to treat cancer, cardiovascular and hepatic disease and 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 patients that are underserved by available alternatives or for which there are no current alternatives.

# 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 potential commercialization of our small molecule product candidates. While we currently have no ongoing collaborations for the development and commercialization of our product candidates, our strategy includes selectively partnering or collaborating with leading pharmaceutical and biotechnology companies to assist us in furthering the development and potential commercialization of our product candidates.

In July 2007, we and the University of Tennessee Research Foundation, or 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 enobosarm, and certain improvements thereto, and exclusive rights to certain 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.

Under the SARM License Agreement, we paid UTRF a one-time, upfront fee of \$290,000 as consideration for entering into the SARM License Agreement. 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 & Co., Inc. We also agreed to pay all expenses to file, prosecute and maintain the patents relating to the licensed SARM technologies, and are obligated to use commercially reasonable efforts to develop and commercialize products based on the licensed SARM technologies. In December 2008, we and UTRF amended the SARM License Agreement, or the SARM License Amendment, 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 SARM License Amendment, we paid UTRF \$494,000.

#### 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.

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

# 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.

# Enobosarm for the Prevention and Treatment of Muscle Wasting in Patients with Cancer

There are currently no drugs approved by the FDA for the prevention and treatment of muscle wasting in patients with cancer. Although there are two commercially available steroids, nandrolone and oxandrolone, that are sometimes prescribed off-label for the treatment of weight loss in cancer patients, chronic use of these drugs may result in liver toxicity or other adverse events and has limited their use. For example, oxandrolone has a black box warning for liver toxicity as well as warnings and precautions related to increased risk for prostate cancer in men and virilization in women. 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 and to offset the protein catabolism associated with prolonged administration of corticosteroids.

Testosterone products have been used off-label to treat secondary hypogonadism. Owing to their potentially unwanted effects and inconvenient dosing, we believe that testosterone products have had a limited impact on the market for muscle wasting. 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. and GlaxoSmithKline plc. Pfizer, Inc., Eli Lilly and Company, and Amgen Inc. have previously reported myostatin inhibitors in development that may compete with enobosarm 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) and Novartis AG is developing a human monoclonal antibody for various muscle indications. Moreover, there are other categories of drugs in development, including ghrelin receptor agonists, inflammatory modulators, and growth hormone secretagogues, that may have some muscle activity. A ghrelin receptor agonist is being evaluated by Helsinn Group for the treatment of cancer cachexia in patients with non-small cell lung cancer. Other appetite stimulants such as Megace® (megestrol acetate) and dronabinol are also used off-label for weight loss and loss of appetite in patients with cancer.

# Capesaris® for the Treatment of Metastatic Hormone Sensitive Prostate Cancer and Castration Resistant Prostate Cancer

There are various products approved or under clinical development to treat men with advanced prostate cancer who have metastatic CRPC which may compete with Capesaris®. Dendreon Corporation markets and sells Provenge®, an autologous cellular immunotherapy, for the treatment of asymptomatic or minimally symptomatic metastatic CRPC. Zytiga®, sold by Johnson & Johnson, has been approved for the treatment of metastatic CRPC in both patients who have and have not received prior chemotherapy. Medivation, Inc. has received approval for Xtandi®, an oral androgen receptor antagonist, for the treatment of metastatic CRPC in men previously treated with docetaxel. Medivation continues to develop Xtandi® for men with metastatic CRPC prior to receiving chemotherapy. Millennium Pharmaceuticals, Inc. is developing TAK-700 for the treatment of men with metastatic CRPC prior to chemotherapy and post docetaxel. Capesaris® is being developed as a treatment for this same patient population prior to the initiation of chemotherapy. Aragon Pharmaceuticals, Inc. has developed a second generation anti-androgen (ARN-509) that is currently being evaluated in Phase II studies in men with progressive, advanced prostate cancer.

# **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 enobosarm and our other SARM compounds, 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 treating muscle wasting disorders, including cancer cachexia, and for treating sarcopenia and increasing muscle performance, muscle size and muscle strength and increasing the strength of or mass of a bone and for treating bone related disorders, including bone frailty and osteoporosis. The

patents we licensed from UTRF and issued in the United States for enobosarm expire in 2024. Issued patents for our other SARM compounds in the United States will expire between 2021 and 2029, depending on the specific SARM compound. The patents we licensed from UTRF and issued outside of the United States for enobosarm expire in 2025, and with respect to other SARM compounds, expire in 2021, 2023, and 2027, depending on the specific SARM compound. We have pending patent applications for enobosarm and our other SARM compounds that, if issued, would expire in the United States and in countries outside the United States in 2025 and 2027, depending on the specific SARM compound. We have pending patent applications for SARMs in combination with anti-cancer agents that, if issued, would expire in the United States in 2024 and in countries outside the United States in 2028.

We have our own pending patent applications 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® as the composition of matter of the active pharmaceutical ingredient for products developed with this compound and for pharmaceutical compositions and/or methods of treating advanced prostate cancer and treating bone loss, bone fractures, bone mineral density and osteoporosis in male subjects with prostate cancer having undergone androgen deprivation therapy. Issued patents covering composition of matter for Capesaris® in the United States will expire in 2029, and pending patent applications in the United States covering Capesaris® method of use will expire in 2029 and 2030. Pending patent applications in countries outside of the United States will expire between 2026 and 2030.

We cannot be certain that any of our patent applications, or those of our licensors, will result in issued patents. In addition, because the patent positions of biopharmaceutical companies are highly uncertain and involve complex legal and factual questions, the patents we own and license, or any further patents we may own or license, may not prevent other companies from developing similar or therapeutically equivalent products. Patents also will not protect our product candidates if competitors devise ways of making or using these product candidates without legally infringing our patents. In recent years, several companies have been extremely aggressive in challenging patents covering pharmaceutical products, and the challenges have often been successful. We cannot be assured that our patents will not be challenged by third parties or that we will be successful in any defense we undertake. Failure to successfully defend a patent challenge could materially and adversely affect our business.

In addition, 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. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent defense and enforcement. The regulations and procedures to govern administration of the Leahy-Smith Act, and the substantive and procedural changes to patent law associated with the Leahy-Smith Act are being implemented in stages, beginning from September 16, 2011, and continuing through March 16, 2013. For example, the Leahy-Smith Act has introduced procedures making it easier for third-parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. In addition, the Leahy-Smith Act will change the United States from a "first-to-invent" jurisdiction to a "first-inventor-to-file" jurisdiction and will change the definition of what constitutes prior art for an application. Finally, the Leahy-Smith Act contains new statutory provisions that still require the U.S. Patent and Trademark Office to issue new regulations for their implementation and it may take the courts years to interpret the provisions of the new statute. Accordingly, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of

our issued patents, all of which could have a material adverse effect on our business and financial condition.

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 preapproval 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. 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

Although we previously sold FARESTON® for the treatment of advanced metastatic breast cancer through September 30, 2012, we currently have no marketed products. In both domestic and foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. 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 marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement.

With respect to government payors, FARESTON® was generally covered under Medicaid, Medicare Part D and the Public Health Service (PHS) pharmaceutical pricing program, as well as purchased by federal agencies. If we obtain appropriate approval in the future to market any of our oral drug product candidates, those products could be covered by some or all of the same programs (if at all). Medicaid is a joint federal and state program that is administered by the states for low income and disabled beneficiaries. Under the Medicaid Drug Rebate Program, manufacturers are required to pay a rebate for each unit of product reimbursed by the state Medicaid programs. The amount of the rebate for each product is set by law and may be subject to an additional discount if certain pricing increases more than inflation.

Medicare is a federal program that is administered by the federal government that covers individuals age 65 and over as well as those with certain disabilities. FARESTON® was a drug within the scope of Medicare Part D. Medicare Part D provides coverage to enrolled Medicare patients for self-administered drugs (*i.e.*, drugs that do not need to be injected or otherwise administered by a physician). Medicare Part D is administered by private prescription drug plans approved by the U.S. government and each drug plan establishes its own Medicare Part D formulary for prescription drug coverage and pricing, which the drug plan may modify from time-to-time. The prescription drug plans negotiate pricing with manufacturers and may condition formulary placement on the availability of manufacturer discounts. Since 2011, manufacturers with marketed brand name drugs have been required to provide a 50% discount on brand name prescription drugs utilized by Medicare Part D beneficiaries when those beneficiaries reach the coverage gap in their drug benefits.

Drug products are subject to discounted pricing when purchased by federal agencies via the Federal Supply Schedule (FSS). FSS participation is required for a drug product to be covered and reimbursed by certain federal agencies and for coverage under Medicaid, Medicare Part B and the PHS pharmaceutical pricing program. FSS pricing is negotiated periodically with the Department of Veterans Affairs. FSS pricing is intended not to exceed the price that a manufacturer charges its most-favored non-federal customer for its product. In addition, prices for drugs purchased by the Veterans Administration, Department of Defense (including drugs purchased by military personnel and dependents through the TRICARE retail pharmacy program), Coast Guard, and PHS are subject to a cap on pricing (known as the "federal ceiling price") and may be subject to an additional discount if pricing increases more than the rate of inflation.

To maintain coverage of drugs under the Medicaid Drug Rebate Program, manufacturers are required to extend discounts to certain purchasers under the PHS pharmaceutical pricing program. Purchasers eligible for discounts include hospitals that serve a disproportionate share of financially needy patients, community health clinics and other entities that receive health services grants from the PHS.

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. Adoption of other new legislation at the federal or state level could further limit reimbursement for pharmaceuticals.

#### Regulations Pertaining to Sales and Marketing

Although we currently have no products approved for commercial sale, we may be subject to various federal and state laws pertaining to health care "fraud and abuse," including anti-kickback laws and false claims laws for activities related to our previous sales of FARESTON®, or to future sales of any of our product candidates that may in the future receive regulatory and marketing approval. Anti-kickback laws generally prohibit a prescription drug manufacturer from soliciting, offering, receiving, or paying any remuneration to generate business, including the purchase or prescription of a particular drug. Although the specific provisions of these laws vary, their scope is generally broad and there may not be regulations, guidance or court decisions that apply the laws to particular industry practices. There is therefore a possibility that our practices might be challenged under such anti-kickback laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented, any claims for payment for reimbursed drugs or services to third party payors (including Medicare and Medicaid) that are false or fraudulent. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions, including fines and civil monetary penalties, and/or exclusion from federal health care programs (including Medicare and Medicaid).

Laws and regulations have been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers with marketed products. The laws and regulations generally limit financial interactions between manufacturers and health care providers and/or require disclosure to the government and public of such interactions. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Given the lack of clarity in laws and their implementation, our reporting could be subject to the penalty provisions of the pertinent laws and regulations.

# **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 \$38.9 million for the year ended December 31, 2012, \$31.9 million for the year ended December 31, 2011, and \$28.5 million for the year ended December 31, 2010.

#### **Employees**

As of December 31, 2012, we had 88 employees, 28 of whom were M.D.s and/or Ph.D.s. None of our employees are 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 Web site 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 February 26, 2013.

Name	Age	Position(s)
Executive Officers		
Mitchell S. Steiner, M.D., F.A.C.S	52	Chief Executive Officer and Vice Chairman of the Board of Directors
Marc S. Hanover	50	President and Chief Operating Officer
James T. Dalton, Ph.D	50	Vice President, Chief Scientific Officer
Henry P. Doggrell	64	Vice President, Chief Legal Officer and Secretary
Mark E. Mosteller	50	Vice President, Chief Financial Officer
Other Key Medical, Clinical and Regulatory Office	ers	
Jeffrey G. Hesselberg	54	Vice President, Regulatory Affairs
Mary Ann Johnston, PharmD	41	Vice President, Medical Affairs
Domingo Rodriguez, M.D	51	Vice President, Clinical Operations

# **Executive Officers of the Registrant**

*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 since our inception in September 1997. Mr. Hanover also served as a member of our Board of Directors until August 2011. 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 and Capesaris® 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.

*Henry P. Doggrell* currently serves as our Vice President, Chief Legal Officer and Secretary, after joining GTx in October 2001 as General Counsel and Secretary. 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 served as a Senior Manager in audit services at Ernst & Young LLP. Mr. Mosteller is a Certified Public Accountant and holds a Bachelor's degree in Accounting from the University of Tennessee.

# Other Key Medical, Clinical and Regulatory Officers of the Registrant

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.

Mary Ann Johnston, PharmD, was appointed Vice President, Medical Affairs in November 2012. Dr. Johnston has over 10 years of pharmaceutical experience, most recently at GTx, Inc., where she served as Director, Medical Affairs and Team Leader, Medical Science Liaisons, heading up the field-based medical organization since 2009. Prior to joining GTx, Inc., Dr. Johnston was Director, Medical Science Liaisons and Managed Markets at Actelion Pharmaceuticals specializing in pulmonary arterial hypertension. Before joining the pharmaceutical industry, Dr. Johnston practiced as a clinical specialist at the University of Texas Medical Branch in Galveston where she served as an adjunct professor for the University of Houston and University of Texas schools of pharmacy with a clinical practice focused in cardiology and critical care. Dr. Johnston holds a Doctor of Pharmacy degree from Samford University McWhorter School of Pharmacy and completed a postdoctoral residency at the Department of Veterans Affairs Medical Center in Tuscaloosa, Alabama.

**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 in November 2004 as a Regional Medical Scientist. From 2001 to 2004, Dr. Rodriguez 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.

As of December 31, 2012, we had an accumulated deficit of \$413.2 million. Our net loss for the year ended December 31, 2012 was \$27.1 million, which included a gain of \$18.8 million on the sale of our rights and certain assets related to FARESTON®. We expect to incur significant net losses 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.

Our current product candidates, enobosarm (also known as Ostarine® or GTx-024) and Capesaris® (GTx-758), will require significant additional clinical development and financial resources to obtain necessary regulatory approvals in order to develop these product candidates into commercially viable products. Accordingly, we do not expect to obtain United States Food and Drug Administration, or FDA, approval or any other regulatory approvals to market any of our product candidates in the next twelve months, and it is possible that our product candidates will never receive any regulatory approvals.

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. We also previously recognized product revenue from the sale of FARESTON®, the rights to which we sold to a third party in the third quarter of 2012. Currently, we have no ongoing collaborations for the development and commercialization of our product candidates, and as a result of the sale of our rights and certain assets related to FARESTON®, we also currently have no sources of revenue. 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 is 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 capital 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;
- seek regulatory approval for our product candidates; and

commercialize our product candidates, if any such product candidates receive regulatory approval for commercial sale.

As of the date of this Annual Report on Form 10-K, we estimate that our current cash, cash equivalents, and short-term investments, together with interest thereon, 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. We could utilize our available capital resources sooner than we currently expect, and we could need additional funding sooner than currently anticipated. In any event, to complete the development of Capesaris® and seek regulatory approval for enobosarm, we will need to obtain substantial additional funding. 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 ongoing, planned and any other future clinical trials of enobosarm and Capesaris®;
- the terms and timing of any potential future collaborative, licensing and other arrangements that we may establish;
- the decision to initiate development of new potential medicines from our research and discovery activities;
- the amount and timing of any licensing fees, milestone payments and royalty payments from potential future collaborators, if any;
- 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 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 nor do we currently have any sources of revenue. 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. In June 2011, we announced a workforce reduction of approximately 15% in order to reduce our operating expenses relating to our discontinued toremifene development programs. If we are unable to raise additional funds when needed, we may need to further reduce our expenditures, perhaps

significantly, to preserve our cash. 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 outcomes of ongoing and planned clinical trials of enobosarm and Capesaris®, uncertainty regarding our financial condition and/or current economic conditions, including the effects of, disruptions to and volatility in the credit and financial markets in the United States, the European Union and other regions of the world, including those resulting from or associated with rising government debt levels. 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 and selective ER alpha agonist 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 adequately demonstrate safety and efficacy in humans.

Significant additional research and development and financial resources will be required to obtain necessary regulatory approvals for our product candidates and to develop them into commercially viable products. Preclinical and clinical testing is expensive, can take many years to complete 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. If a product candidate fails at any stage of development, we will not have the anticipated revenues from that product candidate to fund our operations, and we will not receive any return on our investment in that product candidate. For example, we announced in May 2010 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, after we had incurred significant development costs. Even if the results of a clinical trial are positive, the efficacy and/or safety results from the trial may be insufficient to support the submission of a new drug application, or NDA, to the FDA, or if submitted, the approval of the NDA by 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 androgen deprivation therapy, or ADT, notifying us that the FDA would not approve the NDA. We have since discontinued our toremifene development programs.

Significant delays in clinical testing could materially impact our product development costs. We do not know whether planned or other future clinical trials will begin on time, or whether ongoing or planned clinical trials will need to be restructured or will be completed on schedule, if at all. We or any potential future collaborators may experience numerous unforeseen and/or adverse 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, or we may experience substantial delays in obtaining these authorizations;
- 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;
- even if preclinical or clinical trial results are positive, the FDA or foreign regulatory authorities could nonetheless require us to conduct unanticipated additional clinical trials;
- · registration or enrollment in clinical trials may be slower than we anticipate, resulting in significant delays or study terminations;
- 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 materially and adversely impact our business, financial condition and growth prospects.

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 required to cease further development of such product candidates, may be denied regulatory approval of such products, may be forced to change the labeling of such products or may be required to withdraw any such products from the market, any of which would hinder or preclude our ability to generate revenues.

In three Phase II clinical trials of Capesaris®, which we discontinued in February 2012, we observed venous thromboembolic events, or blood clots, in subjects treated with Capesaris® at the doses being studied in the trials (1000 mg and higher per day) and reported those events to the FDA. There were two deaths in subjects treated with Capesaris® and two deaths in subjects treated with Lupron Depot®. In February 2012, the FDA placed all of our then ongoing clinical studies of Capesaris® on full clinical hold and we suspended further enrollment into these studies and notified clinical sites to discontinue treatment of subjects with Capesaris®. In May 2012, the FDA notified us that it had removed the full clinical hold on Capesaris®. In the third quarter of 2012, we initiated a Phase II clinical trial to evaluate Capesaris®, at doses lower than those which were previously being tested in our discontinued Phase II clinical trials, as secondary hormonal therapy in men with metastatic castration resistant prostate cancer, or CRPC. Although our current Phase II clinical trial is evaluating Capesaris® at doses lower than those which were previously being tested in our discontinued Phase II clinical trials, we cannot be confident that we will not observe an unacceptable incidence of venous thromboembolic events or other adverse events in the current Phase II clinical trial. Our ability to develop Capesaris® as an effective secondary hormonal therapy for men with metastatic CRPC or, potentially, as a primary treatment for advanced prostate cancer used in combination with ADT is

dependent on our ability to find an appropriate dose that is both effective and safe for these patient populations. If an unacceptable incidence of venous thromboembolic events or other adverse events are observed in our current Phase II clinical trial of Capesaris®, we may be required to abandon our development of Capesaris®, in which case, we would not receive any return on our investment in that product candidate.

In our Phase II clinical trials for enobosarm for the treatment of muscle wasting in patients with cancer and healthy older males and postmenopausal females, we observed mild elevations of hepatic enzymes, which in certain circumstances may lead to liver failure, in a few patients in both the placebo and enobosarm treated groups. Reductions in high-density lipoproteins have also been observed in subjects treated with enobosarm. Lower levels of high-density lipoproteins could lead to increased risk of adverse cardiovascular events.

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 the 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. 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. 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 2011, we and Ipsen Biopharm Limited, or Ipsen, mutually agreed to terminate our collaboration for the development and commercialization of our toremifene-based product candidate, and, as a result, we will not receive any additional milestone payments from Ipsen on account of our collaboration with 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, 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, at an acceptable cost, and with appropriate quality control, 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 rely on third-party vendors for the manufacture of enobosarm drug substance. If our supply of enobosarm becomes unusable or if the contract manufacturers that we are currently utilizing to meet our supply needs for enobosarm or any future SARM product candidates prove incapable or unwilling to continue to meet our supply needs, we could experience a delay in conducting any additional clinical trials of enobosarm or any future 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 our suppliers fail to meet our requirements for Capesaris®, enobosarm or any future 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 or products.

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

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party because of factors beyond our control;
- the possible termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us; and
- drug product supplies not meeting the requisite requirements for clinical trial use.

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.

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 license from the University of Tennessee Research Foundation, or UTRF, we may be unable to continue a substantial part of our husiness.

We have licensed intellectual property rights and technology from UTRF used in a substantial part of our business. This license agreement, under which we were granted rights to SARM compounds and technologies, 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 this agreement is terminated, then we may lose our rights to utilize the SARM technology and intellectual property covered by that agreement to market, distribute and sell licensed products, including enobosarm, 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. 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. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent defense and enforcement. The regulations

and procedures to govern administration of the Leahy-Smith Act, and the substantive and procedural changes to patent law associated with the Leahy-Smith Act are being implemented in stages, beginning from September 16, 2011, and continuing through March 16, 2013. For example, the Leahy-Smith Act has introduced procedures making it easier for third-parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. In addition, the Leahy-Smith Act will change the United States from a "first-to-invent" jurisdiction to a "first-inventor-to-file" jurisdiction and will change the definition of what constitutes prior art for an application. Finally, the Leahy-Smith Act contains new statutory provisions that still require the U.S. Patent and Trademark Office to issue new regulations for their implementation and it may take the courts years to interpret the provisions of the new statute. Accordingly, it is too early to determine what effect or impact the Leahy-Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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 of utility, 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.

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/or 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 potential future 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 next twelve months, 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, on July 9, 2012 Congress enacted the Food and Drug Administration Safety and Innovation Act (FDASIA) that, among other things, reauthorizes the Prescription Drug User Fee Act, or PDUFA, for an additional five years. FDASIA incorporates new FDA performance goals that effectively extend by two months the time period in which the FDA is expected to review and approve certain NDAs. Although the FDA has stated that it expects to meet PDUFA's updated timing goals, it has in the past provided its managers discretion to miss them due to heightened agency workload or understaffing in the review divisions; accordingly, it remains unclear whether and to what extent the FDA will adhere to PDUFA timing goals 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 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 as a result of certain clinical deficiencies identified in the Complete Response Letter. We have since discontinued our toremifene 80 mg development program, as well as our other toremifene-based products and terminated our license and supply agreement with Orion for toremifene products. While we have met with the FDA to discuss the development program and required endpoints to obtain approval of enobosarm, there can be no assurance that the FDA will ultimately determine that data from our current pivotal Phase III clinical trials of enobosarm will be sufficient for approval of this product candidate. Additionally, there can be no assurance that the FDA will determine that the data from our ongoing clinical trial or future clinical trials of Capesaris® will be sufficient for approval of this product candidate in any indication. For example, we may observe an unacceptable incidence of adverse events in our ongoing, planned or potential future clinical trials of enobosarm or Capesaris®, which could require us to abandon the development of the affected product candidate.

In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent regulatory approval of a product candidate. 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 next twelve months, 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 potential post-approval requirements.

The "fast track" designation for development of any of our product candidates may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood the product candidate will receive regulatory approval.

If a product candidate is intended for the treatment of a serious or life-threatening condition and the product candidate demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA "fast track" designation for a particular indication. Marketing applications filed by sponsors of product candidates in the fast track process may qualify for priority review under the policies and procedures offered by the FDA, but the fast track designation does not assure any such review. Although we have obtained a fast track designation from the FDA for enobosarm for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer, receipt of fast track designation may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures. In addition, the FDA may withdraw our fast track designation at any time. If we lose our fast track designation, the approval process may be delayed. In addition, our fast track designation does not guarantee that we will be able to take advantage of the expedited review procedures and does not increase the likelihood that enobosarm will receive any regulatory approvals.

#### 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, health care 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.

If we are unable to establish 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. In the event one of our product candidates is approved, we will need to establish 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 any products that we and/or any potential future collaborators may develop and sell could negatively impact our future operating and financial results.

Medicare coverage and reimbursement of prescription drugs exists under Medicare Part D for oral drug products capable of self-administration by patients. Our oral drug product candidates would likely be covered by Medicare Part D (if covered by Medicare at all). 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. The legislation, however, also implemented cost containment and other measures that could adversely affect revenues from sales of product candidates, including an increase in drug rebates manufacturers must pay under Medicaid for brand name prescription drugs and extension of these rebates to Medicaid managed care.

Pharmaceutical manufacturers and importers of brand name prescription drugs are assessed a fee based on our proportionate share of sales of brand name prescription drugs to certain government programs, including Medicare and Medicaid, made in the preceding year if such sales exceed a defined threshold. Since 2011, manufacturers have been required to provide a 50% discount on brand name prescription drugs sold to beneficiaries who fall within a gap that exists in the Medicare Part D prescription drug program (commonly known as the "donut hole").

The health care reform legislation has been subject to political and judicial challenge. In 2012, the Supreme Court considered the constitutionality of certain provisions of the law. The court upheld as constitutional the mandate for individuals to obtain health insurance but held that the provision allowing the federal government to withhold certain Medicaid funds to states that do not expand state Medicaid programs was unconstitutional. The impact of the court's ruling remains uncertain. Political and judicial challenges to the law may continue in the wake of the court's ruling.

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 extend well beyond the receipt of regulatory marketing approval for a product and may require us or any potential future collaborators 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. Recently budgetary pressures in many European Union countries are also causing governments to consider or implement various cost-containment measures, such as price freezes, increased price cuts and rebates. If budget pressures continue, governments may implement additional cost containment measures. 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 enactment in the United States of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act in 2010. Federal and state legislatures within the United States and foreign governments will likely 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 of 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 prior commercial sales of FARESTON® and the testing of our product candidates in human clinical trials, and we 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 any commercial products up to a \$30 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 enobosarm and any future SARM product candidates, if approved for commercial sale, including SARMs in development from Ligand Pharmaceuticals Inc. and GlaxoSmithKline plc. Pfizer Inc., Eli Lilly and Company and Amgen Inc. have myostatin inhibitors in development that may compete with enobosarm 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) and Novartis AG is developing a human monoclonal antibody for various muscle indications. Moreover, there are other categories of drugs in development, including ghrelin receptor agonists, growth hormone, secretagogues, inflammatory modulators and other agents, that may have some muscle activity. Helsinn Group is developing anamorelin, a ghrelin receptor agonist, in Phase III clinical trials for treatment of cancer cachexia in patients with non-small cell lung cancer. Appetite stimulants such as Megace® (megestrol acetate) and dronabinol are used off-label for the treatment of weight loss and the treatment of loss of appetite in patients with cancer.

We are developing Capesaris® for secondary hormonal therapy in men with metastatic CRPC, and, potentially, as a primary treatment for advanced prostate cancer used in combination with androgen deprivation therapy. There are various products approved or under clinical development to treat men with advanced prostate cancer who have metastatic CRPC which may compete with Capesaris®. Dendreon Corporation markets and sells Provenge®, an autologous cellular immunotherapy, for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer. Medivation, Inc. has received approval for Xtandi®, an oral androgen receptor antagonist, for the treatment of metastatic castration-resistant prostate cancer in men previously treated with docetaxel. Medivation continues to develop Xtandi® for men with metastatic CRPC prior to receiving chemotherapy. Zytiga®, sold by Johnson & Johnson, has been approved for the treatment of metastatic CRPC prior in patients who have received prior chemotherapy and recently received approval for the treatment of metastatic castrate resistant prostate cancer prior to chemotherapy. Millennium: The Takeda Oncology Company is developing TAK-700 for the treatment of men with metastatic castrate resistant prostate cancer prior to chemotherapy and post docetaxel. Capesaris® is being developed as a treatment for this same patient population prior to the initiation of chemotherapy. Aragon Pharmaceuticals has developed a second generation anti-androgen (ARN-509) that is currently being evaluated in Phase II studies in men with progressive, advanced 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. We also announced a reduction of approximately 15% of our workforce in June 2011 in connection with our decision to discontinue the development of toremifene 80 mg and toremifene 20 mg. These 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 may need to hire experienced sales and marketing personnel to sell and market those product candidates we decide to commercialize, and we will need to expand the number of our managerial, operational, financial and other employees to support commercialization. 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, enrollment or completion of our ongoing and planned clinical trials of enobosarm and Capesaris®, or negative or inconclusive results reported in any of our ongoing and planned clinical trials of enobosarm and Capesaris®;
- reports of unacceptable incidences of adverse events observed in any of our ongoing and planned clinical trials of enobosarm and Capesaris®;
- 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;
- our ability to raise additional capital to carry through with our clinical development plans and current and future operations and the terms of any related financing arrangements;
- 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 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;
- hedging or arbitrage trading activity that may develop regarding our common stock;
- 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. The financial markets continue to face significant uncertainty, 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 December 31, 2012, our executive officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 63.4% of our outstanding common stock, and our executive officers and directors alone beneficially owned approximately 38.3% 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, 2012, the average daily trading volume of our common stock on The NASDAQ Global Market was 284,047 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, 2012, we had 62,818,424 shares of common stock outstanding.

Moreover, J.R. Hyde, III and Oracle Partners, L.P., two of our largest stockholders, and certain of 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; however, as a non-affiliate, Oracle Partners, L.P., is not currently required to register its shares of common stock prior to a public sale of securities. 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 31,000 square feet of laboratory and office space located at 3 North Dunlap Street, Memphis, Tennessee from the University of Tennessee Research Foundation. The sublease expires on December 31, 2014, unless sooner terminated in accordance with the terms of this sublease. We also 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.

#### ITEM 3. LEGAL PROCEEDINGS

We are not currently involved in any material legal proceedings.

#### ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

#### **PART II**

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

## Market for Registrant's Common Equity

Our common stock began trading on The NASDAQ Global Market under the symbol "GTXI" on February 3, 2004. 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.

		2012			2011			
	H	High		Low		ligh	Low	
First Quarter	\$	6.55	\$	3.15	\$	3.12	\$	2.27
Second Quarter		3.92		2.62		6.86		2.60
Third Quarter		5.35		3.29		4.93		2.67
Fourth Quarter		4.92		3.39		4.74		2.34

On February 26, 2013, the closing price of our common stock as reported on The NASDAQ Global Market was \$4.57 per share and there were approximately 76 holders of record of our common stock.

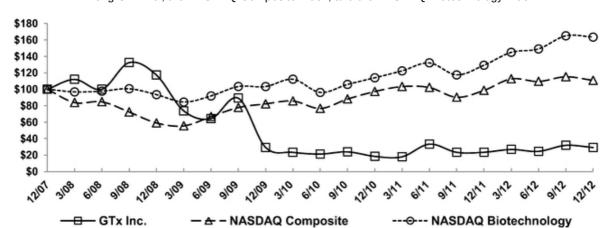
### Performance Graph<sup>1</sup>

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 120 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, 2007 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, 2012 as reported on The NASDAQ Global Market was \$4.20.

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

# COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\* Among GTx Inc., the NASDAQ Composite Index, and the NASDAQ Biotechnology Index



<sup>\*\$100</sup> invested on 12/31/07 in stock or index, including reinvestment of dividends.

## **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.

<sup>&</sup>lt;sup>1</sup> 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.

#### 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 following selected financial data have been derived from our audited historical financial statements, certain of which are included elsewhere in the Annual Report on Form 10-K. Certain prior year amounts have been reclassified to conform to the current year presentation. Historical results are not indicative of the results to be expected in the future.

				Years E	nde	ed Decem	ber	· 31,	
		2012		2011	2010		2009		2008
			(ir	thousand	ls, e	xcept per	sha	are data)	
Statement of Operations Data:									
Revenues:									
Collaboration revenue	\$	-	\$	8,066	\$	56,786	\$	11,441	\$ 12,440
Expenses:									
Research and development expenses		38,887		31,938		28,495		32,344	44,259
General and administrative expenses		10,845		12,027		13,194		27,165	22,571
Total expenses		49,732		43,965		41,689		59,509	66,830
(Loss) income from operations		(49,732)		(35,899)		15,097		(48,068)	(54,390)
Other (expense) income, net		(19)		398		1,363		188	2,740
(Loss) income from operations before income taxes		(49,751)		(35,501)		16,460		(47,880)	(51,650)
Income tax benefit		8,821		886		-		770	-
Net (loss) income from continuing operations		(40,930)		(34,615)		16,460		(47,110)	(51,650)
Income (loss) from discontinued operations before	_								
income taxes		22,676		2,207		(1,166)		1,386	(130)
Income tax expense		(8,821)		(886)		-		(532)	-
Net (loss) income from discontinued operations		13,855		1,321		(1,166)		854	(130)
Net (loss) income	\$	(27,075)	\$	(33,294)	\$	15,294	\$	(46,256)	\$ (51,780)
Net (loss) income per share — basic and diluted:									
Net (loss) income from continuing operations	\$	(0.65)	\$	(0.60)	\$	0.42	\$	(1.29)	\$ (1.43)
Net (loss) income from discontinued operations	_	0.22		0.02		(0.03)		0.02	_
Net (loss) income per share	\$	(0.43)	\$	(0.58)	\$	0.39	\$	(1.27)	\$ (1.43)

	 As of December 31,										
	 2012		2011		2010		2009		2008		
	 	(in thousands)									
Balance Sheet Data:											
Cash, cash equivalents and short-term											
investments	\$ 56,089	\$	74,440	\$	58,631	\$	49,044	\$	97,667		
Working capital	47,320		71,015		55,149		34,876		79,000		
Total assets	57,774		78,656		64,583		56,034		108,310		
Accumulated deficit	(413,249)		(386,174)		(352,880)		(368,174)		(321,918)		
Total stockholders' equity (deficit)	47,701		71,874		51,727		(8,750)		32,018		

#### 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

#### **Business Overview**

We are a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules for the treatment of cancer, cancer supportive care, and other serious medical conditions.

#### **Business Highlights**

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). Our lead SARM product candidate, enobosarm (also known as Ostarine® or GTx-024), has to date been evaluated in eight completed clinical trials enrolling approximately 600 subjects, including in a Phase Ib and two Phase II efficacy studies. Enobosarm is the generic name given to the compound by the USAN Council and the World Health Organization and is the first compound to receive the SARM stem in its name, recognizing enobosarm as the first in this new class of compounds.

We are conducting the POWER 1 and POWER 2 (Prevention and treatment Of muscle Wasting in patients with cancER) pivotal Phase III clinical trials evaluating enobosarm for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer. We are conducting these trials in clinical sites in the United States, Europe, Russia and South America. Each of the pivotal Phase III placebo-controlled, double-blind clinical trials was fully enrolled during the fourth quarter of 2012, with approximately 325 patients in each clinical trial. In each of these clinical trials, patients with Stage III or IV non-small cell lung cancer have been randomized to placebo or enobosarm 3 mg at the time they began first line chemotherapy. The trials are evaluating as co-primary endpoints the effect of enobosarm versus placebo on total lean body mass (muscle) assessed by dual x-ray absorptiometry, or DXA, and on physical function assessed by the Stair Climb Test at three months. Durability of effect is being assessed as a secondary endpoint at five months. In October 2012, after a prespecified safety review in subjects currently enrolled in these two clinical trials, the independent Data Safety Monitoring Board determined that the trials could continue as planned. In January 2013, the FDA designated enobosarm for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer as a fast track development program. Fast track status is a process designed by the FDA to facilitate the development and expedite the review of new drug candidates that are intended to treat serious diseases and have the potential to fill an unmet medical need. We currently expect topline data from these pivotal Phase III clinical trials during the third quarter of 2013. Subject to obtaining positive data from these pivotal Phase III clinical trials and receiving marketing authorization from the appropriate regulatory authorities, we will consider either building a specialized sales and marketing or

Additionally, we are developing Capesaris® (GTx-758), an oral nonsteroidal selective estrogen receptor alpha agonist, for secondary hormonal therapy in men with metastatic castration resistant prostate cancer, or CRPC, and, potentially, as a primary treatment for advanced prostate cancer used in combination with androgen deprivation therapy, or ADT. We believe Capesaris® has the potential to reduce free testosterone without also causing certain estrogen deficiency side effects, such as bone loss, hot flashes and insulin resistance, which are common with current androgen deprivation therapies for prostate cancer. We also believe that Capesaris® may be effective, in combination with ADT, as a primary treatment of advanced prostate cancer by reducing free testosterone to levels lower than those attainable with ADT alone and potentially reducing the estrogen deficiency side effects caused by the use of ADT.

In May 2012, we announced that the United States Food and Drug Administration, or FDA, had removed its full clinical hold on our Investigational New Drug, or IND, application for Capesaris®. The full clinical hold was placed on our three then ongoing Phase II clinical trials evaluating Capesaris® to treat men with advanced prostate cancer in February 2012 and resulted in the discontinuation of these trials. The full clinical hold followed our reports to the FDA of venous thromboembolic events (blood clots), or VTEs, in subjects treated with Capesaris® at the doses being studied in those trials (1000 mg and higher per day). Based upon feedback from the FDA in connection with the removal of the full clinical hold, we initiated in the third quarter of 2012 a Phase II clinical trial to evaluate the safety and efficacy of lower doses of Capesaris® as secondary hormonal therapy in men with metastatic CRPC.

Capesaris® has previously demonstrated the ability to increase the production of a protein called sex hormone binding globulin, or SHBG, in men with advanced prostate cancer and reduce free testosterone. By reducing free testosterone, we believe serum prostate specific antigen, or PSA, will be reduced in men with CRPC. The primary endpoint of the current Phase II open-label clinical trial is the proportion of subjects with a ³50% decline from baseline in serum PSA by day 90. Other key endpoints include serum SHBG, total and free testosterone levels and progression free survival in the study subjects. In addition, the clinical study will evaluate the ability of Capesaris® to treat certain estrogen deficiency side effects associated with luteinizing hormone releasing hormone agonists such as hot flashes, bone loss, and insulin resistance. The clinical trial requires subjects to continue receiving their ADT treatment, which will allow us to assess the safety and tolerability of Capesaris® in these subjects, including the incidence of VTEs. The trial design provides for 75 total subjects, with three sequential dosing arms. The first 25 subjects in the Phase II clinical trial are being enrolled in the Capesaris® 125 mg dosing arm. Assuming that an acceptable incidence of VTEs has been observed when the last subject enrolled in the Capesaris® 125 mg dose arm has completed one 30 day cycle of therapy, enrollment of the final 25 subjects when the last subject enrolled in the 250 mg dose arm has completed one 30 day cycle of therapy, assuming an acceptable incidence of VTEs has been observed in both of the lower dosage arms.

#### Financial Highlights

Effective September 30, 2012, we sold our rights and certain assets related to FARESTON® to Strakan International S.á r.l., an affiliate of ProStrakan Group plc, or ProStrakan, for a purchase price of approximately \$21.7 million in cash and recognized a gain on the sale of \$18.8 million. Through September 30, 2012, we sold FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of metastatic breast cancer in postmenopausal women, in the United States. We acquired the rights to FARESTON® in 2005 in connection with our then development of toremifene-based products, including toremifene 80 mg and toremifene 20 mg. In connection with our decision to discontinue development of toremifene 20 mg and toremifene 80 mg in 2010 and 2011, respectively, we discontinued all further development of toremifene-based products.

Our net loss for the year ended December 31, 2012 was \$27.1 million. Our net loss included a gain of \$18.8 million on the sale of our rights and certain assets related to FARESTON®. We expect to incur significant net losses in 2013 and for the foreseeable future as we continue our clinical development and research and development activities and seek regulatory approval of our product candidates. Currently, we have no ongoing collaborations for the development and commercialization of our product candidates, and, as a result of the sale of our rights and certain assets related to FARESTON®, we also currently have no source of revenue. Our current product candidates, enobosarm and Capesaris®, will require significant additional clinical development and financial resources to obtain necessary regulatory approvals in order to develop these product candidates into commercially viable products. Accordingly, we do not expect to obtain FDA approval or any other regulatory approvals to market any of our product candidates in the next twelve months, and it is possible that our product candidates will never receive any regulatory approvals.

At December 31, 2012, we had cash, cash equivalents and short-term investments of \$56.1 million, compared to \$74.4 million at December 31, 2011.

As of the date of this Annual Report on Form 10-K, we estimate that our current cash, cash equivalents, and short-term investments, together with interest thereon, 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. We could utilize our available capital resources sooner than we currently expect, and we could need additional funding sooner than currently anticipated. In any event, to complete the development of Capesaris® and seek regulatory approval for enobosarm, we will need to obtain substantial additional funding.

#### **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 and supplies 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.

We expect that our research and development expenses for fiscal year 2013 will increase as compared to fiscal year 2012 and to be primarily focused on the following:

- the continued clinical development of enobosarm;
- 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 New Drug Application, or 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 a 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 a 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 our 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 ongoing, planned and any other future clinical trials of enobosarm and Capesaris®;
- the terms and timing of any potential future collaborative, licensing and other arrangements that we may establish;
- the decision to initiate development of new potential medicines from our research and discovery activities;
- the amount and timing of any licensing fees, milestone payments and royalty payments from potential future collaborators, if any;
- 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 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.

#### **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, and investor relations functions. General and administrative expenses also include facility costs, insurance costs, and professional fees for legal, accounting, and public relation services. We expect our general and administrative expenses for fiscal year 2013 to be consistent with fiscal year 2012.

### **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.

#### **Discontinued Operations**

Effective September 30, 2012, we completed the sale of FARESTON® for a total cash purchase price of \$21.7 million, including payment for purchased inventory. We have accounted for FARESTON® as a discontinued operation. As a result, revenue, cost of goods sold, and operating expenses relating to FARESTON® have been excluded from their respective captions in the statements of operations and have been included in discontinued operations for the year ended December 31, 2012. We have also applied retroactive adjustments to the statements of operations for the years ended December 31, 2011 and 2010 to reflect the effects of the discontinued operations.

#### **Revenue Recognition**

Our revenues consisted of product sales of FARESTON®, which is included in income from discontinued operations before income taxes, and in 2011, also consisted of revenues derived from our former collaboration and license agreements.

Revenue from product sales of FARESTON® was recognized less deductions for estimated sales discounts and sales returns. Revenue from product sales was recognized when persuasive evidence of an arrangement existed, title passed, the price was fixed or determinable, and collectability was reasonably

assured. We accounted 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. Although we sold our rights and certain assets related to FARESTON® effective September 30, 2012, we retain the liability for future product returns relating to sales of FARESTON® by us prior to September 30, 2012. Therefore, we estimate an accrual for product returns based on factors which include historical product returns and estimated product in the distribution channel which is expected to exceed its expiration date. At December 31, 2012 and December 31, 2011, our accrual for product returns, was \$1.2 million and \$1.1 million, respectively.

Collaboration revenue consisted of non-refundable upfront payments, license fees, reimbursements for research and development activities, and milestone payments associated with our former collaboration and license agreements and was based on the performance requirements of the specific agreements. We analyzed 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, could have been separated or whether all of the deliverables must have been accounted for as a single unit of accounting. Performance obligations typically consisted 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.

#### 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 and medical 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 measure 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, 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.

The following table summarizes share-based compensation expense included within the statements of operations for the years ended December 31, 2012, 2011 and 2010:

	Years ended December 31,						
		2012		2011		2010	
	(in thousands)						
Research and development expenses	\$	1,046	\$	1,972	\$	2,340	
General and administrative expenses		1,771		2,432		2,546	
Total share-based compensation	\$	2,817	\$	4,404	\$	4,886	

Share-based compensation expense recorded in the statement of operations as general and administrative expense for the years ended December 31, 2012, 2011 and 2010 included share-based compensation expense related to deferred compensation arrangements for our non-employee directors of \$169,000, \$178,000 and \$187,000, respectively. At December 31, 2012, the total compensation cost related to non-vested awards not yet recognized was approximately \$4.2 million with a weighted average expense recognition period of 2.83 years.

#### **Income Taxes**

We have recognized the tax effect of discontinued operations in the statements of operations in accordance with the intra-period accounting rules. An offsetting tax benefit or expense is recorded in continuing operations in each year in which tax expense or benefit was recognized for discontinued operations.

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, 2012 and 2011, net of the valuation allowance, the net deferred tax assets were reduced to zero.

### Impairment of Long-Lived Assets

We review long-lived assets for impairment whenever events or changes in facts and circumstances are present, both internally and externally, that may indicate impairment of long-lived assets. 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.

In 2011, after discontinuing our toremifene 80 mg development program, we recorded an impairment charge of \$1.6 million. The impaired intangible asset consisted of capitalized license fees paid to Orion Corporation, or Orion, related to our toremifene 80 mg program. The impairment charge was included in research and development expenses in the statement of operations for the year ended December 31, 2011.

In 2010, after discontinuing our toremifene 20 mg development program, we recorded an impairment charge of \$1.7 million. The impaired intangible assets consisted of capitalized license fees related to our toremifene 20 mg program paid to Orion and the University of Tennessee Research

Foundation. The impairment charge was included in research and development expenses in the statement of operations for the year ended December 31, 2010.

#### **Results of Operations**

#### **Collaboration Revenue**

There was no collaboration revenue recognized for the year ended December 31, 2012. Collaboration revenue was \$8.1 million for the year ended December 31, 2011, which resulted from recognition of all remaining unamortized deferred revenue due to the termination of our license and collaboration agreement with Ipsen Biopharm Limited, or Ipsen, in March 2011. Collaboration revenue for the year ended December 31, 2010 was \$56.8 million, which consisted of approximately \$1.9 million from Ipsen and \$54.9 million from Merck & Co., or Merck, resulting from the termination of our license and collaboration agreement with Merck in March 2010.

#### **Research and Development Expenses**

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. Research and development spending for past periods is not indicative of spending in future periods.

Proposed Candidate / Proposed Indication	Program	Years Ended December 3				31,		
		2012		2011		2010		
		(in thousands)						
<b>Enobosarm</b> Prevention and treatment of muscle wasting in patients	SARM	\$	24,320	\$	10,474	\$	3,20	
with advanced non-small cell lung cancer								
Capesaris®								
Secondary hormonal therapy in men with metastatic castration resistant prostate cancer	Selective ER alpha agonist		7,458		12,052		8,64	
Other research and development			7,109		9,412		16,64	
Total research and development expenses		\$	38,887	\$	31,938	\$	28,49	

Research and development expenses increased 22% to \$38.9 million for the year ended December 31, 2012 from \$31.9 million for the year ended December 31, 2011. The increase in research and development expenses related to the enobosarm product candidate was due primarily to a \$13.8 million increase in the costs related to the enrollment of and operations related to the two pivotal Phase III clinical trials for enobosarm. The decrease in research and development expenses related to Capesaris® was due to the discontinuance in February 2012 of the three Phase II clinical trials of Capesaris® to treat men with advanced prostate cancer that were placed on full clinical hold by the FDA, partially offset by the initiation in the third quarter of 2012 of the Phase II clinical trial to evaluate lower doses of Capesaris® as secondary hormonal therapy in men with metastatic CRPC.

Research and development expenses increased 12% to \$31.9 million for the year ended December 31, 2011 from \$28.5 million for the year ended December 31, 2010. The increase in research and development expenses during the year ended December 31, 2011 compared to the year ended December 31, 2010 was due primarily to a \$7.3 million increase in research and development expenses from the initiation of the two pivotal Phase III clinical trials for enobosarm, and a \$3.4 million increase in expenses from the initiation of our three since discontinued Phase II clinical trials for Capesaris® in 2011.

"Other research and development" expenses include the cost of personnel, supplies and facilities associated with preclinical and discovery research and development activities, as well as the cost of our former toremifene 80 mg and toremifene 20 mg clinical programs for the years ended December 31, 2011 and 2010. For the year ended December 31, 2011, "Other research and development" includes research and development expenses of \$2.0 million, which included an impairment charge of \$1.6 million, for toremifene 80 mg development and \$486,000 for toremifene 20 mg development. For the year ended December 31, 2010, "Other research and development" includes research and development expenses of \$4.3 million for toremifene 80 mg development and \$5.1 million, which included an impairment charge of \$1.7 million, for toremifene 20 mg development.

#### General and Administrative Expenses

General and administrative expenses decreased 10% to \$10.8 million for the year ended December 31, 2012 from \$12.0 million for the year ended December 31, 2011. This decrease was primarily due to reduced salary and benefit expenses related to employee attrition of \$739,000 and decreased legal expenses of \$373,000.

General and administrative expenses decreased 9% to \$12.0 million for the year ended December 31, 2011 from \$13.2 million for the year ended December 31, 2010. This decrease was primarily due to reduced insurance, legal and occupancy expenses of \$360,000, \$280,000, and \$240,000, respectively.

#### Other (Expense) Income, Net

Other expense, net for the year ended December 31, 2012 was \$19,000 compared to other income, net of \$398,000 for the year ended December 31, 2011. Other income, net for the year ended December 31, 2011 decreased \$965,000 from \$1.4 million for the year ended December 31, 2010. 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.

#### **Discontinued Operations**

Income from discontinued operations before income taxes was \$22.7 million for the year ended December 31, 2012 and consisted of FARESTON® operating income of \$3.8 million and the recognition of a gain of \$18.8 million on the sale of rights and certain assets related to FARESTON®. Income (loss) from discontinued operations before income taxes for the years ended December 31, 2011 and December 31, 2010 consisted of FARESTON® operating income (loss).

The components of FARESTON® operating income (loss) for the years ended December 31, 2012, 2011 and 2010 were as follows:

	Years Ended December 31,							
	 2012		2011		2010			
	 	(in t	housands	)				
Product sales, net	\$ 5,284	\$	6,673	\$	3,827			
Cost of product sales	(784)		(1,055)		(768)			
Operating expenses	(655)		(3,411)		(4,225)			
FARESTON® operating income (loss)	\$ 3,845	\$	2,207	\$	(1,166)			

FARESTON® product sales, net decreased for the year ended December 31, 2012 compared to the prior year due primarily to the sale of the rights and certain assets related to FARESTON®, effective September 30, 2012. FARESTON® operating expenses decreased for the year ended December 31, 2012 as compared to the prior year due to the sale of FARESTON® and due to a reduction in FARESTON® marketing and medical education expenses.

FARESTON® product sales, net for the year ended December 31, 2011increased from the prior year due primarily to an increase of 35% in the sales price of FARESTON® and, to a lesser extent, an increase of 25% in sales volume. FARESTON® operating expenses decreased for the year ended December 31, 2011 as compared to prior year due to our workforce reduction that occurred in 2011 and a reduction in FARESTON® marketing expenses.

#### **Liquidity and Capital Resources**

Through December 31, 2012, we have financed our operations 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, 2012, we had an accumulated deficit of \$413.2 million, which resulted primarily from:

- our research and development activities associated with:
  - the preclinical and clinical development of our SARM compounds, including enobosarm for the prevention and treatment of muscle
    wasting in patients with cancer;
  - the preclinical and clinical development of Capesaris® for first and second line hormonal treatment of advanced prostate cancer;
  - the development of toremifene 80 mg to reduce fractures and treat other estrogen deficiency side effects of androgen deprivation therapy 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 prostatic intraepithelial neoplasia, including a Phase IIb clinical trial and a Phase III clinical trial;
  - the preclinical development of other product candidates; and
- general and administrative expenses.

We expect to incur significant operating losses in 2013 and for the foreseeable future as we continue our clinical development and research and development activities and seek regulatory approval for our product candidates. We do not expect to obtain FDA or any other regulatory approvals to market any of our product candidates in the next twelve months.

At December 31, 2012, we had cash, cash equivalents and short-term investments of \$56.1 million, compared to \$74.4 million at December 31, 2011 and \$58.6 million at December 31, 2010. As of December 31, 2012, 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 Federal Deposit Insurance Corporation insured certificates of deposit with original maturities greater than three months and less than one year.

In October 2012, we increased our cash and short-term investments when we received net cash proceeds of \$18.9 million related to the sale of our rights and certain assets related to FARESTON®.

In June 2011, we completed an underwritten public offering of 11,023,000 shares of our common stock at a price to the public of \$4.75 per share. Net cash proceeds from the public offering were approximately \$49.0 million, after deducting the underwriting discount and offering expenses.

In November 2010, we completed an underwritten public offering of 15,285,715 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 \$40.3 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 from Ipsen that were 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 from Merck that were provided for under our former collaboration with Merck. We have 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 Net cash provided by (used in) investing activities Net cash provided by financing activities Net (decrease) increase in cash and cash equivalents

rears Ending December 31,									
2012		2011	2010						
(in thousands)									
\$ (37,109)	\$	(33,089)	\$	(30,527)					
21,405		(10,299)		8,280					
3		48,952		40,209					
\$ (15,701)	\$	5,564	\$	17,962					

Net cash used in operating activities 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.

Net cash provided by investing activities for the year ended December 31, 2012 resulted from the proceeds from the sale of FARESTON®, net of cash expenses, of \$18.9 million and the maturities of short-term investments of \$14.6 million, offset by the purchase of short-term investments of \$12.0 million and the purchase of information technology equipment and research and development equipment of approximately \$142,000. Net cash used in investing activities for the year ended December 31, 2011 resulted from the purchase of short-term investments of \$15.1 million and the purchase of information technology equipment and research and development equipment of approximately \$54,000, offset by the maturities of short-term investments of \$4.9 million. Net cash provided by investing activities for the year ended December 31, 2010 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 provided by financing activities for the year ended December 31, 2012 reflected proceeds from the exercise of employee stock options. Net cash provided by financing activities for the year ended December 31, 2011 and 2010 reflected proceeds from our underwritten public offering of common stock in June 2011 and November 2010, respectively, and proceeds from the exercise of employee stock options. Proceeds in all years presented were reduced by payments on our capital lease and financed equipment obligations.

As of the date of this Annual Report on Form 10-K, we estimate that our current cash, cash equivalents, and short-term investments, together with interest thereon, 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. We could utilize our available capital resources sooner than we currently expect, and we could need additional funding sooner than currently anticipated. In any event, to complete the development of Capesaris® and seek regulatory approval for enobosarm, we will need to obtain substantial additional funding.

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 ongoing and any other future clinical trials of enobosarm and Capesaris®;
- the terms and timing of any potential future collaborative, licensing and other arrangements that we may establish;
- the decision to initiate development of new potential medicines from our research and discovery activities;
- the amount and timing of any license fees, milestone payments and royalty payments from potential future collaborators, if any;
- 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 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 nor do we currently have any sources of revenue. 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. In June 2011, we announced a workforce reduction of approximately 15% in order to reduce our operating expenses relating to our discontinued toremifene development programs. If we are unable to raise additional funds when needed, we may need to further reduce our expenditures, perhaps significantly, to preserve our cash. 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 outcomes of ongoing and potential future clinical trials of enobosarm and Capesaris®, uncertainty regarding our financial condition and/or current economic conditions, including the effects of, disruptions to and volatility in the credit and financial markets in the United States, the European Union and other regions of the world, including those resulting from or associated with rising government debt levels. 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 and selective ER alpha agonist programs, or conduct additional workforce or other expense reductions, any of which could have a material adverse effect on our business.

#### **Contractual Obligations**

At December 31, 2012, we had contractual obligations as follows:

	Payment Due by Period (in thousands)								
		Le	ss than					More th	ıan
Contractual Obligations <sup>(1)</sup>	 otal	1	year	1-3	3 years	4-5 y	ears	5 year	îs
Operating lease obligations <sup>(2)</sup>	\$ 2,733	\$	1,200	\$	1,533	\$	_	\$	_

- (1) This table does not include any royalty obligations under our license agreement as the timing and likelihood of such payments are not known. In addition to the minimum payments due under our current license agreement, we may be required to pay royalties on any net sales of product if we receive regulatory approval for a SARM product candidate, including enobosarm, and successfully market the product. Additionally, if we sublicense rights under our SARM License Agreement, we also are obligated to pay a sublicense royalty on any licensing fee or milestone payments we may receive from a sublicensee.
- Our long-term commitments under the operating leases 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, 2014. The sublease for the premises at 175 Toyota Plaza expires on April 30, 2015 and includes escalating rental payments.

#### **Off-Balance Sheet Arrangements**

We have not engaged in any off-balance sheet arrangements, including the use of standard finance, special purpose entities or variable interest entities.

#### 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 Federal Deposit Insurance Corporation insured 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, 2012.

In addition, we have exposure to fluctuations in certain foreign currencies in countries in which we conduct clinical trials. Most of our foreign expenses incurred are associated with conducting clinical trials for enobosarm at clinical trial sites in Europe. Consequently, changes in exchange rates could result in material exchange losses and could unpredictably, materially and adversely affect our financial position, results of operations and cash flows. A hypothetical 10% increase or decrease in foreign exchange rates would result in an approximate \$440,000 increase or decrease in our financial assets and liabilities denominated in euros. This potential change is based on a sensitivity analysis performed on our financial position at December 31, 2012. Actual results may differ materially. We have elected not to hedge our exposure to foreign currency fluctuations.

#### 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, 2012 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, 2012, our internal control over financial reporting was effective. The effectiveness of our internal control over financial reporting has been audited by Ernst & Young LLP, 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 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### ITEM 9B. OTHER INFORMATION

None.

#### 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 2013 Annual Meeting of Stockholders with the U.S. Securities and Exchange Commission pursuant to Regulation 14A (the "2012 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 2013 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 2013 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 2013 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 "Management 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 Web site (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 Web site 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 2013 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 2013 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 2013 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 2013 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 2013 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 2013 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 2013 Proxy Statement under the section entitled "Additional Information About the Board of Directors and Certain Corporate Governance Matters Director Independence."

#### ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item is incorporated herein by reference to the information from the 2013 Proxy Statement under the section entitled "Proposal No. 2 — Ratification of Appointment of Independent Registered Public Accounting Firm."

# PART IV

# ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

# (a)(1) Index to Financial Statements

Page	Description
Page F-2	Management's Report on Internal Control Over Financial Reporting
F-3	Reports of Independent Registered Public Accounting Firm
F-5	Balance Sheets at December 31, 2012 and 2011
F-6	Statements of Operations for the Years Ended December 31, 2012, 2011 and 2010
F-7	Statements of Stockholders' Equity (Deficit) for the Years Ended December 31, 2012, 2011 and 2010
F-8	Statements of Cash Flows for the Years Ended December 31, 2012, 2011 and 2010
F-9	Notes to Financial Statements

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

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

(b) Exhibits — The following exhibits are included herein or incorporated herein by reference:

Exhibit		Incorporation By Reference				
Number	Exhibit Description	Form	SEC File No.	Exhibit	Filing Date	
2.1	Asset Purchase Agreement dated as of September 28, 2012 between the Registrant and Strakan International S.à r.l.	8-K	000-50549	2.1	10/03/2012	
3.1	Restated Certificate of Incorporation of GTx, Inc.	S-3	333-127175	4.1	08/04/2005	
3.2	Certificate of Amendment of Restated Certificate of Incorporation of GTx, Inc.	8-K	000-50549	3.2	05/06/2011	
3.3	Amended and Restated Bylaws of GTx, Inc.	8-K	000-50549	3.2	07/26/2007	
4.1	Reference is made to Exhibits 3.1, 3.2 and 3.3					
4.2	Specimen of Common Stock Certificate	S-1	333-109700	4.2	12/22/2003	
4.3	Amended and Restated Registration Rights Agreement between Registrant and Oracle Partners, L.P. dated August 7, 2003	S-1	333-109700	4.3	10/15/2003	
4.4	Amended and Restated Registration Rights Agreement between Registrant and J. R. Hyde, III dated August 7, 2003	S-1	333-109700	4.4	10/15/2003	
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Exhibit		Incorporation By Reference							
Number	Exhibit Description	Form	SEC File No.	Exhibit	Filing Date				
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	S-3	333-148321	4.5	12/26/2007				
4.6	Consent, Waiver and Amendment between Registrant and J. R. Hyde, III and Pittco Associates, L.P. dated December 3, 2007	S-3	333-148321	4.6	12/26/2007				
10.1†	Consolidated, Amended, and Restated License Agreement dated July 24, 2007, between Registrant and University of Tennessee Research Foundation	10-Q	000-50549	10.40	11/09/2007				
10.2	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	10-K	000-50549	10.47	03/03/2009				
10.3†	Purchase Agreement dated December 13, 2004, between Registrant and Orion Corporation	8-K/A	000-50549	10.1	03/07/2005				
10.4†	Amended and Restated License and Supply Agreement effective January 1, 2005, between Registrant and Orion Corporation	8-K/A	000-50549	10.2	03/07/2005				
10.5†	Amendment dated May 23, 2006 to the Amended and Restated License and Supply Agreement effective January 1, 2005, between Registrant and Orion Corporation	10-Q	000-50549	10.33	08/09/2006				
10.6†	Amendment dated June 30, 2006 to the Amended and Restated License and Supply Agreement effective January 1, 2005, between Registrant and Orion Corporation	10-Q	000-50549	10.34	08/09/2006				
10.7*	Form of Indemnification Agreement	S-1	333-109700	10.12	12/22/2003				
10.8*	Genotherapeutics, Inc. 1999 Stock Option Plan, as amended through December 10, 2009, and Form of Stock Option Agreement	10-K	000-50549	10.1	03/15/2010				
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Exhibit		Incorporation By Reference				
Number	Exhibit Description	Form	SEC File No.	Exhibit	Filing Date	
10.9*	GTx, Inc. 2000 Stock Option Plan, as amended through December 10, 2009, and Form of Stock Option Agreement	10-K	000-50549	10.2	03/15/2010	
10.10*	$\ensuremath{GTx},$ Inc. 2001 Stock Option Plan, as amended through November 3, 2009, and Form of Stock Option Agreement	10-K	000-50549	10.3	03/15/2010	
10.11*	GTx, Inc. 2002 Stock Option Plan, as amended through November 3, 2009, and Form of Stock Option Agreement	10-K	000-50549	10.4	03/15/2010	
10.12*	GTx, Inc. 2004 Equity Incentive Plan and Form of Stock Option Agreement	S-1	333-109700	10.5	01/15/2004	
10.13*	GTx, Inc. 2004 Equity Incentive Plan, as amended effective April 30, 2008	8-K	000-50549	10.6	05/06/2008	
10.14*	GTx, Inc. 2004 Equity Incentive Plan, as amended effective November 4, 2008 and Form of Stock Option Agreement	10-K	000-50549	10.52	03/03/2009	
10.15*	GTx, Inc. 2004 Non-Employee Directors' Stock Option Plan and Form of Stock Option Agreement	S-1	333-109700	10.6	01/15/2004	
10.16*	Amended and Restated GTx, Inc. 2004 Non-Employee Directors' Stock Option Plan, effective April 26, 2006	8-K	000-50549	10.1	04/27/2006	
10.17*	Form of Stock Option Agreement under the Amended and Restated GTx, Inc. 2004 Non-Employee Directors' Stock Option Plan	10-Q	000-50549	10.35	08/09/2006	
10.18*	Amended and Restated GTx, Inc. 2004 Non-Employee Directors' Stock Option Plan, as amended effective November 4, 2008	10-K	000-50549	10.51	03/03/2009	
10.19*+	Amended and Restated Employment Agreement dated February 14, 2013, between Registrant and Mitchell S. Steiner, M.D.					
10.20*+	Amended and Restated Employment Agreement dated February 14, 2013, between Registrant and Marc S. Hanover					
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Exhibit		Incorporation By Reference				
Number	Exhibit Description	Form	SEC File No.	Exhibit	Filing Date	
10.21*+	Amended and Restated Employment Agreement dated February 14, 2013, between Registrant and Mark E. Mosteller					
10.22*+	Amended and Restated Employment Agreement dated February 14, 2013, between Registrant and Henry P. Doggrell					
10.23*+	Amended and Restated Employment Agreement dated February 14, 2013 between Registrant and James T. Dalton					
10.24*	Amended and Restated GTx, Inc. Executive Bonus Compensation Plan, effective November 4, 2008	10-K	000-50549	10.53	03/03/2009	
10.25*	2012 Compensation Information for Registrant's Executive Officers	10-K	000-50549	10.60	03/02/2012	
10.26*+	2013 Compensation Information for Registrant's Executive Officers					
10.27*	Directors' Deferred Compensation Plan, as amended effective November 4, 2008	10-K	000-50549	10.49	03/03/2009	
10.28*+	Directors' Deferred Compensation Plan, as amended and restated effective February 14, 2013					
10.29*	Non-Employee Director Compensation Policy of GTx, Inc., effective February 18, 2011	10-Q	000-50549	10.50	05/09/2011	
10.30*+	Non-Employee Director Compensation Policy of GTx, Inc., effective February 14, 2013					
10.31	Lease Agreement, dated March 7, 2001, between The University of Tennessee and TriStar Enterprises, Inc.	S-1	333-109700	10.13	10/15/2003	
10.32	Sublease Agreement dated October 1, 2000, as amended, between Registrant and TriStar Enterprises, Inc.	S-1	333-109700	10.14	10/15/2003	
10.33	Sublease Agreement dated April 1, 2005, as amended, between Registrant and TriStar Enterprises, Inc.	10-Q	000-50549	10.27	07/27/2005	
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Exhibit		Incorporation By Reference			
Number	Exhibit Description	Form	SEC File No.	Exhibit	Filing Date
10.34	Sublease Agreement dated October 1, 2009 between Registrant and University of Tennessee Research Foundation	10-K	000-50549	10.55	03/15/2010
10.35	Memorandum of Understanding Concerning the Lease Agreement between The University of Tennessee Research Foundation and the Registrant as Amended July 20, 2009	10-Q	000-50549	10.59	08/09/2011
10.36	Sublease Agreement, dated December 17, 2007 by and between the Registrant and ESS SUSA Holdings, LLC	10-K	000-50549	10.46	03/11/2008
10.37	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	10-K	000-50549	10.54	03/03/2009
10.38	Second Amendment to Sublease and Parking Sublicense Agreements dated January 1, 2011 by and between the Registrant and ESS SUSA Holdings, LLC	10-K	000-50549	10.57	03/08/2011
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) <sup>(1)</sup>				
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) <sup>(1)</sup>				
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Exhibit		Incorporation By Reference				
Number	Exhibit Description	Form	SEC File No.	Exhibit	Filing Date	
101.INS <sup>+</sup>	XBRL Instance Document <sup>(2)</sup>					
101.SCH <sup>+</sup>	XBRL Taxonomy Extension Schema Document <sup>(2)</sup>					
101.CAL <sup>+</sup>	XBRL Taxonomy Extension Calculation Linkbase Document <sup>(2)</sup>					
101.DEF <sup>+</sup>	XBRL Taxonomy Extension Definition Linkbase Document <sup>(2)</sup>					
101.LAB <sup>+</sup>	XBRL Taxonomy Extension Labels Linkbase Document <sup>(2)</sup>					
101.PRE <sup>+</sup>	XBRL Taxonomy Extension Presentation Linkbase Document <sup>(2)</sup>					

- † 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
- 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.
- Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

#### **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.	
Ву	/s/ Mitchell S. Steiner	
-	Mitchell S. Steiner, M.D., F.A.C.S.	<del>_</del>
	Chief Executive Officer, Vice Chairman and Director	Date: March 5, 2013

#### 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 5, 2013
/s/ Mitchell S. Steiner Mitchell S. Steiner, M.D., F.A.C.S.	Chief Executive Officer, Vice Chairman and Director (Principal Executive Officer)	March 5, 2013
/s/ Mark E. Mosteller  Mark E. Mosteller, CPA	Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 5, 2013
/s/ Michael G. Carter  Michael G. Carter, M. D.	Director	March 5, 2013
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/s/ Barrington J. A. Furr	Director	March 5, 2013
Barrington J. A. Furr	_	
/s/ J. Kenneth Glass	Director	March 5, 2013
J. Kenneth Glass	_	
/s/ Kenneth S. Robinson	Director	March 5, 2013
Kenneth S. Robinson, M.D.	_	
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#### GTx, Inc.

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### 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, 2012 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, 2012, our internal control over financial reporting was effective. The effectiveness of our internal control over financial reporting has been audited by Ernst & Young LLP, independent registered public accounting firm.

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

Memphis, Tennessee March 5, 2013 /s/ Mark E. Mosteller

Mark E. Mosteller, CPA

Vice President and Chief Financial Officer

#### 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, 2012, 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, 2012, 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, 2012 and 2011, and the related statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2012 and our report dated March 5, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Memphis, Tennessee March 5, 2013

#### 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, 2012 and 2011, and the related statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2012. 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, 2012 and 2011, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, 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, 2012, 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 5, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Memphis, Tennessee March 5, 2013

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

	December 31,			
		2012		2011
ASSETS				
Current assets:				
Cash and cash equivalents	\$	48,044	\$	63,745
Short-term investments		8,045		10,695
Accounts receivable, net		9		981
Inventory		-		161
Prepaid expenses and other current assets		717		1,266
Total current assets	· ·	56,815		76,848
Property and equipment, net		507		1,096
Intangible and other assets, net		452		712
Total assets	\$	57,774	\$	78,656
LIABILITIES AND STOCKHOLDERS' EQUITY			-	
Current liabilities:				
Accounts payable	\$	1,707	\$	1,219
Accrued expenses and other current liabilities		7,788		4,614
Total current liabilities		9,495		5,833
Other long-term liabilities		578		949
Commitments and contingencies				
Stockholders' equity:				
Common stock, \$0.001 par value: 120,000,000 shares authorized at both December 31, 2012 and December 31, 2011; 62,818,424 and 62,790,223 shares				
issued and outstanding at December 31, 2012 and December 31, 2011, respectively		63		63
Additional paid-in capital		460,887		457,985
Accumulated deficit		(413,249)		(386,174)
Total stockholders' equity		47,701		71,874
Total liabilities and stockholders' equity	\$	57,774	\$	78,656

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

	Years Ended December 31,				,	
		2012 2011			2010	
Revenues:						
Collaboration revenue	\$	-	\$	8,066	\$	56,786
Expenses:						
Research and development expenses		38,887		31,938		28,495
General and administrative expenses		10,845		12,027		13,194
Total expenses		49,732		43,965		41,689
(Loss) income from operations		(49,732)		(35,899)		15,097
Other (expense) income, net		(19)		398		1,363
(Loss) income from operations before income taxes		(49,751)		(35,501)		16,460
Income tax benefit		8,821		886		<u>-</u>
Net (loss) income from continuing operations		(40,930)		(34,615)		16,460
Income (loss) from discontinued operations before income taxes		22,676		2,207		(1,166)
Income tax expense		(8,821)		(886)		-
Net income (loss) from discontinued operations		13,855		1,321		(1,166)
Net (loss) income	\$	(27,075)	\$	(33,294)	\$	15,294
Net (loss) income per share — basic and diluted:						
Net (loss) income from continuing operations	\$	(0.65)	\$	(0.60)	\$	0.42
Net income (loss) from discontinued operations		0.22		0.02		(0.03)
Net (loss) income per share	\$	(0.43)	\$	(0.58)	\$	0.39
Weighted average shares outstanding:						
Basic and diluted		62,809,219		57,359,466		38,874,721
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# GTx, Inc. STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) For the Years Ended December 31, 2012, 2011 and 2010 (in thousands, except share data)

Stockholders' Equity (Deficit)

	Common Stock		Additional Paid-in Capital	Accumulated	Total Stockholders'		
Dalamana at January 1, 2010		Amount 420.901 \$ 36		<b>Deficit</b> \$ (368,174)	Equity (Deficit)		
Balances at January 1, 2010 Issuance of common stock, net of	36,420,901	\$ 50	\$ 359,388	\$ (368,174)	\$ (8,750)		
offering costs	15,285,715	15	40,273		40,288		
Issuance of common stock under	13,203,713	13	40,273		40,200		
deferred compensation arrangements	8,321	_	_	_	_		
Exercise of employee stock options	4,250	_	9	_	9		
Directors' deferred compensation	4,230	1	186		187		
Share-based compensation	_		4,699	_	4,699		
Net income	-	-	-	15,294	15,294		
Balances at December 31, 2010	51,719,187	52	404,555	(352,880)	51,727		
Issuance of common stock, net of							
offering costs	11,023,000	11	48,971	-	48,982		
Issuance of common stock under							
deferred compensation arrangements	35,036	-	-	-	-		
Exercise of employee stock options	13,000	-	55	-	55		
Directors' deferred compensation	-	-	178	-	178		
Share-based compensation	-	-	4,226	-	4,226		
Net loss	-	-	-	(33,294)	(33,294)		
Balances at December 31, 2011	62,790,223	63	457,985	(386,174)	71,874		
Exercise of employee stock options	28,201	-	85	-	85		
Directors' deferred compensation	-	-	169	-	169		
Share-based compensation	-	-	2,648	-	2,648		
Net loss	-	-	-	(27,075)	(27,075)		
Balances at December 31, 2012	62,818,424	\$ 63	\$ 460,887	\$ (413,249)	\$ 47,701		

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

	Years Ended December 31,				1,	
	2012 2011 2			2010		
Cash flows from operating activities:						
Net (loss) income	\$	(27,075)	\$	(33,294)	\$	15,294
Adjustments to reconcile net (loss) income to net cash used in operating						
activities:						
Gain on sale of FARESTON®		(18,831)		-		-
Share-based compensation		2,648		4,226		4,699
Directors' deferred compensation		169		178		187
Depreciation and amortization		750		1,040		1,573
Deferred revenue amortization		-		(8,066)		(51,786)
Impairment of intangible assets		-		1,598		1,687
Changes in assets and liabilities:						
Accounts receivable, net		972		(298)		(277)
Inventory		133		(24)		(55)
Receivable from collaboration partners		-		-		189
Prepaid expenses and other assets		752		(527)		16
Accounts payable		488		371		(420)
Accrued expenses and other liabilities		2,885		1,707		(1,634)
Net cash used in operating activities		(37,109)		(33,089)		(30,527)
Cash flows from investing activities:						
Purchase of property and equipment		(142)		(54)		(95)
Purchase of short-term investments, held to maturity		(11,980)		(15,145)		(8,569)
Proceeds from maturities of short-term investments, held to maturity		14,630		4,900		16,944
Proceeds from the sale of FARESTON®, net of cash expenses		18,897		-		-
Net cash provided by (used in) investing activities		21,405		(10,299)		8,280
Cash flows from financing activities:						
Proceeds from issuance of common stock		-		48,982		40,288
Proceeds from exercise of employee stock options		85		55		9
Payments on capital lease and financed equipment obligations		(82)		(85)		(88)
Net cash provided by financing activities		3		48,952		40,209
Net (decrease) increase in cash and cash equivalents		(15,701)		5,564		17,962
Cash and cash equivalents, beginning of period		63,745		58,181		40,219
Cash and cash equivalents, end of period	\$	48,044	\$	63,745	\$	58,181

#### 1. 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 for the treatment of cancer, cancer supportive care, and other serious medical conditions.

The Company is developing selective androgen receptor modulators ("SARMs"), including enobosarm (also known as Ostarine® or GTx-024). SARMs are 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). The Company is conducting two fully enrolled pivotal Phase III clinical trials evaluating enobosarm for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer.

Additionally, the Company is developing Capesaris® (GTx-758), an oral nonsteroidal selective estrogen receptor alpha agonist, for secondary hormonal therapy in men with castration resistant prostate cancer, and, potentially, as a primary treatment for advanced prostate cancer used in combination with androgen deprivation therapy. Based upon feedback from the FDA, the Company initiated in the third quarter of 2012 a Phase II clinical trial to evaluate the safety and efficacy of lower doses of Capesaris® as secondary hormonal therapy in men with metastatic castration resistant prostate cancer.

Effective September 30, 2012, the Company sold its rights and certain assets related to FARESTON® to Strakan International S.á r.l., an affiliate of ProStrakan Group plc ("ProStrakan") for \$21,671 in cash. Through September 30, 2012, the Company sold FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of metastatic breast cancer in postmenopausal women, in the United States. See Note 4, *Discontinued Operations*, for further discussion

#### 2. Significant Accounting Policies

#### **Basis of Presentation**

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). Additionally, GTx operates in one business segment.

#### Use of Estimates

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

#### **Discontinued Operations**

On September 28, 2012, the Company entered into an asset purchase agreement (the "FARESTON® Purchase Agreement") with ProStrakan pursuant to which the Company agreed to transfer, sell and assign to ProStrakan all of the Company's rights and certain assets related to

FARESTON®. Effective September 30, 2012, the Company completed the sale of FARESTON® pursuant to the FARESTON® Purchase Agreement for a total cash purchase price of \$21,671, including payment for purchased inventory. The Company has accounted for FARESTON® as a discontinued operation. As a result, revenue, cost of goods sold, and operating expenses relating to FARESTON® have been excluded from their respective captions in the statements of operations and have been included in discontinued operations for the year ended December 31, 2012. The Company has also applied retroactive adjustments to the statements of operations for the years ended December 31, 2011 and 2010 to reflect the effects of the discontinued operations. The Company has set forth the assets and liabilities relating to the FARESTON® discontinued operations in Note 4, *Discontinued Operations*. See Note 4, *Discontinued Operations*, for further discussion.

#### 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, 2012 and 2011, short-term investments consisted of Federal Deposit Insurance Corporation ("FDIC") insured certificates of deposit with original maturities of greater than three months and less than one year.

#### Accounts Receivable

Accounts receivable from the product sales of FARESTON® were recorded net of allowances for cash discounts for prompt payment. The Company made judgments as to its ability to collect outstanding receivables and provided allowances for the portion of receivables if and when collection became doubtful. The Company did not record any reserves related to the collectability of its accounts receivable for the years ended December 31, 2012 and 2011.

#### Inventory

All inventory was purchased from the Company by ProStrakan upon the completion of the sale of FARESTON®, effective September 30, 2012. Historical inventory consisted of FARESTON® tablets that were manufactured by Orion Corporation ("Orion") and delivered to the Company as finished goods and was stated at the lower of cost (first-in, first-out method) or market.

#### **Property and Equipment**

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

Laboratory and office equipment 3 to 5 years

Leasehold improvements 3 to 7 years

Furniture and fixtures 5 years

Computer equipment and software 3 years

#### Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in facts and circumstances are present, both internally and externally, that may indicate impairment of long-lived assets. 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 9, *Intangible Assets*, *Net* 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. As the Company has the positive intent and ability to hold the certificates of deposit classified as short-term investments until maturity, these investments have been classified as held to maturity investments and are stated at cost, which approximates fair value. The Company considers these to be Level 2 investments as the fair values of these investments are determined using third-party pricing sources, which generally utilize observable inputs, such as interest rates and maturities of similar assets.

#### Concentration of Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents and short-term investments. 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 and 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 FDIC insured certificates of deposit with original maturities of greater than three months and less than one year.

#### FARESTON® Revenue Recognition

Revenue from product sales of FARESTON®, which is included in income from discontinued operations before income taxes, was recognized less deductions for estimated sales discounts and sales returns. Revenue from product sales was recognized when persuasive evidence of an arrangement existed, title passed, the price was fixed or determinable, and collectability was reasonably assured. The Company accounted 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. Although the Company sold its rights and certain assets related to FARESTON® effective September 30, 2012, the Company retains the liability for future product returns relating to sales of FARESTON® made by the Company prior to September 30, 2012. Therefore, the Company estimates an accrual for product returns based on factors which include historical product returns and estimated product in the distribution channel which is expected to exceed its expiration date. At December 31, 2012 and December 31, 2011, the Company's accrual for product returns, was \$1,189 and \$1,114, respectively. Of these amounts, \$370 and \$715 have been included in "Other long-term liabilities" in the balance sheet at December 31, 2012 and December 31, 2011, respectively, and represents the portion of the Company's product returns accrual estimated to be payable after one year. See Note 4, *Discontinued Operations*, for further discussion.

#### **Collaboration Revenue Recognition**

Collaboration revenue consisted of non-refundable upfront payments, license fees, reimbursements for research and development activities, and milestone payments associated with the Company's former collaboration and license agreements. Revenues from the Company's prior collaboration and license agreements were recognized based on the performance requirements of the specific agreements. The Company analyzed 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, could have been separated or whether all of the deliverables must have been accounted for as a single unit of accounting. See Note 8, *Collaboration and License Agreements*, for further discussion.

#### 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 and medical 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 has recognized the tax effect of discontinued operations in the statements of operations in accordance with the intra-period accounting rules. An offsetting tax benefit or expense is recorded in continuing operations in each year in which tax expense or benefit was recognized for discontinued operations.

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, 2012 and December 31, 2011, net of the valuation allowance, the net deferred tax assets were reduced to zero. See Note 10, *Income Taxes*, for further discussion.

#### **Share-Based Compensation**

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 non-employee 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 non-employee director is required to provide service in exchange for the award. See Note 3, *Share-Based Compensation*, for further discussion.

#### Other (Expense) Income, Net

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

For the year ended December 31, 2010, other (expense) 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.

#### Basic and Diluted Net (Loss) Income Per Share

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

Weighted average options outstanding to purchase shares of common stock of 5,574,915, 5,327,752, and 4,473,576 were excluded from the calculation of diluted net (loss) income per share for the years ended December 31, 2012, 2011 and 2010, respectively, as inclusion of the options would have had an anti-dilutive effect on the net (loss) income per share for the periods. At December 31, 2012, the Company had outstanding 62,818,424 shares of common stock.

#### Comprehensive (Loss) Income

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

#### Reclassification

Certain prior period amounts have been reclassified to conform to the current period discontinued operations presentation. See note 4, Discontinued Operations, for further discussion. Additionally, in the balance sheet at December 31, 2011, the Company has included \$472 of current deferred income tax liabilities, which were previously reported net of noncurrent deferred income tax assets, in accrued expenses and other current liabilities, which is consistent with the current year balance sheet presentation.

#### Subsequent Events

The Company has evaluated all events or transactions that occurred after December 31, 2012 up through the date the financial statements were issued. There were no material recognizable or nonrecognizable subsequent events during the period evaluated.

#### 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.

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, 2012:

	Years Ended December 31,						
	2	2012 2011				2010	
Research and development expenses	\$	1,046	\$	1,972	\$	2,340	
General and administrative expenses		1,771		2,432		2,546	
Total share-based compensation	\$	2,817	\$	4,404	\$	4,886	

Share-based compensation expense recorded in the statement of operations as general and administrative expense for the years ended December 31, 2012, 2011 and 2010 included share-based compensation expense related to deferred compensation arrangements for the Company's non-employee directors of \$169, \$178 and \$187, respectively. See Note 11, *Directors' Deferred Compensation Plan*, for further discussion of deferred compensation arrangements for the Company's non-employee directors. Share-based compensation expense recorded as research and development expenses for the year ended December 31, 2012 was reduced by the reversal of previously recognized share-based compensation expense for non-vested stock options that were canceled in conjunction with the resignation of an executive officer during the year. Additionally, share-based compensation expense of \$137 and \$477 included in the table above as general and administrative expenses was reported as discontinued operations in the statement of operations for the years ended December 31, 2011 and

2010, respectively. There was no share-based compensation expense included in discontinued operations for the year ended December 31, 2012.

Additionally, as part of the June 2011 workforce reduction, the Company modified certain stock options of three terminated non-executive officers to accelerate the vesting of certain outstanding non-vested stock options and to extend the post-termination exercise period of their vested stock options. As a result of these modifications, the Company incurred a one-time share-based compensation charge of \$481, which was included in general and administrative expenses for the year ended December 31, 2011. This charge was offset by the reversal of \$704 of previously recognized share-based compensation expense for non-vested stock options that were canceled in conjunction with the total workforce reduction. Of this amount, \$646 was included in general and administrative expenses and \$58 was included in research and development expenses for the year ended December 31, 2011.

For the years ended December 31, 2012, 2011 and 2010, the weighted average grant date fair value per share of options granted was \$2.14, \$1.75 and \$2.62, respectively. The weighted average for key assumptions used in determining the grant date fair value of options granted in 2012, 2011 and 2010, and a summary of the methodology applied to develop each assumption is as follows:

	Years Ei	Years Ended December 31,				
	2012	2011	2010			
Expected price volatility	69.6%	64.9%	64.6%			
Risk-free interest rate	1.22%	2.54%	3.36%			
Weighted average expected life in years	6.5 years	6.5 years	6.5 years			
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.

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, 2012:

		Weighted Average
	Number of	<b>Exercise Price</b>
	Shares	Per Share
Options outstanding at January 1, 2010,	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 granted	1,395,000	2.82
Options forfeited or expired	(866,930)	8.23
Options exercised	(13,000)	4.20
Options outstanding at December 31, 2011	4,945,565	9.12
Options granted	1,141,250	3.35
Options forfeited or expired	(675,755)	8.82
Options exercised	(28,201)	3.05
Options outstanding at December 31, 2012	5,382,859	7.96
Options vested and expected to vest at December 31, 2012	5,239,584	8.07

The following table summarizes information about stock options outstanding at December 31, 2012:

Options Outstanding					Options Exercisable				
Weighted Average Remaining W							eighted verage		
	Number	Contractual	Average		Number		Exercise		
Exercise Price	Outstanding	Life (years)	Exercise Price		Exercise Price		Exercisable	F	Price
\$2.65 - \$3.36	1,948,500	8.13	\$	3.00	297,668	\$	2.79		
\$3.44 - \$11.58	1,799,063	4.65		6.00	1,207,016		6.74		
\$12.15 - \$20.40	1,635,296	4.45	16.03		1,152,586		16.01		
	5,382,859	5.85		7.96	2,657,270		10.32		

At December 31, 2012, the aggregate intrinsic value of all outstanding options was \$2,359 with a weighted average remaining contractual term of 5.85 years. Of the Company's outstanding options, 2,657,270 options were exercisable and had a weighted average remaining contractual term of 3.87 years and an aggregate intrinsic value of \$421. Additionally, the Company's vested and expected to vest options had a weighted average remaining contractual term of 5.78 years and an intrinsic value of \$2,233.

Options to purchase 28,201 shares were exercised during the year ended December 31, 2012. The total intrinsic value of options exercised during the years ended December 31, 2012, 2011and 2010 was \$36, \$15 and \$6, respectively. At December 31, 2012, the total compensation cost related to non-vested options not yet recognized was \$4,211, with a weighted average expense recognition period of 2.83 years. Shares available for

future issuance under the Company's stock option and equity incentive plans were 4,573,224 at December 31, 2012. On January 1, 2013, shares available for future issuance under the Company's stock option and equity incentive plans increased to 4,648,224 shares in accordance with the provisions of such plans.

#### 4. Discontinued Operations

On September 28, 2012, the Company entered into the FARESTON® Purchase Agreement with ProStrakan pursuant to which the Company agreed to transfer, sell and assign to ProStrakan all of the Company's rights to FARESTON® and certain assets related thereto. Effective September 30, 2012, the Company completed the sale of FARESTON® pursuant to the FARESTON® Purchase Agreement for a total cash purchase price of \$21,671, including payment for purchased inventory. The Company recognized a gain of \$18,831 on the sale of FARESTON® for the year ended December 31, 2012. The gain represents the gross proceeds received from the sale reduced by a contract termination fee of \$1,000 due to Orion (as discussed further in Note 8, *Collaboration and License Agreements*), a financial advisory fee related to the transaction of \$1,712, and other transaction expenses of approximately \$128.

The Company has accounted for FARESTON® as a discontinued operation. The FARESTON® operating income, along with the gain recognized on the sale of FARESTON® for the year ended December 31, 2012, has been reported as "net income from discontinued operations" in the statements of operations. In addition, the assets and liabilities related to FARESTON® that are included in the balance sheets for the periods presented have been presented below.

FARESTON® operating income (loss) for each period presented was as follows:

	Years Ended December 31,					
		2012		2011		2010
Product sales, net	\$	5,284	\$	6,673	\$	3,827
Cost of product sales		(784)		(1,055)		(768)
Operating expenses		(655)		(3,411)		(4,225)
FARESTON® operating income (loss)	\$	3,845	\$	2,207	\$	(1,166)

Under the FARESTON® Purchase Agreement, the Company remains responsible for the collection of accounts receivable and remains liable for future product returns in each case relating to sales of FARESTON® made by the Company prior to September 30, 2012. The assets and liabilities related to

FARESTON® discontinued operations included in the balance sheets for the periods presented were as follows:

	December 31,	December 31,
	2012	2011
Accounts receivable, net	\$	9 \$ 981
Inventory		- 161
Prepaid expenses and other assets	5	5 178
Total assets	14	4 1,320
Accounts payable	15	5 116
Accrued expenses and other current liabilities	1,013	3 919
Other long-term liabilities	370	715
Total liabilities	1,398	1,750
Net liabilities	\$ (1,384	4) \$ (430)

#### 5. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,			31,
	2012			2011
Laboratory and office equipment	\$	4,177	\$	4,173
Computer equipment and software		2,706		2,646
Furniture and fixtures		1,361		1,361
Leasehold improvements		1,024		1,024
		9,268		9,204
Less: accumulated depreciation		(8,761)		(8,108)
	\$	507	\$	1,096

Depreciation and amortization expense for the years ended December 31, 2012, 2011 and 2010 was \$730, \$998 and \$1,346, respectively. Of these amounts, \$290, \$425 and \$543, respectively, were included in research and development expenses in the statements of operations.

#### 6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,			31,
	2012			2011
Clinical trials	\$	5,621	\$	2,286
Product returns		819		399
Selling, general and administrative		730		1,037
Research and development		46		73
Employee compensation		294		265
Net deferred income tax liabilities		271		472
Current portion of capital lease and financed equipment liabilities		7		82
	\$	7,788	\$	4,614

#### 7. Common and Preferred Stock

The Company's certificate of incorporation authorizes the Company to issue 120,000,000 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 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 approximately \$37,700 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 approximately \$2,600 after deducting underwriting discounts and commissions and other offering expenses.

On May 6, 2011, the Company filed a Certificate of Amendment to the Company's Restated Certificate of Incorporation with the Secretary of the State of Delaware to increase the number of authorized shares of the Company's common stock, par value \$0.001 per share, from 60,000,000 shares to 120,000,000 shares. The amendment was approved by the Company's stockholders at the Company's 2011 Annual Meeting of Stockholders held on May 5, 2011.

On June 28, 2011, the Company completed an underwritten public offering of 10,000,000 shares of its common stock at a price to the public of \$4.75 per share. The Company also granted the underwriters a 30-day option to purchase up to an additional 1,500,000 shares of common stock to cover over-allotments, if any. The underwriters exercised this option and purchased an additional 1,023,000 shares of the Company's common stock on June 28, 2011 at a price of \$4.75 per share. Net cash proceeds from the public offering were approximately \$49,000 after deducting the underwriting discount and offering expenses.

#### 8. Collaboration and License Agreements

#### University of Tennessee Research Foundation License Agreement

The Company and the University of Tennessee Research Foundation ("UTRF") are parties to a consolidated, amended and restated license agreement (the "SARM License Agreement") pursuant to which the Company has been 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. Under the SARM 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.

#### Former Orion Corporation License and Supply Agreement

In connection with the Company's sale of its rights and certain assets related to FARESTON® to ProStrakan, the Company and Orion agreed to terminate the Amended and Restated License and Supply Agreement, dated January 1, 2005, as amended, between the Company and Orion (the "Orion Supply Agreement") as well as certain other agreements between the Company and Orion related to the Orion Supply Agreement (collectively, the "Orion Agreements"). Pursuant to the Orion Supply Agreement, the Company 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, and Orion agreed to manufacture and supply all of the Company's 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. The termination of the Orion Agreements was effective September 30, 2012. As consideration for Orion's agreement to terminate the Orion Agreements and to enter into certain agreements with ProStrakan to effect the FARESTON® sale, the Company paid Orion \$1,000 in October 2012. See Note 4, Discontinued Operations, for further discussion.

#### Former Ipsen Collaboration and License Agreement

In September 2006, the Company entered into a collaboration and license agreement with Ipsen Biopharm Limited (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. Under the Ipsen Collaboration Agreement, the Company recorded deferred revenue of \$29,330 related to the Ipsen upfront license fee and expense reimbursement which was being amortized into revenue on a straight-line basis over the estimated ten year development period for toremifene in the European Territory.

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.

During the first quarter of 2011, the Company recognized as collaboration revenue all of the remaining \$8,066 unamortized revenue. This amount is included in collaboration revenue in the statement of operations for the year ended December 31, 2011. The Company recognized as collaboration revenue \$1,930 under the Ipsen Collaboration Agreement for the year ended December 31, 2010.

#### Former Merck & Co., Inc. Collaboration and License Agreement

In December 2007, GTx and Merck & Co., Inc. ("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 enobosarm, 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 paid the Company \$15,000 in cost reimbursements for research and development activities in equal annual installments over a three year period.

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 amounts were being recognized as collaboration revenue over the period of the Company's performance obligation, which the Company estimated to be ten years. 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 \$54,856 as collaboration revenue under the terms of the Merck Collaboration Agreement.

#### 9. Intangible Assets, Net

In accordance with the terms of the former Orion Supply Agreement, the Company paid a license fee to Orion of \$4,826. In accordance with the terms of the SARM License Agreement and the former Amended and Restated License Agreement ("SERM License Agreement") that the Company entered into with UTRF in July 2007 and September 2007, respectively, the Company paid a one-time up-front fee of \$290 per agreement.

In 2010 after discontinuing its toremifene 20 mg development program, the Company recorded an impairment charge of \$1,687. The impaired intangible assets consisted of capitalized license fees related to the Company's toremifene 20 mg program paid under the Orion Supply Agreement and the SERM License Agreement. The impairment charge was included in research and development expenses in the statement of operations for the year ended December 31, 2010.

In 2011 after discontinuing the toremifene 80 mg development program, the Company recorded an impairment charge of \$1,598. The impaired intangible asset consisted of capitalized license fees related

to the Company's toremifene 80 mg program paid under the Orion Supply Agreement. The impairment charge was included in research and development expenses in the statement of operations for the year ended December 31, 2011.

The Company's remaining intangible asset, net at December 31, 2012 and 2011 consisted of \$181 and \$201, respectively, related to the SARM License Agreement.

#### 10. 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,			
	2012			2011
Deferred income tax assets, net:				
Net federal and state operating loss carryforwards	\$	112,233	\$	101,777
Research and development credits		9,799		10,921
Share-based compensation		8,852		8,307
Depreciation and amortization		331		1,334
Other, net		328		368
Total deferred tax assets, net.		131,543		122,707
Valuation allowance	_	(131,543)		(122,707)
Net deferred tax assets and liabilities	\$	-	\$	-

Realization of deferred income tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, due to the Company's history of net operating losses, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$8,836 in 2012, increased by \$13,218 in 2011 and decreased by \$3,878 in 2010.

At December 31, 2012, the Company had net federal operating loss carryforwards of approximately \$289,766, which expire from 2018 to 2032 if not utilized. The Company had state operating loss carryforwards of approximately \$271,275, which expire from 2013 to 2032 if not utilized. The Company also had research and development credits at December 31, 2012 of approximately \$9,799, which expire from 2020 to 2031 if not utilized.

In January 2013, the American Tax Payer Relief Act ("the Act") was signed into law. The Act reinstated the research and development tax credit retroactively to January 1, 2012, with expiration set for December 31, 2013. The Company's research and development tax credit for 2012 was \$1,319 and expires at the end of 2032. As the Company cannot recognize the impact of the tax law change until 2013, the Company has not included the research and development tax credit for 2012 in its schedule of net deferred income tax assets and liabilities shown above.

Both of the net federal and state operating loss carryforwards include approximately \$2,145 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 income 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.

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, 2012, 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, although the Company periodically reviews assumptions in its calculations to reflect its best estimate of expected credit. The Company has reduced the cumulative eligible credit by \$1,122 as a result of its review in 2012. An in depth 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. The Company's net deferred income 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.

The Company has recognized the tax effect of discontinued operations in the statements of operations in accordance with the intra-period accounting rules. An offsetting tax benefit or expense is recorded in continuing operations in each year in which tax expense or benefit was recognized for discontinued operations.

#### 11. 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, 2012, 2011 and 2010, the Company incurred non-employee director fee expense of \$237, \$260 and \$279, respectively, of which \$169, \$178 and \$187 was deferred into stock accounts and will be paid in common stock following separation from service as a director. At December 31, 2012, 175,743 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.

#### 12. 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 \$17.0 for employees under age 50 and \$22.5 for employees 50 and older in calendar year 2012. 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 \$363, \$388 and \$433 in 2012, 2011 and 2010, respectively.

#### 13. 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 and expires on December 31, 2014. 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. Total rent expense under these operating leases was approximately \$963, \$933 and \$1,508 for the years ended December 31, 2012, 2011 and 2010, respectively.

As of December 31, 2012, annual minimum payments under operating lease arrangements were as follows:

2013	\$ 1,200
2014	1,348
2015	185
Total	\$ 2,733

#### 14. Quarterly Financial Data (Unaudited)

The following is a summary of the quarterly results of operations for the years ended December 31, 2012 and 2011:

		2012 Quarters Ended						
	I	March 31		June 30	5	September 30	Г	ecember 31
_						(a)		
Revenues:					_			
Collaboration revenue	\$	-	\$	-	\$	-	\$	-
Expenses:								
Research and development expenses		9,835		9,237		9,764		10,051
General and administrative expenses		2,588		2,400		2,999		2,858
Total expenses		12,423	_	11,637	-	12,763	-	12,909
Loss from operations		(12,423)	_	(11,637)	-	(12,763)	_	(12,909)
Other (expense) income, net		(12,423)		53		(47)		(33)
Loss from operations before income taxes	_	(12,415)		(11,584)	_	(12,810)	_	(12,942)
Income tax benefit		381		355		5,812		2,273
Net loss from continuing operations		(12,034)		(11,229)		(6,998)	_	(10,669)
Income (loss) from discontinued operations before		,			_		_	-
income taxes		1,335		1,203		20,214		(76)
Income tax (expense) benefit		(381)		(355)		(8,115)		30
Net income (loss) from discontinued operations		954		848		12,099		(46)
Net (loss) income	\$	(11,080)	\$	(10,381)	\$	5,101	\$	(10,715)
	:							
Net (loss) income per share — basic and diluted:								
Net (loss) income from continuing operations	\$	(0.19)	\$	(0.18)	\$	(0.11)	\$	(0.17)
Net income from discontinued operations		0.01		0.01		0.19		-
Net (loss) income per share	\$	(0.18)	\$	(0.17)	\$	0.08	\$	(0.17)
	-							
Weighted average shares outstanding:								
Basic and diluted		62,798,008		62,805,662		62,815,549		62,817,495
	_		_		_		_	

<sup>(</sup>a) The income tax benefit and income tax expense shown in the table above for the quarter ended September 30, 2012 have been changed from the amounts previously reported in the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2012 to correct immaterial misstatements.

2011 Quarters Ended March 31 June 30 September 30 December 31 (b) Revenues: \$ \$ Collaboration revenue 8,066 \$ - \$ Expenses: 8,863 Research and development expenses 7,303 7,591 8,181 2,977 2,708 General and administrative expenses 3,201 3,141 Total expenses 10,504 10,568 10,889 12,004 (10,568)Loss from operations (2,438)(10,889)(12,004)Other income, net 302 23 66 Loss from operations before income taxes (2,136)(10,561)(10,866)(11,938)Income tax benefit 264 271 298 53 Net loss from continuing operations (2,083)(10,297)(10,595)(11,640)(Loss) income from discontinued operations before income taxes (459)(112)1,522 1,256 Income tax expense (53)(264)(271)(298)(512) 1,251 Net (loss) income from discontinued operations (376)958 Net loss \$ (2,595) \$ (10,673) \$ (9,344) \$ (10,682)Net loss per share — basic and diluted: Net loss from continuing operations \$ (0.04) \$ (0.20) \$ (0.17) \$ (0.19)Net (loss) income from discontinued operations (0.01)(0.01)0.02 0.02 Net loss per share (0.05)(0.21)(0.15)(0.17)Weighted average shares outstanding: Basic and diluted 51,719,187 51,968,667 62,778,575 62,790,223

<sup>(</sup>b) The income tax benefit and income tax expense shown in the table above for the quarter ended September 30, 2011 have been changed from the amounts previously reported in the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2012 to correct immaterial misstatements.

### AMENDED AND RESTATED EMPLOYMENT AGREEMENT

This Amended and Restated Employment Agreement (this "Agreement") is made and entered into as of February 14, 2013 (the "Effective Date") by and between **GTx, Inc.**, located at 175 Toyota Plaza, 7<sup>th</sup> Floor, Memphis, Tennessee 38103 (the "Employer"), and **MITCHELL S. STEINER, M.D.** (the "Employee"), residing at 2600 Forest Hill Irene Road, Germantown, Tennessee 38139.

WHEREAS, the Employee has been providing services to the Employer as Chief Executive Officer under the terms of an Amended and Restated Employment Agreement that was effective as of November 10, 2008 (the "Prior Employment Agreement"); and

WHEREAS, the Employer and the Employee wish to amend and restate the Prior Employment Agreement as set forth herein; and

WHEREAS, during the course of the Employee's employment with the Employer, the Employer will train and continue to train the Employee and to impart to the Employee proprietary, confidential, and/or trade secret information, data and/or materials of the Employer; and

WHEREAS, the Employer has a vital interest in maintaining its confidential information and trade secrets, as well as rights to inventions, since doing so allows the Employer to compete fairly and enhances the value of the Employer to shareholders and job security for employees; and

WHEREAS, the Employer desires to retain the services of the Employee and the Employee is willing to be employed and continue to be employed with the Employer upon the terms and subject to the conditions set forth in this Agreement;

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained in this Agreement, the employment and continued employment of the Employee in accordance with the terms and conditions of this Agreement, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties, intending to be legally bound, agree and covenant as follows:

#### 1. DEFINITIONS

For the purposes of this Agreement, the following terms have the meanings specified or referred to in this Section 1.

"Agreement" has the meaning set forth in first paragraph of this Agreement.

"Basic Compensation" means Salary and Benefits.

"Benefits" has the meaning stated in Section 3.1(b) of this Agreement.

"Board of Directors" means the Board of Directors of the Employer.

"Change of Control" means any of the following events: (a) the sale or other disposition of all or substantially all of the assets of the Employer in a single transaction or in a series of transactions (including, without limitation, any liquidation or dissolution of the Employer); (b) any Person or group becomes the beneficial owner, directly, or indirectly, of securities of the Employer representing more than fifty percent (50%) of the combined voting power of the Employer's then outstanding securities other than by virtue of a merger, consolidation or similar transaction (for such purposes, "voting stock" shall mean the capital stock of the Employer of any class or classes, the holders of which are ordinarily, in the absence of contingencies, entitled to vote for the election of members of the Board of Directors (or Persons performing similar functions) of the Employer); (c) a merger or consolidation of the Employer with or into any other entity, if immediately after giving effect to such transaction more than fifty percent (50%) of the issued and outstanding voting stock of the surviving entity of such transaction is held by Persons who were not holders (taking into account their individual and affiliated holdings) as of the Effective Date of at least fifty percent (50%) of the voting stock of the Employer; or (d) individuals who, on the Effective Date, are members of the Board of Directors (the "Incumbent Board") cease for any reason to constitute at least a majority of the members of the Board of Directors; provided, however, that if the appointment or election (or nomination for election) of any new member of the Board of Directors was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member will, for purposes of this Agreement, be considered as a member of the Incumbent Board. A Change of Control shall not include: (1) any transfer or issuance of stock of the Employer to one or more of the Employer's lenders (or to any agents or representatives thereof) in exchange for debt of the Employer owed to any such lenders; (2) any transfer of stock of the Employer to or by any Person or entity, including but not limited to one or more of the Employer's lenders (or to any agents or representatives thereof), pursuant to the terms of any pledge of said stock as collateral for any loans or financial accommodations to the Employer and/or its subsidiaries; (3) any transfer or issuance to any Person or entity, including but not limited to one or more of the Employer's lenders (or to any agents or representatives thereof), in connection with the workout or restructuring of the Employer's debts to any one of the Employer's lenders, including but not limited to the issuance of new stock in exchange for any equity contribution to the Employer in connection with the workout or restructuring of such debt; (4) any transfer of stock by a stockholder of the Employer which is a partnership or corporation to the partners or stockholders in such stockholder or any transfer of stock by a stockholder of the Employer to an entity affiliated with such stockholder or the immediate family of such stockholder or a trust or similar entity for the benefit of such family members; or (5) any transfer or issuance of stock in connection with an offering of the Employer's stock in a registered public transaction not involving a transaction described in Rule 145, promulgated under the Securities Act of 1933, as amended, provided that the Employer's officers and Board of Directors shall not materially change as a result thereof.

"Change of Control Termination" means (i) a Termination Without Cause of the Employee's employment by the Employer (other than for death or disability) within twelve (12) months after a Change of Control or (ii) the Employee's resignation for Good Reason within twelve (12) months after a Change of Control.

"Competing Business" means any individual or entity, other than the Employer, that is engaging in, or proposes to engage in, the development, manufacture, distribution or sale of a Competing Product in North America, South America, Europe and Eastern Europe, and in the countries of Russia, Australia, Japan, China, Taiwan, South Korea and India; provided, however, that (i) an entity that develops, manufactures, distributes or sells a Competing Product in a separate business unit than the business unit in which the Employee is then employed shall not be deemed a Competing Business unless the Employee provides Confidential Information and/or Proprietary Information to the business unit that is engaging in or proposes to engage in the development, manufacture, distribution or sale of a Competing Product, and (ii) nothing in this Agreement shall prevent the Employee from conducting research for non-commercial purposes utilizing institutional or governmental grant funds in areas relating to any Competing Product as long as such research is not in areas that are protected or intended to be protected by patents of the Employer.

"Competing Product" means any pharmaceutical or other compound, composition, formulation, method, process, product or material that is competitive with any product of the Employer under development, manufacture, distribution or commercialization at any time from and after October 1, 2003 (the effective date of the Employee's initial employment agreement with the Employer) through the date of termination of the Employee's employment, including, without limitation, small molecules that target androgen, estrogen, glucocorticoid, and/or other hormone receptors for purposes of treating, diagnosing, or imaging humans in health and disease, including treating cancer, osteoporosis and bone loss and muscle loss.

#### "Confidential Information and/or Proprietary Information" means any and all:

- (a) information disclosed to the Employee or known by the Employee as a consequence of, or through, the Employee's employment with the Employer since his initial date of employment on September 24, 1997 (including information conceived, originated, discovered, or developed in whole or in part by the Employee), not generally known in the relevant trade or industry, about the Employer's business, products, processes, and services; and trade secrets concerning the business and affairs of the Employer, product specifications, data, know-how, formulae, compositions, research, processes, designs, sketches, photographs, graphs, drawings, samples, inventions and ideas, past, current, and planned research and development, current and planned manufacturing or distribution methods and processes, customer lists, current and anticipated customer requirements, price lists, market studies, business plans, computer software and programs (including object code and source code), computer software and database technologies, systems, structures, and architectures (and related formulae, compositions, processes, improvements, devices, know-how, inventions, discoveries, concepts, ideas, designs, methods and information); and any other information, however documented, that is a trade secret within the meaning of Tenn. Code §39-14-138 or any other applicable law; and
- (b) information concerning the business and affairs of the Employer (which includes historical financial statements, financial projections and budgets, historical and projected sales, capital spending budgets and plans, the names and backgrounds of key personnel, personnel training and techniques and materials), however documented; and

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- (c) intellectual property, inventions, methods, processes, techniques, computer programs, devices, products, services, compounds, gene therapy products, pharmaceuticals, substances, vectors, enzymes, genes, concepts, discoveries, improvements, and designs, whether or not patentable in the United States or foreign countries, any trade secrets, information, procedures, technologies, data, results, conclusions, know-how or show-how and business information; and
- (d) notes, analysis, compilations, studies, summaries, and other material prepared by or for the Employer containing or based, in whole or in part, on any information included in the foregoing.
  - "Delayed Initial Payment Date" has the meaning stated in Section 9.2 of this Agreement.
  - "Effective Date" means the date stated in the first paragraph of this Agreement.
  - "Employee" has the meaning stated in the first paragraph of this Agreement.
- "Employee Invention" means any idea, invention, technique, modification, process, improvement (whether patentable or not), industrial design (whether registerable or not), work of authorship (whether or not copyright protection may be obtained for it), design, copyrightable work, discovery, trademark, copyright, trade secret, formula, device, method, compound, gene, prodrug, pharmaceutical, structure, product concept, marketing plan, strategy, customer list, technique, blueprint, sketch, record, note, drawing, know-how, data, patent application, continuation application, continuation-in-part application, file wrapper continuation application or divisional application, created, conceived, or developed by the Employee, either solely or in conjunction with others, during the Employee's employment, or a period that includes a portion of the Employee's employment, that relates in any way to, or is useful in any manner in, the business then being conducted or proposed to be conducted by the Employer, and any such item created by the Employee, either solely or in conjunction with others, following termination of the Employee's employment with the Employer, that is based upon or uses Confidential Information and/or Proprietary Information.
- <u>"Employer"</u> means GTx, Inc., its successors and assigns, and any of its current or future subsidiaries, or organizations controlled by, controlling, or under common control with it.
  - "Expenses" has the meaning stated in Section 4.1 of this Agreement.
  - "Good Reason" for termination means that the Employee voluntarily resigns from all positions he then holds with the Employer if and only if:
  - (a) one of the following actions have been taken without the Employee's express written consent:
- (i) following a Change of Control, an adverse change in the Employee's authority, duties or responsibilities (including reporting responsibilities) which, without the Employee's consent, represents a material reduction in or a material demotion of the Employee's authority, duties or responsibilities as in effect immediately prior to a Change of

Control or the assignment to the Employee of any duties or responsibilities which are materially inconsistent with and materially adverse to such authority, duties or responsibilities;

- (ii) following a Change of Control, a material reduction in the then current Salary of the Employee;
- (iii) following a Change of Control, the relocation of the Employer's principal employee offices to a location that increases the Employee's one-way commute by more than twenty (20) miles;
- (iv) the failure of the Employer to obtain an agreement reasonably satisfactory to the Employee from any successor or assign of the Employer upon a Change of Control to assume and agree to perform this Agreement in all material respects following the Change of Control; or
- (v) the Employer materially breaches its obligations under this Agreement or any other then-effective agreement with the Employee (including any agreement or arrangement providing for incentive compensation or employee benefits, including the Benefits provided in this Agreement).
  - (b) the Employee provides written notice to the Board of Directors within the thirty (30) day period immediately following such action; and
  - (c) such action is not remedied by the Employer within thirty (30) days following the Employer's receipt of such written notice; and
  - (d) the Employee's resignation is effective not later than sixty (60) days after the expiration of such thirty (30)-day cure period.

<u>"Person"</u> means any individual, corporation (including any non-profit corporation), general or limited partnership, limited liability company, joint venture, estate, trust, association, organization, or governmental body.

<u>"Proprietary Items"</u> means any Proprietary and/or Confidential Information embodied in any document, record, recording, electronic media, formulae, notebook, plan, model, component, device, or computer software or code, whether embodied in a disk or in any other form.

"Release" means a general release of claims in favor of the Employer, in a form acceptable to the Employer, which shall specifically relate to all of the Employee's rights and claims in existence at the time of such execution and shall confirm the Employee's continuing obligations to the Employer (including but not limited to obligations under Section 7 and Section 8 of this Agreement, the Agreement on Condition of Employment and any other confidentiality and/or non-competition agreement with the Employer).

<u>"Salary"</u> has the meaning stated in Section 3.1(a) of this Agreement.

"Section 409A" has the meaning stated in Section 9.2 of this Agreement.

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"Termination Date" has the meaning stated in Section 6.1 of this Agreement.

"Termination With Cause" means the termination of the Employee's employment by act of the Board of Directors for any of the following reasons, any of which shall constitute "Cause" for purposes of this Agreement:

- (a) the Employee's conviction of a felony;
- (b) the Employee's theft, embezzlement, misappropriation of or intentional infliction of material damage to the Employer's property or business opportunities;
- (c) the Employee's breach of the provisions contained in Section 7 or Section 8 of this Agreement or the provisions in the Agreement on Condition of Employment regarding confidentiality, non-competition or non-solicitation; or
- (d) the Employee's ongoing willful neglect of or failure to perform his duties hereunder or his ongoing willful failure or refusal to follow any reasonable, unambiguous duly adopted written direction of the Board of Directors that is not inconsistent with the description of the Employee's duties set forth in Section 2.3, if such willful neglect or failure is materially damaging or materially detrimental to the business and operations of the Employer; provided that, if curable, the Employee shall have received written notice of such neglect or failure and shall have continued to engage in such neglect or failure after 30 days following receipt of such notice from the Board of Directors, which notice specifically identifies the manner in which the Board of Directors believes that the Employee has engaged in such neglect or failure. For purposes of this subsection, no act, or failure to act, shall be deemed "willful" unless done, or omitted to be done, by the Employee not in good faith, and without reasonable belief that such action or omission was in the best interest of the Employer.

<u>"Termination Without Cause"</u> means the termination of the Employee's employment by the Employer for any reason other than (i) Termination With Cause, or (ii) a termination by the Employer due to the Employee's death or disability.

#### 2. EMPLOYMENT TERMS AND DUTIES

#### 2.1 <u>Employment</u>

The Employer hereby continues the employment of the Employee, and the Employee hereby accepts continued employment by the Employer, upon the terms and conditions set forth in this Agreement.

2.2 Term

Either the Employee or the Employer may terminate this Agreement and the Employee's employment and compensation with or without Cause or notice, at any time, at either the Employer's or the Employee's option. No officer or manager of the Employer has the authority to enter into any other agreement for employment for a specified period of time, or to modify or to make any agreement contrary to the foregoing, except by written amendment to this Agreement, dated and signed by the President of the Employer.

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#### 2.3 Duties

The Employee will continue to have such duties as are assigned or delegated to the Employee by the Board of Directors and will initially serve as Chief Executive Officer for the Employer. The Employee will devote his full time, attention, skill and energy to the business of the Employer, will use his best efforts to promote the success of the Employer's business, and will cooperate fully with the Board of Directors in the advancement of the best interest of the Employer. The Employee agrees to abide by all bylaws, policies, practices, procedures or rules of the Employer. The Employee may be reassigned or transferred to another management position, as designated by the Board of Directors, which may or may not provide the same level of responsibility as the initial assignment, in accordance with the terms and conditions of this Agreement.

#### 3. COMPENSATION

#### 3.1 Basic Compensation

- (a) <u>Salary.</u> As of the Effective Date, the Employee will be paid for each of the twenty-six pay periods during the calendar year approximately \$21,735, which is the equivalent of \$565,110 per calendar year (the "Salary"), subject to review and adjustment from time to time by the Board of Directors in its sole discretion.
- (b) <u>Benefits.</u> The Employee will, during his employment with the Employer, be permitted to participate in such life insurance, hospitalization, major medical, short term disability, long term disability, 401(k) plan and other employee benefit plans of the Employer that may be in effect from time to time, to the extent the Employee is eligible under the terms of those plans (collectively, the "Benefits"). All matters of eligibility for coverage or benefits under any such plan shall be determined in accordance with the provisions of such plan. The Employer reserves the right to change, alter, or terminate any such plan, in its sole discretion, subject to the terms of such plan.
- (c) The Employer may withhold from the Salary or Benefits payable to the Employee all federal, state, local, and other taxes and other amounts as permitted or required pursuant to law, rules or regulations.

#### 4. FACILITIES AND EXPENSES

#### 4.1 General

The Employer will furnish the Employee office space, equipment, supplies, and such other facilities and personnel as the Employer deems necessary or appropriate for the performance of the Employee's duties under this Agreement. The Employer will pay the Employee's dues in such professional societies and organizations as the Board of Directors deems appropriate, and will pay on behalf of the Employee (or reimburse the Employee for) reasonable expenses incurred by the Employee at the request of, or on behalf of, the Employer in the performance of the Employee's duties pursuant to this Agreement, and in accordance with the Employer's employment policies, including reasonable expenses incurred by the Employee in attending conventions, seminars, and other business meetings, in appropriate business

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entertainment activities, and for promotional expenses (the "Expenses"). To the extent that any reimbursements payable or in-kind benefits provided pursuant to this Agreement are subject to the provisions of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), any such reimbursements payable pursuant to this Agreement shall be paid no later than December 31 of the year following the year in which the expense was incurred, the amount of expenses reimbursed or in-kind benefits provided in one year shall not affect the amount eligible for reimbursement or in-kind benefits to be provided in any subsequent year, and the right to reimbursement or in-kind benefits under this Agreement will not be subject to liquidation or exchange for another benefit. The Employee must file expense reports with respect to such expenses in accordance with the Employer's policies.

#### 5. VACATIONS AND HOLIDAYS

The Employee will be eligible to accrue paid vacation each calendar year in accordance with the vacation policies of the Employer in effect from time to time. Under such policies of the Employer as of the Effective Date, the Employee is eligible to accrue up to four (4) weeks of paid vacation each calendar year. Vacation must be taken by the Employee at such time or times during the calendar year as approved by the Board of Directors or President. Additionally, the Employee will be entitled to the paid holidays set forth in the Employer's policies. Any accrued vacation days and holidays that are not used by the Employee by the end of the calendar year in which they were accrued will be lost and may not be used in any subsequent calendar year; *provided*, *however*, that upon termination of the Employee's employment, the Employee will be paid the equivalent compensation attributable to any accrued vacation days which were accrued during the calendar year in which such termination occurs and are not otherwise used by the Employee as of the date of such termination.

#### 6. TERMINATION

6.1 <u>At-Will Employment</u>. The Employee's employment is at-will, which means that either the Employee or the Employer may terminate this Employment Agreement (with the exception of the provisions of Sections 7 and 8 which shall survive termination of this Agreement and the Employee's employment) with or without Cause or notice, at any time at either the Employee's or the Employer's option. Except as otherwise specifically set forth herein, or as provided in any plan documents governing any compensatory equity awards that have been or may be granted to the Employee from time to time in the sole discretion of the Employer or an affiliate, upon termination of the Employee's employment the Employer shall be released from any and all further obligations under this Agreement, except the Employer shall be obligated to pay the Employee his accrued but unpaid Basic Compensation and

Expenses owing to the Employee through the day on which the Employee's employment is terminated (the "Termination Date"). The Employee's obligations under Sections 7 and 8 shall continue pursuant to the terms and conditions of this Agreement.

6.2 <u>Termination Upon Death</u>. The employment of the Employee shall terminate on the date of the Employee's death, in which event the Employee's accrued but unpaid Basic Compensation and Expenses, owing to the Employee through the date of the Employee's death, shall be paid to his estate. The Employee's estate will not be entitled to any other compensation under this Agreement.

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- 6.3 <u>Termination Related to a Change of Control</u>. As additional consideration for the covenants in Section 7 and Section 8, in the event of a Change of Control Termination, and provided that the Employee signs and allows to become effective a Release within the time period provided therein (but not later than the 60<sup>th</sup> day following the Termination Date, such latest permitted effective date is the "Release Deadline" for purposes of this Agreement), then subject to Section 9.2:
  - (a) The Employee shall receive as severance one (1) year of his Salary, payable in accordance with the Employer's then current payroll schedule over the one (1) year period following the Termination Date, less deductions required by law; *provided, however*, that if the Employee terminates his employment on account of a material reduction in his Salary, as provided in paragraph (a)(ii) of the definition of Good Reason, the amount of such severance shall be based on the Employee's Salary immediately prior to such reduction. Notwithstanding the foregoing payment schedule, no severance will be paid prior to the effective date of the Release. Subject to Section 9.2, on the first regular payroll pay day following the effective date of the Release, the Employer will pay the Employee the severance that the Employee would otherwise have received on or prior to such date but for the delay in payment related to the effectiveness of the Release, with the balance of the severance being paid as originally scheduled.
  - (b) If the Employee timely elects group health insurance coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA"), the Employer will pay the Employee's monthly COBRA premiums (including the cost of eligible dependent coverage, if any) through the earliest of the following (the "COBRA Payment Period"): (i) for twelve (12) months following the Termination Date; (ii) the date that the Employee becomes eligible for group health insurance coverage through a new employer; or (iii) the date that the Employee is no longer eligible for COBRA coverage. Notwithstanding the foregoing, if at any time the Employer determines, in its sole discretion, that its payment of the Employee's COBRA premiums would result in a violation of applicable law (including, without limitation, Section 105(h)(2) of the Code and Section 2716 of the Public Health Service Act), then in lieu of paying such COBRA premiums, the Employer will pay the Employee on the last day of each remaining month of the COBRA Payment Period a fully taxable cash payment equal to the COBRA premium for that month, subject to applicable tax withholding (such amount, the "Special Severance Payment"); provided, however, that any such Special Severance Payment will be made without regard to the Employee's payment of COBRA premiums and for purposes of any such Special Severance Payment, the "COBRA Payment Period" will be determined without regard to the expiration of the Employee's eligibility for continued coverage under COBRA.

#### 7. NON-DISCLOSURE COVENANT; EMPLOYEE INVENTIONS

#### 7.1 <u>Acknowledgements by the Employee</u>

The Employee acknowledges and agrees that (a) during the course of his employment and as a part of his employment, the Employee will be afforded access to Confidential Information and/or Proprietary Information; (b) public disclosure of such

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Confidential Information and/or Proprietary Information could have an adverse effect on the Employer and its business; (c) because the Employee possesses substantial technical expertise and skill with respect to the Employer's business, the Employer desires to obtain exclusive ownership of each Employee Invention, and the Employer will be at a substantial competitive disadvantage if it fails to acquire exclusive ownership of each Employee Invention; and (d) the provisions of this Section 7 are reasonable and necessary to prevent the improper use or disclosure of Confidential Information and/or Proprietary Information and to provide the Employer with exclusive ownership of all Employee Inventions.

#### 7.2 <u>Agreements of the Employee</u>

In consideration of the compensation and benefits to be paid or provided to the Employee by the Employer under this Agreement and otherwise, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Employee covenants and agrees as follows:

#### (a) <u>Confidentiality</u>

- (i) That all of such Confidential Information and/or Proprietary Information is a unique asset of the business of the Employer, the disclosure of which would be damaging to the Employer.
- (ii) That the Employee will not at any time, whether during or after termination or cessation of the Employee's employment, except as authorized by the Employer and for its benefit, use, divulge or disclose (or enable anyone else to use, divulge or disclose) to any Person, association or entity any Confidential Information and/or Proprietary Information which the Employee presently possesses or which the Employee may obtain during the course of the Employee's employment with respect to the business, finances, customers or affairs of the Employer or trade secrets, developments, methods or other information and data pertaining to the Employer's business. The Employee shall keep strictly confidential all matters and information entrusted to the Employee and shall not use or attempt to use any such Confidential Information and/or Proprietary Information in any manner which may injure or cause loss or may be calculated to injure or cause loss, whether directly or indirectly, to the Employer.
- (iii) That during the course of this Agreement or at any time after termination, the Employee will keep in strictest confidence and will not disclose or make accessible to any other Person without the prior written consent of the Employer, the Confidential Information and/or Proprietary Information; the Employee agrees: (a) not to use any such Confidential Information and/or Proprietary

- (iv) The Employee agrees to hold in confidence, and not to distribute or disseminate to any Person or entity for any reason, any Confidential Information and/or Proprietary Information of the Employer under this Agreement, or information relating to experiments or results obtained based on the duties of the Employee, except for information which: (a) is in or which becomes a part of the public domain not as a result of a breach of this Agreement, (b) is information lawfully received from a third party who had the right to disclose such information or (c) is required by legal process before a court of proper jurisdiction (by oral questions, deposition, interrogatories, requests for information or documents, subpoena, civil investigative domain or other similar process) to disclose all or any part of any Confidential Information and/or Proprietary Information, provided that the Employee will provide the Employer with prompt notice of such request or requirement, as well as notice of the terms and circumstances surrounding such request or requirements, so that the Employer may seek an appropriate protective order or waive compliance with the provisions of this Agreement. In such case, the parties will consult with each other on the advisability of pursuing any such order or other legal action or available step to resist or narrow such request or requirement. If, failing the entry of a protective order or the receipt of a waiver hereunder, the Employee is, in the opinion of counsel reasonably acceptable to the Employer, legally compelled to disclose Confidential Information and/or Proprietary Information, the Employee may disclose that portion of such information which counsel advises is necessary to disclose. The Employee will not oppose any action by the Employer to prevent disclosure pursuant to an appropriate protective order or to request other reliable assurances that confidential treatment will be accorded to the disclosure of such information.
- (v) Upon termination of this Agreement by either party or upon written notice by the Employer, the Employee shall promptly redeliver to the Employer, or, if requested by the Employer, promptly destroy all written Confidential Information and/or Proprietary Information and any other written material containing any information included in the Confidential Information and/or Proprietary Information (whether prepared by the Employer, the Employee, or a third party), and will not retain any copies, extracts or other reproductions in whole or in part of such written Confidential Information and/or Proprietary Information (and upon request certify such redelivery or destruction to the Employer in a written instrument reasonably acceptable to the Employer and its counsel).
- (vi) This Agreement and the terms and conditions recited herein are confidential and non-public, except as may be expressly permitted by the Employer. The Employee agrees not to disclose the contents of this Agreement to any Person or entity, including, but not limited to the press, other media, any public body, or any competitor of the Employer, except to the Employee's legal counsel or as may be required by law.

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- (vii) Any trade secrets of the Employer will be entitled to all of the protections and benefits of State of Tennessee law and any other applicable law. If any information that the Employer deems to be a trade secret is found by a court of competent jurisdiction not be to a trade secret for purposes of this Agreement, such information will, nevertheless, be considered Confidential Information and/or Proprietary Information for purposes of this Agreement. The Employee hereby waives any requirement that the Employer submits proof of the economic value of any trade secret or posts a bond or other security.
- (viii) None of the foregoing obligations and restrictions applies to any part of the Confidential Information and/or Proprietary Information that the Employee demonstrates was or became generally available to the public other than as a result of a disclosure by the Employee.
- (ix) The Employee will not remove from the Employer's premises (except to the extent such removal is for purposes of the performance of the Employee's duties at home or while traveling, or except as otherwise specifically authorized by the Employer) any Proprietary Items. The Employee recognizes that, as between the Employer and the Employee, all of the Proprietary Items, whether or not developed by the Employee, are the exclusive property of the Employer. Upon termination of this Agreement by either party, or upon the request of the Employer during the employment of the Employee, the Employee will return to the Employer all of the Proprietary Items in the Employee's possession or subject to the Employee's control, and the Employee shall not retain any copies, abstracts, sketches, or other physical or electronic embodiment of any of the Proprietary Items.
- (x) During the Employee's employment with the Employer, the Employee will not improperly use or disclose any confidential information or trade secrets, if any, of any former employer or any other Person to whom the Employee has an obligation of confidentiality, and the Employee will not bring onto the premises of the Employer any unpublished documents or any property belonging to any former employer or any other Person to whom the Employee has an obligation of confidentiality unless consented to in writing by that former employer or Person.

#### (b) <u>Employee Inventions</u>

(i) Each Employee Invention will belong exclusively to the Employer. The Employee agrees that the Employer shall have sole and exclusive ownership rights in any conception, invention, trade secrets, information, ideas, improvement, substance, know-how, whether or not patentable, arising out of, resulting from, or derivative of: (1) the work or services of the Employee, or (2) within the scope of the duties of the Employee, or (3) using any materials, compounds, devices, or monies of the Employer. Any resulting or derivative rights, including patent rights, shall become the exclusive property of the Employer and the Employer shall be entitled to the entire right, title and interest

with respect hereto. The Employee agrees, without additional compensation, to convey, assign the entire right, title, and interest in and to any inventions for the United States and all foreign jurisdictions to the Employer arising out of, resulting from, or derivative of: (1) the work or services of the Employee, or (2) within the scope of the duties of the Employee, or (3) using any materials, compounds, devices, or monies.

- (ii) The Employer shall retain the entire right, title and interest in and to any and all Confidential Information and/or Proprietary Information provided by the Employer to the Employee and to any methods, compounds, improvements, substances, and compositions using or incorporating such Confidential Information and/or Proprietary Information.
- (iii) The Employee agrees that Confidential Information and/or Proprietary Information provided to the Employee by the Employer shall be used for work purposes only and shall not be used for any other uses, studies, experiments or tests.
- (iv) The Employee agrees that he will promptly disclose to the Employer, or any Persons designated by the Employer, all the Employee Inventions, made or conceived or reduced to practice or learned by him, either alone or jointly with others, during the employment of the Employee. The Employee further agrees to assist the Employer in every proper way (but at the Employer's expense) to obtain and from time to time enforce patents, copyrights or other rights on Employee Inventions in any and all countries, and to that end the Employee will execute all documents necessary: (a) to apply for, obtain and vest in the name of the Employer alone (unless the Employer otherwise directs) letters patent, copyrights or other analogues protection in any country throughout the world and when so obtained or vested to renew and restore the same; and (b) to defend (including the giving of testimony and rendering any other assistance) any opposition proceedings in respect of such applications and any opposition proceedings or petitions or applications for revocation of such letters patent, copyright or other analogous protection. The Employee's obligation to assist the Employer in obtaining and enforcing patents and copyrights for Employee Inventions in any and all countries shall continue beyond and after the termination of the Employee.
- (v) Any copyrightable work whether published or unpublished created by the Employee in connection with or during the performance of services below shall be considered a work made for hire, to the fullest extent permitted by law and all right, title and interest therein, including the worldwide copyrights, shall be the property of the Employer as the employer and party specially commissioning such work. In the event that any such copyrightable work or portion thereof shall not be legally qualified as a work made for hire, or shall subsequently be so held, the Employee agrees to properly convey to the Employer, without additional compensation, the entire right, title and interest in and to such work or portion thereof, including but not limited to the worldwide

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copyrights, extensions of such copyrights, and renewal copyrights therein, and further including all rights to reproduce the copyrighted work in copies or phonorecords, to prepare derivative works based on the copyrighted work, to distribute copies of the copyrighted work, to perform the copyrighted work publicly, to display the copyrighted work publicly, and to register the claim of copyright therein and to execute any and all documents with respect hereto.

(vi) The Employee may not publish or disclose any Confidential Information and/or Proprietary Information relating to, arising from, derivative of, or as a result of his employment pursuant to this Agreement, including but not limited to: information, improvements, results, experiments, data, or methods that makes reference to any of the Confidential Information and/or Proprietary Information. Any work performed under, or arising from, or a result of his employment with the Employer shall not be published or disclosed in written, electronic, or oral form without the express written permission of the Employer.

#### 7.3 <u>Disputes or Controversies</u>

The Employee recognizes that should a dispute or controversy arising from or relating to this Agreement be submitted for adjudication to any court, arbitration panel, or other third party, the preservation of the secrecy of Confidential Information and/or Proprietary Information may be jeopardized. All pleadings, documents, testimony, and records relating to any such adjudication will be maintained in secrecy and will be available for inspection by the Employer, the Employee, and their respective attorneys and experts, who will agree, in advance and in writing, to receive and maintain all such information in secrecy, except as may be limited by them in writing.

#### 7.4 Agreement on Condition of Employment

As a condition of employment, the Employee agrees to execute and abide by the Employer's current form of Agreement on Condition of Employment, which may be amended by the parties from time to time without regard to this Agreement. The Agreement on Condition of Employment contains provisions that are intended by the parties to survive and do survive termination or expiration of this Agreement. In the event that the terms of this Agreement differ from or are in conflict with the Agreement on Condition of Employment, this Agreement shall control.

#### 8. NON-COMPETITION

#### 8.1 Acknowledgments by the Employee

The Employee understands and recognizes that the Employee's services provided to the Employer are special, unique, unusual, extraordinary and intellectual in character. Subject to Section 8.4 below, the Employee agrees that, during the employment of the Employee and for a period of two (2) years from the date of termination of the Employee's employment with the Employer, he will not in any manner, directly or indirectly, on behalf of himself or any Person, firm, partnership, joint venture, corporation or other business entity, engage or invest in, own,

any Competing Business; *provided*, *however*, that the Employee may purchase or otherwise acquire up to (but not more than) one percent of any class of securities of any enterprise (but without otherwise participating in the activities of such enterprise) if such securities are listed on any national or regional securities exchange or have been registered under Section 12(g) of the Securities Exchange Act of 1934.

- 8.2 In consideration of the acknowledgements by the Employee, and in consideration of the compensation and benefits to be paid or provided to the Employee by the Employee covenants that, subject to Section 8.4 below, he will not, directly or indirectly, whether for the Employee's own account or the account of any other Person (i) at any time during the employment of the Employee and for a period of two (2) years from the termination of the Employee's employment with the Employer, solicit, employ, or otherwise engage as an employee, independent contractor, or otherwise, any Person who is or was an employee of the Employer at any time during the Employee's employment with the Employer or in any manner induce or attempt to induce any employee of the Employer to terminate his employment with the Employer; or (ii) at any time during the employment of the Employee with the Employer and for two (2) years from the termination of the Employee's employment with the Employer, interfere with the Employer's relationship with any Person, including any Person who at any time during the Employee's employment with the Employer was an employee, contractor, supplier, or customer of the Employer.
- 8.3 In further consideration of these promises, the Employee agrees that he will not at any time during or after the Employee's employment with the Employer, disparage the Employer or any of its shareholders, directors, officers, employees, parents, subsidiaries, affiliates or agents in any manner likely to be harmful to them or their business, business reputation or personal reputation; *provided*, *however*, that the Employee may respond accurately and fully to any question, inquiry or request for information when required by legal process.
- 8.4 <u>Change of Control.</u> In the event of a Change of Control Termination, the Employee's obligations under Sections 8.1 and 8.2 above and the non-competition and non-solicitation provisions in the Agreement on Condition of Employment shall expire one (1) year from the date of termination of his employment with the Employer (or any entity acquiring the Employer as a result of a Change of Control).
- 8.5 If any covenant in Section 8 is held to be unreasonable, arbitrary, or against public policy, such covenant will be considered to be divisible with respect to scope, time, and geographic area, and such lesser scope, time, or geographic area, or all of them, as a court of competent jurisdiction may determine to be reasonable, not arbitrary, and not against public policy, will be effective, binding, and enforceable against the Employee.

The period of time applicable to any covenant in Section 8 will be extended by the duration of any violation by the Employee of such covenant.

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The Employee will, while the covenants under Section 8 are in effect, give notice to the Employer, within ten days after accepting any other employment, of the identity of the Employee's employer. The Employer may notify such employer that the Employee is bound by this Agreement and, at the Employer's election, furnish such employer with a copy of this Agreement or relevant portions thereof.

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# 9. TAX MATTERS

- 9.1 <u>Responsibility for Tax Obligations</u>. The Employee agrees that he is responsible for any applicable taxes of any nature (including any penalties or interest that may apply to such taxes) that the Employer reasonably determines apply to any payment or equity award made to the Employee hereunder (or any arrangement contemplated hereunder), that the Employee's receipt of any payment or benefit hereunder is conditioned on the Employee's satisfaction of any applicable withholding or similar obligations that apply to such payment or benefit, and that any cash payment owed to the Employee hereunder will be reduced to satisfy any such withholding or similar obligations that may apply thereto.
- 9.2 Compliance with Section 409A. Any payments or benefits provided under this Agreement that constitute "deferred compensation" within the meaning of Section 409A of the Code and the regulations and other guidance thereunder and any state law of similar effect (collectively "Section 409A") shall not commence in connection with the Employee's termination of employment unless the Employee has also incurred a "separation from service," as such term is defined in Treasury Regulation Section 1.409A-1(h) (without regard to any permissible alternative definition thereunder) ("Separation from Service"). It is intended that each installment of the payments and benefits provided for in this Agreement is a separate "payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2)(i). For the avoidance of doubt, it is intended that payments of the amounts set forth in this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9). However, if the Employer determines that the payments and benefits provided under this Agreement constitute "deferred compensation" under Section 409A and the Employee is, on the date of the Employee's Separation from Service, a "specified employee" of the Employer or any successor entity thereto, as such term is defined in Section 409A(a)(2)(B)(i) of the Code, then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of any such payments or benefits shall be delayed as follows: on the earlier to occur of (i) the date that is six (6) months and one (1) day after the Employee's Separation from Service or (ii) the date of the Employee's death (such earlier date, the "Delayed Initial Payment Date"), the Employer shall (A) pay to the Employee a lump sum amount equal to the sum of the payments that the Employee would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the payments had not been so delayed pursuant to this Section 9.2 and (B) commence paying the balance of the payments in accordance with the applicable payment schedules set forth in this Agreement. If the Employer determines that any payments or benefits provided under this Agreement constitute "deferred compensation" under Section 409A and the Release could become effective in the calendar year following the calendar year in which the Employee's Separation from Service occurs, the Release will not be deemed effective any earlier than the Release Deadline for purposes of determining the timing of payment of any such payments or benefits.

# 9.3 <u>Parachute Payments</u>

(a) Notwithstanding anything in this Agreement to the contrary, if any payment or benefit the Employee will or may receive from the Employer or otherwise (a "280G Payment") would (i) constitute a "parachute payment" within the meaning of

Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then any such 280G Payment pursuant to this Agreement (a "Payment") shall be equal to the Reduced Amount. The "Reduced Amount" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount (*i.e.*, the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in the Employee's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "Reduction Method") that results in the greatest economic benefit for the Employee. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "Pro Rata Reduction Method").

- (b) Notwithstanding any provision of Section 9.3(a) to the contrary, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for the Employee as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (*e.g.*, being terminated without Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.
- (c) If the Employee receives a Payment for which the Reduced Amount was determined pursuant to clause (x) of Section 9.3(a) and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, the Employee shall promptly return to the Employer a sufficient amount of the Payment (after reduction pursuant to clause (x) of Section 9.3(a)) so that no portion of the remaining Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) of Section 9.3(a), the Employee shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

## 10. CLAWBACK/RECOVERY

Any amounts paid to the Employee by the Employer, whether or not under this Agreement or any incentive plan of the Employer, will be subject to recoupment in accordance with The Sarbanes-Oxley Act of 2002, The Dodd-Frank Wall Street Reform and Consumer Protection Act and any implementing regulations under these acts, any clawback policy adopted

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by the Employer, or as otherwise required by applicable law. In addition, in consideration of the Employee's continued employment with the Employer and in recognition of the Employee's position of trust and authority with the Employer, the Employee agrees to promptly consent to any clawback policy adopted by the Employer.

# 11. GENERAL PROVISIONS

# 11.1 <u>Injunctive Relief and Additional Remedy</u>

The Employee acknowledges that the injury that would be suffered by the Employer as a result of a breach of the provisions of this Agreement (including any provision of Sections 7 and 8) would be irreparable and that an award of monetary damages to the Employer for such a breach would be an inadequate remedy. Consequently, the Employer will have the right, in addition to any other rights it may have, to obtain injunctive relief to restrain any breach or threatened breach or otherwise to specifically enforce any provision of this Agreement, and the Employer will not be obligated to post bond or other security in seeking such relief. Without limiting the Employer's rights under this Section 11 or any other remedies of the Employer, if the Employee breaches any of the provisions of Section 7 or 8, the Employer will have the right to cease making any payments otherwise due to the Employee under this Agreement.

# 11.2 <u>Covenants of Sections 7 and 8 are Essential and Independent Covenants</u>

The covenants by the Employee in Sections 7 and 8 are essential elements of this Agreement, and without the Employee's agreement to comply with such covenants, the Employer would not have entered into this Agreement or employed or continued the employment of the Employee. The Employer and the Employee have independently consulted their respective counsel and have been advised in all respects concerning the reasonableness and propriety of such covenants, with specific regard to the nature of the business conducted by the Employer. The Employee agrees that this Agreement does not prevent him from earning a living or pursuing his career and that he has the ability to secure other non-competitive employment using his marketable skills. The Employee agrees that the restrictions contained in this Agreement are reasonable, proper, and necessitated by the Employer's legitimate business interests, including without limitation, the Employer's Confidential and/or Proprietary Information and the goodwill of its customers.

The Employee's covenants in Sections 7 and 8 are independent covenants and the existence of any claim by the Employee against the Employer under this Agreement or otherwise will not excuse the Employee's breach of any covenant in Section 7 or 8.

If the Employee's employment hereunder is terminated by either party, this Agreement will continue in full force and effect as is necessary or appropriate to enforce the covenants and agreements of the Employee in Sections 7 and 8.

## 11.3 Representations and Warranties by the Employee

The Employee represents and warrants to the Employer that the execution and delivery by the Employee of this Agreement do not, and the performance by the Employee of the Employee's obligations hereunder will not, with or without the giving of notice or the passage of

time, or both: (a) violate any judgment, writ, injunction, or order of any court, arbitrator, or governmental agency applicable to the Employee; or (b) conflict with, result in the breach of any provisions of or the termination of, or constitute a default under, any agreement to which the Employee is a party or by which the Employee is or may be bound.

## 11.4 Waiver

The rights and remedies of the parties to this Agreement are cumulative and not alternative. Neither the failure nor any delay by either party in exercising any right, power, or privilege under this Agreement will operate as a waiver of such right, power, or privilege, and no single or partial exercise of any such right, power, or privilege will preclude any other or further exercise of such right, power, or privilege or the exercise of any other right, power, or privilege. To the maximum extent permitted by applicable law, (a) no claim or right arising out of this Agreement can be discharged by one party, in whole or in part, by a waiver or renunciation of the claim or right unless in writing signed by the other party; (b) no waiver that may be given by a party will be applicable except in the specific instance for which it is given; and (c) no notice to or demand on one party will be deemed to be a waiver of any obligation of such party or of the right of the party giving such notice or demand to take further action without notice or demand as provided in this Agreement.

#### 11.5 <u>Binding Effect; Delegation of Duties Prohibited</u>

This Agreement shall inure to the benefit of, and shall be binding upon, the parties hereto and their respective successors, assigns, heirs, and legal representatives, including any entity with which the Employer may merge or consolidate or to which all or substantially all of its assets may be transferred. The duties and covenants of the Employee under this Agreement, being personal, may not be delegated.

#### 11.6 Notices

All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when (a) delivered by hand (with written confirmation of receipt), (b) sent by facsimile (with written confirmation of receipt), provided that a copy is mailed by registered mail, return receipt requested, or (c) when received by the addressee, if sent by a nationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses and facsimile numbers set forth below (or to such other addresses and facsimile numbers as a party may designate by notice to the other parties):

If to the Employer: GTx, Inc.

175 Toyota Plaza, 7<sup>th</sup> Floor Memphis, Tennessee 38103

Attention: Vice President, Chief Legal Officer

Facsimile No.: 901-844-8075

If to the Employee: Mitchell S. Steiner

2600 Forest Hill Irene Road Germantown, Tennessee 38139

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The Employee shall notify the Employer in writing of any change of his address. Otherwise, the Employer shall send all notices to the Employee's address herein.

## 11.7 Entire Agreement; Amendments

This Agreement, including the Agreement on Condition of Employment, contains the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral or written, between the parties hereto with respect to the subject matter hereof. The Employer and the Employee further acknowledge and agree that the provisions of this Agreement amend and supersede the Prior Employment Agreement, which shall be of no further force and effect. This Agreement may not be amended orally, but only by an agreement in writing signed by the Employee and a duly authorized officer or director of the Employer.

# 11.8 Governing Law

This Agreement will be governed by the laws of the State of Tennessee without regard to conflicts of laws principles.

# 11.9 <u>Jurisdiction</u>

Any action or proceeding seeking to enforce any provision of, or based on any right arising out of, this Agreement shall be brought against either of the parties in the courts of the State of Tennessee, County of Shelby, or, if it has or can acquire jurisdiction, in the United States District Court for the Western District of Tennessee, and each of the parties consents to the jurisdiction of such courts (and of the appropriate appellate courts) in any such action or proceeding and waives any objection to venue laid therein. Process in any action or proceeding referred to in the preceding sentence may be served on either party anywhere in the world.

# 11.10 <u>Section Headings, Construction</u>

The headings of Sections in this Agreement are provided for convenience only and will not affect its construction or interpretation. All references to "Section" or "Sections" refer to the corresponding Section or Sections of this Agreement unless otherwise specified. All words used in this Agreement will be construed to be of such gender or number as the circumstances require. Unless otherwise expressly provided, the word "including" does not limit the preceding words or terms.

# 11.11 <u>Severability</u>

If any provision of this Agreement is held invalid or unenforceable by any court of competent jurisdiction, the other provisions of this Agreement will remain in full force and effect. Any provision of this Agreement held invalid or unenforceable only in part or degree will remain in full force and effect to the extent not held invalid or unenforceable.

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## 11.12 <u>Counterparts</u>

This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of this Agreement and all of which, when taken together, will be deemed to constitute one and the same agreement.

# 11.13 Waiver of Jury Trial

THE PARTIES HERETO HEREBY WAIVE A JURY TRIAL IN ANY LITIGATION WITH RESPECT TO THIS AGREEMENT, OR ARISING OUT OF OR CONCERNING THE EMPLOYEE'S EMPLOYMENT WITH THE EMPLOYER OR TERMINATION THEREOF.

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IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date above first written above.

# MITCHELL S. STEINER, M.D.

/s/ Mitchell S. Steiner, M.D.

GTx, Inc.

By: /s/ Henry P. Doggrell
Name: Henry P. Doggrell

Title: VP, Chief Legal Officer

# AMENDED AND RESTATED EMPLOYMENT AGREEMENT

This Amended and Restated Employment Agreement (this "Agreement") is made and entered into as of February 14, 2013 (the "Effective Date") by and between **GTx, Inc.**, located at 175 Toyota Plaza, 7<sup>th</sup> Floor, Memphis, Tennessee 38103 (the "Employer"), and **MARC S. HANOVER** (the "Employee"), residing at 5597 St. Joseph Fairway, Memphis, Tennessee 38120.

WHEREAS, the Employee has been providing services to the Employer as President and Chief Operating Officer under the terms of an Amended and Restated Employment Agreement that was effective as of November 10, 2008 (the "Prior Employment Agreement"); and

WHEREAS, the Employer and the Employee wish to amend and restate the Prior Employment Agreement as set forth herein; and

WHEREAS, during the course of the Employee's employment with the Employer, the Employer will train and continue to train the Employee and to impart to the Employee proprietary, confidential, and/or trade secret information, data and/or materials of the Employer; and

WHEREAS, the Employer has a vital interest in maintaining its confidential information and trade secrets, as well as rights to inventions, since doing so allows the Employer to compete fairly and enhances the value of the Employer to shareholders and job security for employees; and

WHEREAS, the Employer desires to retain the services of the Employee and the Employee is willing to be employed and continue to be employed with the Employer upon the terms and subject to the conditions set forth in this Agreement;

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained in this Agreement, the employment and continued employment of the Employee in accordance with the terms and conditions of this Agreement, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties, intending to be legally bound, agree and covenant as follows:

#### 1. DEFINITIONS

For the purposes of this Agreement, the following terms have the meanings specified or referred to in this Section 1.

"Agreement" has the meaning set forth in first paragraph of this Agreement.

"Basic Compensation" means Salary and Benefits.

"Benefits" has the meaning stated in Section 3.1(b) of this Agreement.

"Board of Directors" means the Board of Directors of the Employer.

"CEO" has the meaning set forth in Section 2.2.

"Change of Control" means any of the following events: (a) the sale or other disposition of all or substantially all of the assets of the Employer in a single transaction or in a series of transactions (including, without limitation, any liquidation or dissolution of the Employer); (b) any Person or group becomes the beneficial owner, directly, or indirectly, of securities of the Employer representing more than fifty percent (50%) of the combined voting power of the Employer's then outstanding securities other than by virtue of a merger, consolidation or similar transaction (for such purposes, "voting stock" shall mean the capital stock of the Employer of any class or classes, the holders of which are ordinarily, in the absence of contingencies, entitled to vote for the election of members of the Board of Directors (or Persons performing similar functions) of the Employer); (c) a merger or consolidation of the Employer with or into any other entity, if immediately after giving effect to such transaction more than fifty percent (50%) of the issued and outstanding voting stock of the surviving entity of such transaction is held by Persons who were not holders (taking into account their individual and affiliated holdings) as of the Effective Date of at least fifty percent (50%) of the voting stock of the Employer; or (d) individuals who, on the Effective Date, are members of the Board of Directors (the "Incumbent Board") cease for any reason to constitute at least a majority of the members of the Board of Directors; provided, however, that if the appointment or election (or nomination for election) of any new member of the Board of Directors was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member will, for purposes of this Agreement, be considered as a member of the Incumbent Board. A Change of Control shall not include: (1) any transfer or issuance of stock of the Employer to one or more of the Employer's lenders (or to any agents or representatives thereof) in exchange for debt of the Employer owed to any such lenders; (2) any transfer of stock of the Employer to or by any Person or entity, including but not limited to one or more of the Employer's lenders (or to any agents or representatives thereof), pursuant to the terms of any pledge of said stock as collateral for any loans or financial accommodations to the Employer and/or its subsidiaries; (3) any transfer or issuance to any Person or entity, including but not limited to one or more of the Employer's lenders (or to any agents or representatives thereof), in connection with the workout or restructuring of the Employer's debts to any one of the Employer's lenders, including but not limited to the issuance of new stock in exchange for any equity contribution to the Employer in connection with the workout or restructuring of such debt; (4) any transfer of stock by a stockholder of the Employer which is a partnership or corporation to the partners or stockholders in such stockholder or any transfer of stock by a stockholder of the Employer to an entity affiliated with such stockholder or the immediate family of such stockholder or a trust or similar entity for the benefit of such family members; or (5) any transfer or issuance of stock in connection with an offering of the Employer's stock in a registered public transaction not involving a transaction described in Rule 145, promulgated under the Securities Act of 1933, as amended, provided that the Employer's officers and Board of Directors shall not materially change as a result thereof.

"Change of Control Termination" means (i) a Termination Without Cause of the Employee's employment by the Employer (other than for death or disability) within twelve (12)

months after a Change of Control or (ii) the Employee's resignation for Good Reason within twelve (12) months after a Change of Control.

"Competing Business" means any individual or entity, other than the Employer, that is engaging in, or proposes to engage in, the development, manufacture, distribution or sale of a Competing Product in North America, South America, Europe and Eastern Europe, and in the countries of Russia, Australia, Japan, China, Taiwan, South Korea and India; provided, however, that an entity that develops, manufactures, distributes or sells a Competing Product in a separate business unit than the business unit in which the Employee is then employed shall not be deemed a Competing Business unless the Employee provides Confidential Information and/or Proprietary Information to the business unit that is engaging in or proposes to engage in the development, manufacture, distribution or sale of a Competing Product.

"Competing Product" means any pharmaceutical or other compound, composition, formulation, method, process, product or material that is competitive with any product of the Employer under development, manufacture, distribution or commercialization at any time from and after October 1, 2003 (the effective date of the Employee's initial employment agreement with the Employer) through the date of termination of the Employee's employment, including, without limitation, small molecules that target androgen, estrogen, glucocorticoid, and/or other hormone receptors for purposes of treating, diagnosing, or imaging humans in health and disease, including treating cancer, osteoporosis and bone loss and muscle loss.

#### "Confidential Information and/or Proprietary Information" means any and all:

- (a) information disclosed to the Employee or known by the Employee as a consequence of, or through, the Employee's employment with the Employer since his initial date of employment on September 24, 1997 (including information conceived, originated, discovered, or developed in whole or in part by the Employee), not generally known in the relevant trade or industry, about the Employer's business, products, processes, and services; and trade secrets concerning the business and affairs of the Employer, product specifications, data, know-how, formulae, compositions, research, processes, designs, sketches, photographs, graphs, drawings, samples, inventions and ideas, past, current, and planned research and development, current and planned manufacturing or distribution methods and processes, customer lists, current and anticipated customer requirements, price lists, market studies, business plans, computer software and programs (including object code and source code), computer software and database technologies, systems, structures, and architectures (and related formulae, compositions, processes, improvements, devices, know-how, inventions, discoveries, concepts, ideas, designs, methods and information); and any other information, however documented, that is a trade secret within the meaning of Tenn. Code §39-14-138 or any other applicable law; and
- (b) information concerning the business and affairs of the Employer (which includes historical financial statements, financial projections and budgets, historical and projected sales, capital spending budgets and plans, the names and backgrounds of key personnel, personnel training and techniques and materials), however documented; and
- (c) intellectual property, inventions, methods, processes, techniques, computer programs, devices, products, services, compounds, gene therapy products, pharmaceuticals,

substances, vectors, enzymes, genes, concepts, discoveries, improvements, and designs, whether or not patentable in the United States or foreign countries, any trade secrets, information, procedures, technologies, data, results, conclusions, know-how or show-how and business information; and

- (d) notes, analysis, compilations, studies, summaries, and other material prepared by or for the Employer containing or based, in whole or in part, on any information included in the foregoing.
  - "Delayed Initial Payment Date" has the meaning stated in Section 9.2 of this Agreement.
  - "Effective Date" means the date stated in the first paragraph of this Agreement.
  - "Employee" has the meaning stated in the first paragraph of this Agreement.
- "Employee Invention" means any idea, invention, technique, modification, process, improvement (whether patentable or not), industrial design (whether registerable or not), work of authorship (whether or not copyright protection may be obtained for it), design, copyrightable work, discovery, trademark, copyright, trade secret, formula, device, method, compound, gene, prodrug, pharmaceutical, structure, product concept, marketing plan, strategy, customer list, technique, blueprint, sketch, record, note, drawing, know-how, data, patent application, continuation application, continuation-in-part application, file wrapper continuation application or divisional application, created, conceived, or developed by the Employee, either solely or in conjunction with others, during the Employee's employment, or a period that includes a portion of the Employee's employment, that relates in any way to, or is useful in any manner in, the business then being conducted or proposed to be conducted by the Employer, and any such item created by the Employee, either solely or in conjunction with others, following termination of the Employee's employment with the Employer, that is based upon or uses Confidential Information and/or Proprietary Information.
- <u>"Employer"</u> means GTx, Inc., its successors and assigns, and any of its current or future subsidiaries, or organizations controlled by, controlling, or under common control with it.
  - "Expenses" has the meaning stated in Section 4.1 of this Agreement.
  - "Good Reason" for termination means that the Employee voluntarily resigns from all positions he then holds with the Employer if and only if:
  - $\hbox{(a)} \qquad \hbox{one of the following actions have been taken without the Employee's express written consent:}$
- (i) following a Change of Control, an adverse change in the Employee's authority, duties or responsibilities (including reporting responsibilities) which, without the Employee's consent, represents a material reduction in or a material demotion of the Employee's authority, duties or responsibilities as in effect immediately prior to a Change of Control or the assignment to the Employee of any duties or responsibilities which are materially inconsistent with and materially adverse to such authority, duties or responsibilities;

- (ii) following a Change of Control, a material reduction in the then current Salary of the Employee;
- (iii) following a Change of Control, the relocation of the Employer's principal employee offices to a location that increases the Employee's one-way commute by more than twenty (20) miles;
- (iv) the failure of the Employer to obtain an agreement reasonably satisfactory to the Employee from any successor or assign of the Employer upon a Change of Control to assume and agree to perform this Agreement in all material respects following the Change of Control; or
- (v) the Employer materially breaches its obligations under this Agreement or any other then-effective agreement with the Employee (including any agreement or arrangement providing for incentive compensation or employee benefits, including the Benefits provided in this Agreement).
  - (b) the Employee provides written notice to the Board of Directors within the thirty (30) day period immediately following such action; and
  - (c) such action is not remedied by the Employer within thirty (30) days following the Employer's receipt of such written notice; and
  - (d) the Employee's resignation is effective not later than sixty (60) days after the expiration of such thirty (30)-day cure period.
- <u>"Person"</u> means any individual, corporation (including any non-profit corporation), general or limited partnership, limited liability company, joint venture, estate, trust, association, organization, or governmental body.
- <u>"Proprietary Items"</u> means any Proprietary and/or Confidential Information embodied in any document, record, recording, electronic media, formulae, notebook, plan, model, component, device, or computer software or code, whether embodied in a disk or in any other form.
- <u>"Release"</u> means a general release of claims in favor of the Employer, in a form acceptable to the Employer, which shall specifically relate to all of the Employee's rights and claims in existence at the time of such execution and shall confirm the Employee's continuing obligations to the Employer (including but not limited to obligations under Section 7 and Section 8 of this Agreement, the Agreement on Condition of Employment and any other confidentiality and/or non-competition agreement with the Employer).

"Salary" has the meaning stated in Section 3.1(a) of this Agreement.

"Section 409A" has the meaning stated in Section 9.2 of this Agreement.

"Termination Date" has the meaning stated in Section 6.1 of this Agreement.

<u>"Termination With Cause"</u> means the termination of the Employee's employment by act of the Board of Directors for any of the following reasons, any of which shall constitute "Cause" for purposes of this Agreement:

- (a) the Employee's conviction of a felony;
- (b) the Employee's theft, embezzlement, misappropriation of or intentional infliction of material damage to the Employer's property or business opportunities;
- (c) the Employee's breach of the provisions contained in Section 7 or Section 8 of this Agreement or the provisions in the Agreement on Condition of Employment regarding confidentiality, non-competition or non-solicitation; or
- (d) the Employee's ongoing willful neglect of or failure to perform his duties hereunder or his ongoing willful failure or refusal to follow any reasonable, unambiguous duly adopted written direction of the CEO that is not inconsistent with the description of the Employee's duties set forth in Section 2.3, if such willful neglect or failure is materially damaging or materially detrimental to the business and operations of the Employer; provided that, if curable, the Employee shall have received written notice of such neglect or failure and shall have continued to engage in such neglect or failure after 30 days following receipt of such notice from the CEO, which notice specifically identifies the manner in which the CEO believes that the Employee has engaged in such neglect or failure. For purposes of this subsection, no act, or failure to act, shall be deemed "willful" unless done, or omitted to be done, by the Employee not in good faith, and without reasonable belief that such action or omission was in the best interest of the Employer.

<u>"Termination Without Cause"</u> means the termination of the Employee's employment by the Employer for any reason other than (i) Termination With Cause, or (ii) a termination by the Employer due to the Employee's death or disability.

# 2. EMPLOYMENT TERMS AND DUTIES

# 2.1 <u>Employment</u>

The Employer hereby continues the employment of the Employee, and the Employee hereby accepts continued employment by the Employer, upon the terms and conditions set forth in this Agreement.

# 2.2 <u>Term</u>

Either the Employee or the Employer may terminate this Agreement and the Employee's employment and compensation with or without Cause or notice, at any time, at either the Employer's or the Employee's option. No officer or manager of the Employer has the authority to enter into any other agreement for employment for a specified period of time, or to modify or to make any agreement contrary to the foregoing, except by written amendment to this Agreement, dated and signed by the Chief Executive Officer ("CEO") of the Employer.

#### 2.3 Duties

The Employee will continue to have such duties as are assigned or delegated to the Employee by the Board of Directors or the CEO and will initially serve as President and Chief Operating Officer for the Employer. The Employee will devote his full time, attention, skill and energy to the business of the Employer, will use his best efforts to promote the success of the Employer's business, and will cooperate fully with the Board of Directors and the CEO in the advancement of the best interest of the Employer. The Employee agrees to abide by all bylaws, policies, practices, procedures or rules of the Employer. The Employee may be reassigned or transferred to another management position, as designated by the Board of Directors or the CEO, which may or may not provide the same level of responsibility as the initial assignment, in accordance with the terms and conditions of this Agreement.

#### 3. COMPENSATION

# 3.1 <u>Basic Compensation</u>

- (a) <u>Salary.</u> As of the Effective Date, the Employee will be paid for each of the twenty-six pay periods during the calendar year approximately \$18,909.46, which is the equivalent of \$491,646 per calendar year (the "Salary"), subject to review and adjustment from time to time by the CEO in his sole discretion.
- (b) <u>Benefits.</u> The Employee will, during his employment with the Employer, be permitted to participate in such life insurance, hospitalization, major medical, short term disability, long term disability, 401(k) plan and other employee benefit plans of the Employer that may be in effect from time to time, to the extent the Employee is eligible under the terms of those plans (collectively, the "Benefits"). All matters of eligibility for coverage or benefits under any such plan shall be determined in accordance with the provisions of such plan. The Employer reserves the right to change, alter, or terminate any such plan, in its sole discretion, subject to the terms of such plan.
- (c) The Employer may withhold from the Salary or Benefits payable to the Employee all federal, state, local, and other taxes and other amounts as permitted or required pursuant to law, rules or regulations.

# 4. FACILITIES AND EXPENSES

## 4.1 General

The Employer will furnish the Employee office space, equipment, supplies, and such other facilities and personnel as the Employer deems necessary or appropriate for the performance of the Employee's duties under this Agreement. The Employer will pay the Employee's dues in such professional societies and organizations as the CEO deems appropriate, and will pay on behalf of the Employee (or reimburse the Employee for) reasonable expenses incurred by the Employee at the request of, or on behalf of, the Employer in the performance of the Employee's duties pursuant to this Agreement, and in accordance with the Employer's employment policies, including reasonable expenses incurred by the Employee in attending conventions, seminars, and other business meetings, in appropriate business entertainment activities, and for promotional expenses (the "Expenses"). To the extent that any reimbursements payable or in-kind benefits provided pursuant to this Agreement are subject to

the provisions of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), any such reimbursements payable pursuant to this Agreement shall be paid no later than December 31 of the year following the year in which the expense was incurred, the amount of expenses reimbursed or in-kind benefits provided in one year shall not affect the amount eligible for reimbursement or in-kind benefits to be provided in any subsequent year, and the right to reimbursement or in-kind benefits under this Agreement will not be subject to liquidation or exchange for another benefit. The Employee must file expense reports with respect to such expenses in accordance with the Employer's policies.

#### 5. VACATIONS AND HOLIDAYS

The Employee will be eligible to accrue paid vacation each calendar year in accordance with the vacation policies of the Employer in effect from time to time. Under such policies of the Employer as of the Effective Date, the Employee is eligible to accrue up to four (4) weeks of paid vacation each calendar year. Vacation must be taken by the Employee at such time or times during the calendar year as approved by the CEO. Additionally, the Employee will be entitled to the paid holidays set forth in the Employer's policies. Any accrued vacation days and holidays that are not used by the Employee by the end of the calendar year in which they were accrued will be lost and may not be used in any subsequent calendar year; *provided*, *however*, that upon termination of the Employee's employment, the Employee will be paid the equivalent compensation attributable to any accrued vacation days which were accrued during the calendar year in which such termination occurs and are not otherwise used by the Employee as of the date of such termination.

## 6. TERMINATION

- 6.1 <u>At-Will Employment</u>. The Employee's employment is at-will, which means that either the Employee or the Employer may terminate this Employment Agreement (with the exception of the provisions of Sections 7 and 8 which shall survive termination of this Agreement and the Employee's employment) with or without Cause or notice, at any time at either the Employee's or the Employer's option. Except as otherwise specifically set forth herein, or as provided in any plan documents governing any compensatory equity awards that have been or may be granted to the Employee from time to time in the sole discretion of the Employer or an affiliate, upon termination of the Employee's employment the Employer shall be released from any and all further obligations under this Agreement, except the Employer shall be obligated to pay the Employee his accrued but unpaid Basic Compensation and Expenses owing to the Employee through the day on which the Employee's employment is terminated (the "Termination Date"). The Employee's obligations under Sections 7 and 8 shall continue pursuant to the terms and conditions of this Agreement.
- 6.2 <u>Termination Upon Death</u>. The employment of the Employee shall terminate on the date of the Employee's death, in which event the Employee's accrued but unpaid Basic Compensation and Expenses, owing to the Employee through the date of the Employee's death, shall be paid to his estate. The Employee's estate will not be entitled to any other compensation under this Agreement.

- 6.3 <u>Termination Related to a Change of Control</u>. As additional consideration for the covenants in Section 7 and Section 8, in the event of a Change of Control Termination, and provided that the Employee signs and allows to become effective a Release within the time period provided therein (but not later than the 60<sup>th</sup> day following the Termination Date, such latest permitted effective date is the "Release Deadline" for purposes of this Agreement), then subject to Section 9.2:
  - (a) The Employee shall receive as severance one (1) year of his Salary, payable in accordance with the Employer's then current payroll schedule over the one (1) year period following the Termination Date, less deductions required by law; *provided*, *however*, that if the Employee terminates his employment on account of a material reduction in his Salary, as provided in paragraph (a)(ii) of the definition of Good Reason, the amount of such severance shall be based on the Employee's Salary immediately prior to such reduction. Notwithstanding the foregoing payment schedule, no severance will be paid prior to the effective date of the Release. Subject to Section 9.2, on the first regular payroll pay day following the effective date of the Release, the Employee will pay the Employee the severance that the Employee would otherwise have received on or prior to such date but for the delay in payment related to the effectiveness of the Release, with the balance of the severance being paid as originally scheduled.
  - (b) If the Employee timely elects group health insurance coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA"), the Employer will pay the Employee's monthly COBRA premiums (including the cost of eligible dependent coverage, if any) through the earliest of the following (the "COBRA Payment Period"): (i) for twelve (12) months following the Termination Date; (ii) the date that the Employee becomes eligible for group health insurance coverage through a new employer; or (iii) the date that the Employee is no longer eligible for COBRA coverage. Notwithstanding the foregoing, if at any time the Employer determines, in its sole discretion, that its payment of the Employee's COBRA premiums would result in a violation of applicable law (including, without limitation, Section 105(h)(2) of the Code and Section 2716 of the Public Health Service Act), then in lieu of paying such COBRA premiums, the Employer will pay the Employee on the last day of each remaining month of the COBRA Payment Period a fully taxable cash payment equal to the COBRA premium for that month, subject to applicable tax withholding (such amount, the "Special Severance Payment"); *provided*, *however*, that any such Special Severance Payment will be made without regard to the Employee's payment of COBRA premiums and for purposes of any such Special Severance Payment, the "COBRA Payment Period" will be determined without regard to the expiration of the Employee's eligibility for continued coverage under COBRA.

## 7. NON-DISCLOSURE COVENANT; EMPLOYEE INVENTIONS

#### 7.1 <u>Acknowledgements by the Employee</u>

The Employee acknowledges and agrees that (a) during the course of his employment and as a part of his employment, the Employee will be afforded access to Confidential Information and/or Proprietary Information; (b) public disclosure of such

Confidential Information and/or Proprietary Information could have an adverse effect on the Employer and its business; (c) because the Employee possesses substantial technical expertise and skill with respect to the Employer's business, the Employer desires to obtain exclusive ownership of each Employee Invention, and the Employer will be at a substantial competitive disadvantage if it fails to acquire exclusive ownership of each Employee Invention; and (d) the provisions of this Section 7 are reasonable and necessary to prevent the improper use or disclosure of Confidential Information and/or Proprietary Information and to provide the Employer with exclusive ownership of all Employee Inventions.

# 7.2 <u>Agreements of the Employee</u>

In consideration of the compensation and benefits to be paid or provided to the Employee by the Employer under this Agreement and otherwise, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Employee covenants and agrees as follows:

# (a) Confidentiality

- (i) That all of such Confidential Information and/or Proprietary Information is a unique asset of the business of the Employer, the disclosure of which would be damaging to the Employer.
- (ii) That the Employee will not at any time, whether during or after termination or cessation of the Employee's employment, except as authorized by the Employer and for its benefit, use, divulge or disclose (or enable anyone else to use, divulge or disclose) to any Person, association or entity any Confidential Information and/or Proprietary Information which the Employee presently possesses or which the Employee may obtain during the course of the Employee's employment with respect to the business, finances, customers or affairs of the Employer or trade secrets, developments, methods or other information and data pertaining to the Employer's business. The Employee shall keep strictly confidential all matters and information entrusted to the Employee and shall not use or attempt to use any such Confidential Information and/or Proprietary Information in any manner which may injure or cause loss or may be calculated to injure or cause loss, whether directly or indirectly, to the Employer.
- (iii) That during the course of this Agreement or at any time after termination, the Employee will keep in strictest confidence and will not disclose or make accessible to any other Person without the prior written consent of the Employer, the Confidential Information and/or Proprietary Information; the Employee agrees: (a) not to use any such Confidential Information and/or Proprietary Information for himself or others; and (b) not to take any such material or reproductions thereof from the Employer's facilities at any time during his employment except, in each case, as required in connection with the Employee's duties to the Employer.
- (iv) The Employee agrees to hold in confidence, and not to distribute or disseminate to any Person or entity for any reason, any Confidential Information and/or Proprietary Information of the Employer under this Agreement, or information relating to experiments or results obtained based on the duties of the Employee, except for information which: (a) is in or which becomes a part of the public domain not as a result of a breach of this Agreement, (b) is information lawfully received from a third party who had the right to

disclose such information or (c) is required by legal process before a court of proper jurisdiction (by oral questions, deposition, interrogatories, requests for information or documents, subpoena, civil investigative domain or other similar process) to disclose all or any part of any Confidential Information and/or Proprietary Information, provided that the Employee will provide the Employer with prompt notice of such request or requirement, as well as notice of the terms and circumstances surrounding such request or requirements, so that the Employer may seek an appropriate protective order or waive compliance with the provisions of this Agreement. In such case, the parties will consult with each other on the advisability of pursuing any such order or other legal action or available step to resist or narrow such request or requirement. If, failing the entry of a protective order or the receipt of a waiver hereunder, the Employee is, in the opinion of counsel reasonably acceptable to the Employer, legally compelled to disclose Confidential Information and/or Proprietary Information, the Employee may disclose that portion of such information which counsel advises is necessary to disclose. The Employee will not oppose any action by the Employer to prevent disclosure pursuant to an appropriate protective order or to request other reliable assurances that confidential treatment will be accorded to the disclosure of such information.

- (v) Upon termination of this Agreement by either party or upon written notice by the Employer, the Employee shall promptly redeliver to the Employer, or, if requested by the Employer, promptly destroy all written Confidential Information and/or Proprietary Information and any other written material containing any information included in the Confidential Information and/or Proprietary Information (whether prepared by the Employer, the Employee, or a third party), and will not retain any copies, extracts or other reproductions in whole or in part of such written Confidential Information and/or Proprietary Information (and upon request certify such redelivery or destruction to the Employer in a written instrument reasonably acceptable to the Employer and its counsel).
- (vi) This Agreement and the terms and conditions recited herein are confidential and non-public, except as may be expressly permitted by the Employer. The Employee agrees not to disclose the contents of this Agreement to any Person or entity, including, but not limited to the press, other media, any public body, or any competitor of the Employer, except to the Employee's legal counsel or as may be required by law.
- (vii) Any trade secrets of the Employer will be entitled to all of the protections and benefits of State of Tennessee law and any other applicable law. If any information that the Employer deems to be a trade secret is found by a court of competent jurisdiction not be to a trade secret for purposes of this Agreement, such information will, nevertheless, be considered Confidential Information and/or Proprietary Information for purposes of this Agreement. The Employee hereby waives any requirement that the Employer submits proof of the economic value of any trade secret or posts a bond or other security.
- (viii) None of the foregoing obligations and restrictions applies to any part of the Confidential Information and/or Proprietary Information that the Employee demonstrates was or became generally available to the public other than as a result of a disclosure by the Employee.
- (ix) The Employee will not remove from the Employer's premises (except to the extent such removal is for purposes of the performance of the Employee's duties at home or while traveling, or except as otherwise specifically authorized by the Employer) any Proprietary Items. The Employee recognizes that, as between the Employer and the Employee, all of the Proprietary Items, whether or not developed by the Employee, are the exclusive property of the Employer. Upon termination of this Agreement by either party, or upon the request of the Employer during the employment of the Employee, the Employee will return to the Employer all of the Proprietary Items in the Employee's possession or subject to the Employee's control, and the Employee shall not retain any copies, abstracts, sketches, or other physical or electronic embodiment of any of the Proprietary Items.
- (x) During the Employee's employment with the Employer, the Employee will not improperly use or disclose any confidential information or trade secrets, if any, of any former employer or any other Person to whom the Employee has an obligation of confidentiality, and the Employee will not bring onto the premises of the Employer any unpublished documents or any property belonging to any former employer or any other Person to whom the Employee has an obligation of confidentiality unless consented to in writing by that former employer or Person.

#### (b) Employee Inventions

(i) Each Employee Invention will belong exclusively to the Employer. The Employee agrees that the Employer shall have sole and exclusive ownership rights in any conception, invention, trade secrets, information, ideas, improvement, substance, know-how, whether or not patentable, arising out of, resulting from, or derivative of: (1) the work or services of the Employee, or (2) within the scope of the duties of the Employee, or (3) using any materials, compounds, devices, or monies of the Employer. Any resulting or derivative rights, including patent rights, shall become the exclusive property of the Employer and the Employer shall be entitled to the entire right, title and interest

with respect hereto. The Employee agrees, without additional compensation, to convey, assign the entire right, title, and interest in and to any inventions for the United States and all foreign jurisdictions to the Employer arising out of, resulting from, or derivative of: (1) the work or services of the Employee, or (2) within the scope of the duties of the Employee, or (3) using any materials, compounds, devices, or monies.

- (ii) The Employer shall retain the entire right, title and interest in and to any and all Confidential Information and/or Proprietary Information provided by the Employer to the Employee and to any methods, compounds, improvements, substances, and compositions using or incorporating such Confidential Information and/or Proprietary Information.
- (iii) The Employee agrees that Confidential Information and/or Proprietary Information provided to the Employee by the Employer shall be used for work purposes only and shall not be used for any other uses, studies, experiments or tests.

- (iv) The Employee agrees that he will promptly disclose to the Employer, or any Persons designated by the Employer, all the Employee Inventions, made or conceived or reduced to practice or learned by him, either alone or jointly with others, during the employment of the Employee. The Employee further agrees to assist the Employer in every proper way (but at the Employer's expense) to obtain and from time to time enforce patents, copyrights or other rights on Employee Inventions in any and all countries, and to that end the Employee will execute all documents necessary: (a) to apply for, obtain and vest in the name of the Employer alone (unless the Employer otherwise directs) letters patent, copyrights or other analogues protection in any country throughout the world and when so obtained or vested to renew and restore the same; and (b) to defend (including the giving of testimony and rendering any other assistance) any opposition proceedings in respect of such applications and any opposition proceedings or petitions or applications for revocation of such letters patent, copyright or other analogous protection. The Employee's obligation to assist the Employer in obtaining and enforcing patents and copyrights for Employee Inventions in any and all countries shall continue beyond and after the termination of the Employee.
- (v) Any copyrightable work whether published or unpublished created by the Employee in connection with or during the performance of services below shall be considered a work made for hire, to the fullest extent permitted by law and all right, title and interest therein, including the worldwide copyrights, shall be the property of the Employer as the employer and party specially commissioning such work. In the event that any such copyrightable work or portion thereof shall not be legally qualified as a work made for hire, or shall subsequently be so held, the Employee agrees to properly convey to the Employer, without additional compensation, the entire right, title and interest in and to such work or portion thereof, including but not limited to the worldwide

copyrights, extensions of such copyrights, and renewal copyrights therein, and further including all rights to reproduce the copyrighted work in copies or phonorecords, to prepare derivative works based on the copyrighted work, to distribute copies of the copyrighted work, to perform the copyrighted work publicly, to display the copyrighted work publicly, and to register the claim of copyright therein and to execute any and all documents with respect hereto.

(vi) The Employee may not publish or disclose any Confidential Information and/or Proprietary Information relating to, arising from, derivative of, or as a result of his employment pursuant to this Agreement, including but not limited to: information, improvements, results, experiments, data, or methods that makes reference to any of the Confidential Information and/or Proprietary Information. Any work performed under, or arising from, or a result of his employment with the Employer shall not be published or disclosed in written, electronic, or oral form without the express written permission of the Employer.

#### 7.3 <u>Disputes or Controversies</u>

The Employee recognizes that should a dispute or controversy arising from or relating to this Agreement be submitted for adjudication to any court, arbitration panel, or other third party, the preservation of the secrecy of Confidential Information and/or Proprietary Information may be jeopardized. All pleadings, documents, testimony, and records relating to any such adjudication will be maintained in secrecy and will be available for inspection by the Employer, the Employee, and their respective attorneys and experts, who will agree, in advance and in writing, to receive and maintain all such information in secrecy, except as may be limited by them in writing.

## 7.4 Agreement on Condition of Employment

As a condition of employment, the Employee agrees to execute and abide by the Employer's current form of Agreement on Condition of Employment, which may be amended by the parties from time to time without regard to this Agreement. The Agreement on Condition of Employment contains provisions that are intended by the parties to survive and do survive termination or expiration of this Agreement. In the event that the terms of this Agreement differ from or are in conflict with the Agreement on Condition of Employment, this Agreement shall control.

# 8. NON-COMPETITION

# 8.1 <u>Acknowledgments by the Employee</u>

The Employee understands and recognizes that the Employee's services provided to the Employer are special, unique, unusual, extraordinary and intellectual in character. Subject to Section 8.4 below, the Employee agrees that, during the employment of the Employee and for a period of two (2) years from the date of termination of the Employee's employment with the Employer, he will not in any manner, directly or indirectly, on behalf of himself or any Person, firm, partnership, joint venture, corporation or other business entity, engage or invest in, own,

manage, operate, finance, control or participate in the ownership, management, operation, financing, or control of, be employed by, associated with, or in any manner connected with, lend the Employee's name or similar name to, lend the Employee's credit to or render services or advice to, enter into or engage in any Competing Business; *provided*, *however*, that the Employee may purchase or otherwise acquire up to (but not more than) one percent of any class of securities of any enterprise (but without otherwise participating in the activities of such enterprise) if such securities are listed on any national or regional securities exchange or have been registered under Section 12(g) of the Securities Exchange Act of 1934.

8.2 In consideration of the acknowledgements by the Employee, and in consideration of the compensation and benefits to be paid or provided to the Employee by the Employer, the Employee covenants that, subject to Section 8.4 below, he will not, directly or indirectly, whether for the Employee's own account or the account of any other Person (i) at any time during the employment of the Employee and for a period of two (2) years from the termination of the Employee's employment with the Employer, solicit, employ, or otherwise engage as an employee, independent contractor, or otherwise, any Person who is or was an employee of the Employer at any time during the Employee's employment with the Employer or in any manner induce or attempt to induce any employee of the Employer to terminate his employment with the Employer; or (ii) at any time during the employment of the Employee with the Employer and for two (2) years from the termination of the Employee's employment with the Employer, interfere with the Employer's relationship with any Person, including any Person who at any time during the Employee's employment with the Employer was an employee, contractor, supplier, or customer of the Employer.

- 8.3 In further consideration of these promises, the Employee agrees that he will not at any time during or after the Employee's employment with the Employer, disparage the Employer or any of its shareholders, directors, officers, employees, parents, subsidiaries, affiliates or agents in any manner likely to be harmful to them or their business, business reputation or personal reputation; *provided*, *however*, that the Employee may respond accurately and fully to any question, inquiry or request for information when required by legal process.
- 8.4 <u>Change of Control</u>. In the event of a Change of Control Termination, the Employee's obligations under Sections 8.1 and 8.2 above and the non-competition and non-solicitation provisions in the Agreement on Condition of Employment shall expire one (1) year from the date of termination of his employment with the Employer (or any entity acquiring the Employer as a result of a Change of Control).
- 8.5 If any covenant in Section 8 is held to be unreasonable, arbitrary, or against public policy, such covenant will be considered to be divisible with respect to scope, time, and geographic area, and such lesser scope, time, or geographic area, or all of them, as a court of competent jurisdiction may determine to be reasonable, not arbitrary, and not against public policy, will be effective, binding, and enforceable against the Employee.

The period of time applicable to any covenant in Section 8 will be extended by the duration of any violation by the Employee of such covenant.

The Employee will, while the covenants under Section 8 are in effect, give notice to the Employer, within ten days after accepting any other employment, of the identity of the Employee's employer. The Employer may notify such employer that the Employee is bound by this Agreement and, at the Employer's election, furnish such employer with a copy of this Agreement or relevant portions thereof.

## 9. TAX MATTERS

- 9.1 Responsibility for Tax Obligations. The Employee agrees that he is responsible for any applicable taxes of any nature (including any penalties or interest that may apply to such taxes) that the Employer reasonably determines apply to any payment or equity award made to the Employee hereunder (or any arrangement contemplated hereunder), that the Employee's receipt of any payment or benefit hereunder is conditioned on the Employee's satisfaction of any applicable withholding or similar obligations that apply to such payment or benefit, and that any cash payment owed to the Employee hereunder will be reduced to satisfy any such withholding or similar obligations that may apply thereto.
- Compliance with Section 409A. Any payments or benefits provided under this Agreement that constitute "deferred compensation" within the meaning of Section 409A of the Code and the regulations and other guidance thereunder and any state law of similar effect (collectively "Section 409A") shall not commence in connection with the Employee's termination of employment unless the Employee has also incurred a "separation from service," as such term is defined in Treasury Regulation Section 1.409A-1(h) (without regard to any permissible alternative definition thereunder) ("Separation from Service"). It is intended that each installment of the payments and benefits provided for in this Agreement is a separate "payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2)(i). For the avoidance of doubt, it is intended that payments of the amounts set forth in this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9). However, if the Employer determines that the payments and benefits provided under this Agreement constitute "deferred compensation" under Section 409A and the Employee is, on the date of the Employee's Separation from Service, a "specified employee" of the Employer or any successor entity thereto, as such term is defined in Section 409A(a)(2)(B)(i) of the Code, then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of any such payments or benefits shall be delayed as follows: on the earlier to occur of (i) the date that is six (6) months and one (1) day after the Employee's Separation from Service or (ii) the date of the Employee's death (such earlier date, the "Delayed Initial Payment Date"), the Employer shall (A) pay to the Employee a lump sum amount equal to the sum of the payments that the Employee would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the payments had not been so delayed pursuant to this Section 9.2 and (B) commence paying the balance of the payments in accordance with the applicable payment schedules set forth in this Agreement. If the Employer determines that any payments or benefits provided under this Agreement constitute "deferred compensation" under Section 409A and the Release could become effective in the calendar year following the calendar year in which the Employee's Separation from Service occurs, the Release will not be deemed effective any earlier than the Release Deadline for purposes of determining the timing of payment of any such payments or benefits.

# 9.3 Parachute Payments

(a) Notwithstanding anything in this Agreement to the contrary, if any payment or benefit the Employee will or may receive from the Employer or otherwise (a "280G Payment") would (i) constitute a "parachute payment" within the meaning of

Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then any such 280G Payment pursuant to this Agreement (a "Payment") shall be equal to the Reduced Amount. The "Reduced Amount" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount (*i.e.*, the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in the Employee's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "Reduction Method") that results in the greatest economic benefit for the Employee. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "Pro Rata Reduction Method").

(b) Notwithstanding any provision of Section 9.3(a) to the contrary, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the

greatest economic benefit for the Employee as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (*e.g.*, being terminated without Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.

(c) If the Employee receives a Payment for which the Reduced Amount was determined pursuant to clause (x) of Section 9.3(a) and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, the Employee shall promptly return to the Employer a sufficient amount of the Payment (after reduction pursuant to clause (x) of Section 9.3(a)) so that no portion of the remaining Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) of Section 9.3(a), the Employee shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

#### 10. CLAWBACK/RECOVERY

Any amounts paid to the Employee by the Employer, whether or not under this Agreement or any incentive plan of the Employer, will be subject to recoupment in accordance with The Sarbanes-Oxley Act of 2002, The Dodd-Frank Wall Street Reform and Consumer Protection Act and any implementing regulations under these acts, any clawback policy adopted

by the Employer, or as otherwise required by applicable law. In addition, in consideration of the Employee's continued employment with the Employer and in recognition of the Employee's position of trust and authority with the Employer, the Employee agrees to promptly consent to any clawback policy adopted by the Employer.

## 11. GENERAL PROVISIONS

#### 11.1 <u>Injunctive Relief and Additional Remedy</u>

The Employee acknowledges that the injury that would be suffered by the Employer as a result of a breach of the provisions of this Agreement (including any provision of Sections 7 and 8) would be irreparable and that an award of monetary damages to the Employer for such a breach would be an inadequate remedy. Consequently, the Employer will have the right, in addition to any other rights it may have, to obtain injunctive relief to restrain any breach or threatened breach or otherwise to specifically enforce any provision of this Agreement, and the Employer will not be obligated to post bond or other security in seeking such relief. Without limiting the Employer's rights under this Section 11 or any other remedies of the Employer, if the Employee breaches any of the provisions of Section 7 or 8, the Employer will have the right to cease making any payments otherwise due to the Employee under this Agreement.

#### 11.2 Covenants of Sections 7 and 8 are Essential and Independent Covenants

The covenants by the Employee in Sections 7 and 8 are essential elements of this Agreement, and without the Employee's agreement to comply with such covenants, the Employer would not have entered into this Agreement or employed or continued the employment of the Employee. The Employer and the Employee have independently consulted their respective counsel and have been advised in all respects concerning the reasonableness and propriety of such covenants, with specific regard to the nature of the business conducted by the Employer. The Employee agrees that this Agreement does not prevent him from earning a living or pursuing his career and that he has the ability to secure other non-competitive employment using his marketable skills. The Employee agrees that the restrictions contained in this Agreement are reasonable, proper, and necessitated by the Employer's legitimate business interests, including without limitation, the Employer's Confidential and/or Proprietary Information and the goodwill of its customers.

The Employee's covenants in Sections 7 and 8 are independent covenants and the existence of any claim by the Employee against the Employer under this Agreement or otherwise will not excuse the Employee's breach of any covenant in Section 7 or 8.

If the Employee's employment hereunder is terminated by either party, this Agreement will continue in full force and effect as is necessary or appropriate to enforce the covenants and agreements of the Employee in Sections 7 and 8.

# 11.3 <u>Representations and Warranties by the Employee</u>

The Employee represents and warrants to the Employer that the execution and delivery by the Employee of this Agreement do not, and the performance by the Employee's obligations hereunder will not, with or without the giving of notice or the passage of

time, or both: (a) violate any judgment, writ, injunction, or order of any court, arbitrator, or governmental agency applicable to the Employee; or (b) conflict with, result in the breach of any provisions of or the termination of, or constitute a default under, any agreement to which the Employee is a party or by which the Employee is or may be bound.

#### 11.4 Waiver

The rights and remedies of the parties to this Agreement are cumulative and not alternative. Neither the failure nor any delay by either party in exercising any right, power, or privilege under this Agreement will operate as a waiver of such right, power, or privilege, and no single or partial exercise of any such right, power, or privilege will preclude any other or further exercise of such right, power, or privilege or the exercise of any other right, power, or privilege. To the maximum extent permitted by applicable law, (a) no claim or right arising out of this Agreement can be discharged by one party, in whole or in part, by a waiver or renunciation of the claim or right unless in writing signed by the other party; (b) no waiver that may be given by a party will be applicable except in the specific instance for which it is given; and (c) no notice to or demand on one party will be deemed to be a waiver of any obligation of such party or of the right of the party giving such notice or demand to take further action without notice or demand as provided in this Agreement.

## 11.5 <u>Binding Effect; Delegation of Duties Prohibited</u>

This Agreement shall inure to the benefit of, and shall be binding upon, the parties hereto and their respective successors, assigns, heirs, and legal representatives, including any entity with which the Employer may merge or consolidate or to which all or substantially all of its assets may be transferred. The duties and covenants of the Employee under this Agreement, being personal, may not be delegated.

#### 11.6 Notices

All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when (a) delivered by hand (with written confirmation of receipt), (b) sent by facsimile (with written confirmation of receipt), provided that a copy is mailed by registered mail, return receipt requested, or (c) when received by the addressee, if sent by a nationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses and facsimile numbers set forth below (or to such other addresses and facsimile numbers as a party may designate by notice to the other parties):

If to the Employer: GTx, Inc.

175 Toyota Plaza, 7<sup>th</sup> Floor Memphis, Tennessee 38103

Attention: Vice President, Chief Legal Officer

Facsimile No.: 901-844-8075

If to the Employee: Marc S. Hanover

5597 St. Joseph Fairway Memphis, Tennessee 38120

The Employee shall notify the Employer in writing of any change of his address. Otherwise, the Employer shall send all notices to the Employee's address herein.

## 11.7 Entire Agreement; Amendments

This Agreement, including the Agreement on Condition of Employment, contains the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral or written, between the parties hereto with respect to the subject matter hereof. The Employer and the Employee further acknowledge and agree that the provisions of this Agreement amend and supersede the Prior Employment Agreement, which shall be of no further force and effect. This Agreement may not be amended orally, but only by an agreement in writing signed by the Employee and a duly authorized officer or director of the Employer.

# 11.8 Governing Law

This Agreement will be governed by the laws of the State of Tennessee without regard to conflicts of laws principles.

#### 11.9 Jurisdiction

Any action or proceeding seeking to enforce any provision of, or based on any right arising out of, this Agreement shall be brought against either of the parties in the courts of the State of Tennessee, County of Shelby, or, if it has or can acquire jurisdiction, in the United States District Court for the Western District of Tennessee, and each of the parties consents to the jurisdiction of such courts (and of the appropriate appellate courts) in any such action or proceeding and waives any objection to venue laid therein. Process in any action or proceeding referred to in the preceding sentence may be served on either party anywhere in the world.

# 11.10 <u>Section Headings, Construction</u>

The headings of Sections in this Agreement are provided for convenience only and will not affect its construction or interpretation. All references to "Section" or "Sections" refer to the corresponding Section or Sections of this Agreement unless otherwise specified. All words used in this Agreement will be construed to be of such gender or number as the circumstances require. Unless otherwise expressly provided, the word "including" does not limit the preceding words or terms.

# 11.11 Severability

If any provision of this Agreement is held invalid or unenforceable by any court of competent jurisdiction, the other provisions of this Agreement will remain in full force and effect. Any provision of this Agreement held invalid or unenforceable only in part or degree will remain in full force and effect to the extent not held invalid or unenforceable.

# 11.12 <u>Counterparts</u>

This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of this Agreement and all of which, when taken together, will be deemed to constitute one and the same agreement.

# 11.13 Waiver of Jury Trial

THE PARTIES HERETO HEREBY WAIVE A JURY TRIAL IN ANY LITIGATION WITH RESPECT TO THIS AGREEMENT, OR ARISING OUT OF OR CONCERNING THE EMPLOYEE'S EMPLOYMENT WITH THE EMPLOYER OR TERMINATION THEREOF.

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date above first written above.

# MARC S. HANOVER

/s/ Marc S. Hanover

GTx, Inc.

By: /s/ Henry P. Doggrell

Name: Henry P. Doggrell

Title: VP, Chief Legal Officer

# AMENDED AND RESTATED EMPLOYMENT AGREEMENT

This Amended and Restated Employment Agreement (this "Agreement") is made and entered into as of February 14, 2013 (the "Effective Date") by and between **GTx, Inc.**, located at 175 Toyota Plaza, 7<sup>th</sup> Floor, Memphis, Tennessee 38103 (the "Employer"), and **MARK E. MOSTELLER** (the "Employee"), residing at 5064 Anchor Cove, Memphis, Tennessee 38117.

WHEREAS, the Employee has been providing services to the Employer as Vice President, Chief Financial Officer under the terms of an Amended and Restated Employment Agreement that was effective as of November 10, 2008 (the "Prior Employment Agreement"); and

WHEREAS, the Employer and the Employee wish to amend and restate the Prior Employment Agreement as set forth herein; and

WHEREAS, during the course of the Employee's employment with the Employer, the Employer will train and continue to train the Employee and to impart to the Employee proprietary, confidential, and/or trade secret information, data and/or materials of the Employer; and

WHEREAS, the Employer has a vital interest in maintaining its confidential information and trade secrets, as well as rights to inventions, since doing so allows the Employer to compete fairly and enhances the value of the Employer to shareholders and job security for employees; and

WHEREAS, the Employer desires to retain the services of the Employee and the Employee is willing to be employed and continue to be employed with the Employer upon the terms and subject to the conditions set forth in this Agreement;

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained in this Agreement, the employment and continued employment of the Employee in accordance with the terms and conditions of this Agreement, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties, intending to be legally bound, agree and covenant as follows:

#### 1. DEFINITIONS

For the purposes of this Agreement, the following terms have the meanings specified or referred to in this Section 1.

"Agreement" has the meaning set forth in first paragraph of this Agreement.

"Basic Compensation" means Salary and Benefits.

"Benefits" has the meaning stated in Section 3.1(b) of this Agreement.

"Board of Directors" means the Board of Directors of the Employer.

"CEO" has the meaning set forth in Section 2.2.

"Change of Control" means any of the following events: (a) the sale or other disposition of all or substantially all of the assets of the Employer in a single transaction or in a series of transactions (including, without limitation, any liquidation or dissolution of the Employer); (b) any Person or group becomes the beneficial owner, directly, or indirectly, of securities of the Employer representing more than fifty percent (50%) of the combined voting power of the Employer's then outstanding securities other than by virtue of a merger, consolidation or similar transaction (for such purposes, "voting stock" shall mean the capital stock of the Employer of any class or classes, the holders of which are ordinarily, in the absence of contingencies, entitled to vote for the election of members of the Board of Directors (or Persons performing similar functions) of the Employer); (c) a merger or consolidation of the Employer with or into any other entity, if immediately after giving effect to such transaction more than fifty percent (50%) of the issued and outstanding voting stock of the surviving entity of such transaction is held by Persons who were not holders (taking into account their individual and affiliated holdings) as of the Effective Date of at least fifty percent (50%) of the voting stock of the Employer; or (d) individuals who, on the Effective Date, are members of the Board of Directors (the "Incumbent Board") cease for any reason to constitute at least a majority of the members of the Board of Directors; provided, however, that if the appointment or election (or nomination for election) of any new member of the Board of Directors was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member will, for purposes of this Agreement, be considered as a member of the Incumbent Board. A Change of Control shall not include: (1) any transfer or issuance of stock of the Employer to one or more of the Employer's lenders (or to any agents or representatives thereof) in exchange for debt of the Employer owed to any such lenders; (2) any transfer of stock of the Employer to or by any Person or entity, including but not limited to one or more of the Employer's lenders (or to any agents or representatives thereof), pursuant to the terms of any pledge of said stock as collateral for any loans or financial accommodations to the Employer and/or its subsidiaries; (3) any transfer or issuance to any Person or entity, including but not limited to one or more of the Employer's lenders (or to any agents or representatives thereof), in connection with the workout or restructuring of the Employer's debts to any one of the Employer's lenders, including but not limited to the issuance of new stock in exchange for any equity contribution to the Employer in connection with the workout or restructuring of such debt; (4) any transfer of stock by a stockholder of the Employer which is a partnership or corporation to the partners or stockholders in such stockholder or any transfer of stock by a stockholder of the Employer to an entity affiliated with such stockholder or the immediate family of such stockholder or a trust or similar entity for the benefit of such family members; or (5) any transfer or issuance of stock in connection with an offering of the Employer's stock in a registered public transaction not involving a transaction described in Rule 145, promulgated under the Securities Act of 1933, as amended, provided that the Employer's officers and Board of Directors shall not materially change as a result thereof.

"Change of Control Termination" means (i) a Termination Without Cause of the Employee's employment by the Employer (other than for death or disability) within twelve (12)

months after a Change of Control or (ii) the Employee's resignation for Good Reason within twelve (12) months after a Change of Control.

"Competing Business" means any individual or entity, other than the Employer, that is engaging in, or proposes to engage in, the development, manufacture, distribution or sale of a Competing Product in North America, South America, Europe and Eastern Europe, and in the countries of Russia, Australia, Japan, China, Taiwan, South Korea and India; provided, however, that an entity that develops, manufactures, distributes or sells a Competing Product in a separate business unit than the business unit in which the Employee is then employed shall not be deemed a Competing Business unless the Employee provides Confidential Information and/or Proprietary Information to the business unit that is engaging in or proposes to engage in the development, manufacture, distribution or sale of a Competing Product.

"Competing Product" means any pharmaceutical or other compound, composition, formulation, method, process, product or material that is competitive with any product of the Employer under development, manufacture, distribution or commercialization at any time from and after October 1, 2003 (the effective date of the Employee's initial employment agreement with the Employer) through the date of termination of the Employee's employment, including, without limitation, small molecules that target androgen, estrogen, glucocorticoid, and/or other hormone receptors for purposes of treating, diagnosing, or imaging humans in health and disease, including treating cancer, osteoporosis and bone loss and muscle loss.

#### "Confidential Information and/or Proprietary Information" means any and all:

- information disclosed to the Employee or known by the Employee as a consequence of, or through, the Employee's employment with the Employer since his initial date of employment on August 6, 2001 (including information conceived, originated, discovered, or developed in whole or in part by the Employee), not generally known in the relevant trade or industry, about the Employer's business, products, processes, and services; and trade secrets concerning the business and affairs of the Employer, product specifications, data, know-how, formulae, compositions, research, processes, designs, sketches, photographs, graphs, drawings, samples, inventions and ideas, past, current, and planned research and development, current and planned manufacturing or distribution methods and processes, customer lists, current and anticipated customer requirements, price lists, market studies, business plans, computer software and programs (including object code and source code), computer software and database technologies, systems, structures, and architectures (and related formulae, compositions, processes, improvements, devices, know-how, inventions, discoveries, concepts, ideas, designs, methods and information); and any other information, however documented, that is a trade secret within the meaning of Tenn. Code §39-14-138 or any other applicable law; and
- (b) information concerning the business and affairs of the Employer (which includes historical financial statements, financial projections and budgets, historical and projected sales, capital spending budgets and plans, the names and backgrounds of key personnel, personnel training and techniques and materials), however documented; and
- (c) intellectual property, inventions, methods, processes, techniques, computer programs, devices, products, services, compounds, gene therapy products, pharmaceuticals,

substances, vectors, enzymes, genes, concepts, discoveries, improvements, and designs, whether or not patentable in the United States or foreign countries, any trade secrets, information, procedures, technologies, data, results, conclusions, know-how or show-how and business information; and

- (d) notes, analysis, compilations, studies, summaries, and other material prepared by or for the Employer containing or based, in whole or in part, on any information included in the foregoing.
  - "Delayed Initial Payment Date" has the meaning stated in Section 9.2 of this Agreement.
  - "Effective Date" means the date stated in the first paragraph of this Agreement.
  - "Employee" has the meaning stated in the first paragraph of this Agreement.
- "Employee Invention" means any idea, invention, technique, modification, process, improvement (whether patentable or not), industrial design (whether registerable or not), work of authorship (whether or not copyright protection may be obtained for it), design, copyrightable work, discovery, trademark, copyright, trade secret, formula, device, method, compound, gene, prodrug, pharmaceutical, structure, product concept, marketing plan, strategy, customer list, technique, blueprint, sketch, record, note, drawing, know-how, data, patent application, continuation application, continuation-in-part application, file wrapper continuation application or divisional application, created, conceived, or developed by the Employee, either solely or in conjunction with others, during the Employee's employment, or a period that includes a portion of the Employee's employment, that relates in any way to, or is useful in any manner in, the business then being conducted or proposed to be conducted by the Employer, and any such item created by the Employee, either solely or in conjunction with others, following termination of the Employee's employment with the Employer, that is based upon or uses Confidential Information and/or Proprietary Information.
- "Employer" means GTx, Inc., its successors and assigns, and any of its current or future subsidiaries, or organizations controlled by, controlling, or under common control with it.
  - "Expenses" has the meaning stated in Section 4.1 of this Agreement.
  - "Good Reason" for termination means that the Employee voluntarily resigns from all positions he then holds with the Employer if and only if:
  - (a) one of the following actions have been taken without the Employee's express written consent:
- (i) following a Change of Control, an adverse change in the Employee's authority, duties or responsibilities (including reporting responsibilities) which, without the Employee's consent, represents a material reduction in or a material demotion of the Employee's authority, duties or responsibilities as in effect immediately prior to a Change of Control or the assignment to the Employee of any duties or responsibilities which are materially inconsistent with and materially adverse to such authority, duties or responsibilities;

- (ii) following a Change of Control, a material reduction in the then current Salary of the Employee;
- (iii) following a Change of Control, the relocation of the Employer's principal employee offices to a location that increases the Employee's one-way commute by more than twenty (20) miles;
- (iv) the failure of the Employer to obtain an agreement reasonably satisfactory to the Employee from any successor or assign of the Employer upon a Change of Control to assume and agree to perform this Agreement in all material respects following the Change of Control; or
- (v) the Employer materially breaches its obligations under this Agreement or any other then-effective agreement with the Employee (including any agreement or arrangement providing for incentive compensation or employee benefits, including the Benefits provided in this Agreement).
  - (b) the Employee provides written notice to the Board of Directors within the thirty (30) day period immediately following such action; and
  - (c) such action is not remedied by the Employer within thirty (30) days following the Employer's receipt of such written notice; and
  - (d) the Employee's resignation is effective not later than sixty (60) days after the expiration of such thirty (30)-day cure period.
- "Person" means any individual, corporation (including any non-profit corporation), general or limited partnership, limited liability company, joint venture, estate, trust, association, organization, or governmental body.
- <u>"Proprietary Items"</u> means any Proprietary and/or Confidential Information embodied in any document, record, recording, electronic media, formulae, notebook, plan, model, component, device, or computer software or code, whether embodied in a disk or in any other form.
- <u>"Release"</u> means a general release of claims in favor of the Employer, in a form acceptable to the Employer, which shall specifically relate to all of the Employee's rights and claims in existence at the time of such execution and shall confirm the Employee's continuing obligations to the Employer (including but not limited to obligations under Section 7 and Section 8 of this Agreement, the Agreement on Condition of Employment and any other confidentiality and/or non-competition agreement with the Employer).

<u>"Salary"</u> has the meaning stated in Section 3.1(a) of this Agreement.

"Section 409A" has the meaning stated in Section 9.2 of this Agreement.

"Termination Date" has the meaning stated in Section 6.1 of this Agreement.

"Termination With Cause" means the termination of the Employee's employment by act of the Board of Directors for any of the following reasons, any of which shall constitute "Cause" for purposes of this Agreement:

- (a) the Employee's conviction of a felony;
- (b) the Employee's theft, embezzlement, misappropriation of or intentional infliction of material damage to the Employer's property or business opportunities;
- (c) the Employee's breach of the provisions contained in Section 7 or Section 8 of this Agreement or the provisions in the Agreement on Condition of Employment regarding confidentiality, non-competition or non-solicitation; or
- (d) the Employee's ongoing willful neglect of or failure to perform his duties hereunder or his ongoing willful failure or refusal to follow any reasonable, unambiguous duly adopted written direction of the CEO that is not inconsistent with the description of the Employee's duties set forth in Section 2.3, if such willful neglect or failure is materially damaging or materially detrimental to the business and operations of the Employer; provided that, if curable, the Employee shall have received written notice of such neglect or failure and shall have continued to engage in such neglect or failure after 30 days following receipt of such notice from the CEO, which notice specifically identifies the manner in which the CEO believes that the Employee has engaged in such neglect or failure. For purposes of this subsection, no act, or failure to act, shall be deemed "willful" unless done, or omitted to be done, by the Employee not in good faith, and without reasonable belief that such action or omission was in the best interest of the Employer.

<u>"Termination Without Cause"</u> means the termination of the Employee's employment by the Employer for any reason other than (i) Termination With Cause, or (ii) a termination by the Employer due to the Employee's death or disability.

# 2. EMPLOYMENT TERMS AND DUTIES

# 2.1 <u>Employment</u>

The Employer hereby continues the employment of the Employee, and the Employee hereby accepts continued employment by the Employer, upon the terms and conditions set forth in this Agreement.

# 2.2 <u>Term</u>

Either the Employee or the Employer may terminate this Agreement and the Employee's employment and compensation with or without Cause or notice, at any time, at either the Employer's or the Employee's option. No officer or manager of the Employer has the authority to enter into any other agreement for employment for a specified period of time, or to modify or to make any agreement contrary to the foregoing, except by written amendment to this Agreement, dated and signed by the Chief Executive Officer ("CEO") or the President of the Employer.

#### 2.3 <u>Duties</u>

The Employee will continue to have such duties as are assigned or delegated to the Employee by the Board of Directors, the CEO or the President and will initially serve as Vice President, Chief Financial Officer for the Employer. The Employee will devote his full time, attention, skill and energy to the business of the Employer, will use his best efforts to promote the success of the Employer's business, and will cooperate fully with the Board of Directors, the CEO and the President in the advancement of the best interest of the Employer. The Employee agrees to abide by all bylaws, policies, practices, procedures or rules of the Employer. The Employee may be reassigned or transferred to another management position, as designated by the Board of Directors, the CEO or the President, which may or may not provide the same level of responsibility as the initial assignment, in accordance with the terms and conditions of this Agreement.

#### 3. COMPENSATION

## 3.1 Basic Compensation

- (a) <u>Salary.</u> As of the Effective Date, the Employee will be paid for each of the twenty-six pay periods during the calendar year approximately \$12,340.61, which is the equivalent of \$320,856 per calendar year (the "Salary"), subject to review and adjustment from time to time by the CEO in his sole discretion.
- (b) <u>Benefits.</u> The Employee will, during his employment with the Employer, be permitted to participate in such life insurance, hospitalization, major medical, short term disability, long term disability, 401(k) plan and other employee benefit plans of the Employer that may be in effect from time to time, to the extent the Employee is eligible under the terms of those plans (collectively, the "Benefits"). All matters of eligibility for coverage or benefits under any such plan shall be determined in accordance with the provisions of such plan. The Employer reserves the right to change, alter, or terminate any such plan, in its sole discretion, subject to the terms of such plan.
- (c) The Employer may withhold from the Salary or Benefits payable to the Employee all federal, state, local, and other taxes and other amounts as permitted or required pursuant to law, rules or regulations.

#### 4. FACILITIES AND EXPENSES

#### 4.1 General

The Employer will furnish the Employee office space, equipment, supplies, and such other facilities and personnel as the Employer deems necessary or appropriate for the performance of the Employee's duties under this Agreement. The Employer will pay the Employee's dues in such professional societies and organizations as the CEO or President deems appropriate, and will pay on behalf of the Employee (or reimburse the Employee for) reasonable expenses incurred by the Employee at the request of, or on behalf of, the Employer in the performance of the Employee's duties pursuant to this Agreement, and in accordance with the Employer's employment policies, including reasonable expenses incurred by the Employee in

attending conventions, seminars, and other business meetings, in appropriate business entertainment activities, and for promotional expenses (the "Expenses"). To the extent that any reimbursements payable or in-kind benefits provided pursuant to this Agreement are subject to the provisions of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), any such reimbursements payable pursuant to this Agreement shall be paid no later than December 31 of the year following the year in which the expense was incurred, the amount of expenses reimbursed or in-kind benefits provided in one year shall not affect the amount eligible for reimbursement or in-kind benefits to be provided in any subsequent year, and the right to reimbursement or in-kind benefits under this Agreement will not be subject to liquidation or exchange for another benefit. The Employee must file expense reports with respect to such expenses in accordance with the Employer's policies.

#### 5. VACATIONS AND HOLIDAYS

The Employee will be eligible to accrue paid vacation each calendar year in accordance with the vacation policies of the Employer in effect from time to time. Under such policies of the Employer as of the Effective Date, the Employee is eligible to accrue up to four (4) weeks of paid vacation each calendar year. Vacation must be taken by the Employee at such time or times during the calendar year as approved by the CEO or President. Additionally, the Employee will be entitled to the paid holidays set forth in the Employer's policies. Any accrued vacation days and holidays that are not used by the Employee by the end of the calendar year in which they were accrued will be lost and may not be used in any subsequent calendar year; *provided*, *however*, that upon termination of the Employee's employment, the Employee will be paid the equivalent compensation attributable to any accrued vacation days which were accrued during the calendar year in which such termination occurs and are not otherwise used by the Employee as of the date of such termination.

# 6. TERMINATION

- 6.1 <u>At-Will Employment</u>. The Employee's employment is at-will, which means that either the Employee or the Employer may terminate this Employment Agreement (with the exception of the provisions of Sections 7 and 8 which shall survive termination of this Agreement and the Employee's employment) with or without Cause or notice, at any time at either the Employee's or the Employer's option. Except as otherwise specifically set forth herein, or as provided in any plan documents governing any compensatory equity awards that have been or may be granted to the Employee from time to time in the sole discretion of the Employer or an affiliate, upon termination of the Employee's employment the Employer shall be released from any and all further obligations under this Agreement, except the Employer shall be obligated to pay the Employee his accrued but unpaid Basic Compensation and Expenses owing to the Employee through the day on which the Employee's employment is terminated (the "Termination Date"). The Employee's obligations under Sections 7 and 8 shall continue pursuant to the terms and conditions of this Agreement.
- 6.2 <u>Termination Upon Death</u>. The employment of the Employee shall terminate on the date of the Employee's death, in which event the Employee's accrued but unpaid Basic Compensation and Expenses, owing to the Employee through the date of the

Employee's death, shall be paid to his estate. The Employee's estate will not be entitled to any other compensation under this Agreement.

- 6.3 <u>Termination Related to a Change of Control</u>. As additional consideration for the covenants in Section 7 and Section 8, in the event of a Change of Control Termination, and provided that the Employee signs and allows to become effective a Release within the time period provided therein (but not later than the 60<sup>th</sup> day following the Termination Date, such latest permitted effective date is the "Release Deadline" for purposes of this Agreement), then subject to Section 9.2:
  - (a) The Employee shall receive as severance one (1) year of his Salary, payable in accordance with the Employer's then current payroll schedule over the one (1) year period following the Termination Date, less deductions required by law; *provided, however*, that if the Employee terminates his employment on account of a material reduction in his Salary, as provided in paragraph (a)(ii) of the definition of Good Reason, the amount of such severance shall be based on the Employee's Salary immediately prior to such reduction. Notwithstanding the foregoing payment schedule, no severance will be paid prior to the effective date of the Release. Subject to Section 9.2, on the first regular payroll pay day following the effective date of the Release, the Employer will pay the Employee the severance that the Employee would otherwise have received on or prior to such date but for the delay in payment related to the effectiveness of the Release, with the balance of the severance being paid as originally scheduled.
  - (b) If the Employee timely elects group health insurance coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA"), the Employer will pay the Employee's monthly COBRA premiums (including the cost of eligible dependent coverage, if any) through the earliest of the following (the "COBRA Payment Period"): (i) for twelve (12) months following the Termination Date; (ii) the date that the Employee becomes eligible for group health insurance coverage through a new employer; or (iii) the date that the Employee is no longer eligible for COBRA coverage. Notwithstanding the foregoing, if at any time the Employer determines, in its sole discretion, that its payment of the Employee's COBRA premiums would result in a violation of applicable law (including, without limitation, Section 105(h)(2) of the Code and Section 2716 of the Public Health Service Act), then in lieu of paying such COBRA premiums, the Employer will pay the Employee on the last day of each remaining month of the COBRA Payment Period a fully taxable cash payment equal to the COBRA premium for that month, subject to applicable tax withholding (such amount, the "Special Severance Payment"); *provided*, *however*, that any such Special Severance Payment will be made without regard to the Employee's payment of COBRA premiums and for purposes of any such Special Severance Payment, the "COBRA Payment Period" will be determined without regard to the expiration of the Employee's eligibility for continued coverage under COBRA.

#### 7. NON-DISCLOSURE COVENANT; EMPLOYEE INVENTIONS

# 7.1 <u>Acknowledgements by the Employee</u>

The Employee acknowledges and agrees that (a) during the course of his employment and as a part of his employment, the Employee will be afforded access to Confidential Information and/or Proprietary Information; (b) public disclosure of such Confidential Information and/or Proprietary Information could have an adverse effect on the Employer and its business; (c) because the Employee possesses substantial technical expertise and skill with respect to the Employer's business, the Employer desires to obtain exclusive ownership of each Employee Invention, and the Employer will be at a substantial competitive disadvantage if it fails to acquire exclusive ownership of each Employee Invention; and (d) the provisions of this Section 7 are reasonable and necessary to prevent the improper use or disclosure of Confidential Information and/or Proprietary Information and to provide the Employer with exclusive ownership of all Employee Inventions.

#### 7.2 Agreements of the Employee

In consideration of the compensation and benefits to be paid or provided to the Employee by the Employer under this Agreement and otherwise, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Employee covenants and agrees as follows:

# (a) Confidentiality

- (i) That all of such Confidential Information and/or Proprietary Information is a unique asset of the business of the Employer, the disclosure of which would be damaging to the Employer.
- (ii) That the Employee will not at any time, whether during or after termination or cessation of the Employee's employment, except as authorized by the Employer and for its benefit, use, divulge or disclose (or enable anyone else to use, divulge or disclose) to any Person, association or entity any Confidential Information and/or Proprietary Information which the Employee presently possesses or which the Employee may obtain during the course of the Employee's employment with respect to the business, finances, customers or affairs of the Employer or trade secrets, developments, methods or other information and data pertaining to the Employer's business. The Employee shall keep strictly confidential all matters and information entrusted to the Employee and shall not use or attempt to use any such Confidential Information and/or Proprietary Information in any manner which may injure or cause loss or may be calculated to injure or cause loss, whether directly or indirectly, to the Employer.
- (iii) That during the course of this Agreement or at any time after termination, the Employee will keep in strictest confidence and will not disclose or make accessible to any other Person without the prior written consent of the Employer, the Confidential Information and/or Proprietary Information; the Employee agrees: (a) not to use any such Confidential Information and/or Proprietary Information for himself or others; and (b) not to take any such material or reproductions thereof from the Employer's facilities at any time

 $during \ his \ employment \ except, \ in \ each \ case, \ as \ required \ in \ connection \ with \ the \ Employee's \ duties \ to \ the \ Employer.$ 

(iv) The Employee agrees to hold in confidence, and not to distribute or disseminate to any Person or entity for any reason, any Confidential Information and/or Proprietary Information of the Employer under this Agreement, or information relating to

experiments or results obtained based on the duties of the Employee, except for information which: (a) is in or which becomes a part of the public domain not as a result of a breach of this Agreement, (b) is information lawfully received from a third party who had the right to disclose such information or (c) is required by legal process before a court of proper jurisdiction (by oral questions, deposition, interrogatories, requests for information or documents, subpoena, civil investigative domain or other similar process) to disclose all or any part of any Confidential Information and/or Proprietary Information, provided that the Employee will provide the Employer with prompt notice of such request or requirement, as well as notice of the terms and circumstances surrounding such request or requirements, so that the Employer may seek an appropriate protective order or waive compliance with the provisions of this Agreement. In such case, the parties will consult with each other on the advisability of pursuing any such order or other legal action or available step to resist or narrow such request or requirement. If, failing the entry of a protective order or the receipt of a waiver hereunder, the Employee is, in the opinion of counsel reasonably acceptable to the Employer, legally compelled to disclose Confidential Information and/or Proprietary Information, the Employee may disclose that portion of such information which counsel advises is necessary to disclose. The Employee will not oppose any action by the Employer to prevent disclosure pursuant to an appropriate protective order or to request other reliable assurances that confidential treatment will be accorded to the disclosure of such information.

- (v) Upon termination of this Agreement by either party or upon written notice by the Employer, the Employee shall promptly redeliver to the Employer, or, if requested by the Employer, promptly destroy all written Confidential Information and/or Proprietary Information and any other written material containing any information included in the Confidential Information and/or Proprietary Information (whether prepared by the Employer, the Employee, or a third party), and will not retain any copies, extracts or other reproductions in whole or in part of such written Confidential Information and/or Proprietary Information (and upon request certify such redelivery or destruction to the Employer in a written instrument reasonably acceptable to the Employer and its counsel).
- (vi) This Agreement and the terms and conditions recited herein are confidential and non-public, except as may be expressly permitted by the Employer. The Employee agrees not to disclose the contents of this Agreement to any Person or entity, including, but not limited to the press, other media, any

public body, or any competitor of the Employer, except to the Employee's legal counsel or as may be required by law.

- (vii) Any trade secrets of the Employer will be entitled to all of the protections and benefits of State of Tennessee law and any other applicable law. If any information that the Employer deems to be a trade secret is found by a court of competent jurisdiction not be to a trade secret for purposes of this Agreement, such information will, nevertheless, be considered Confidential Information and/or Proprietary Information for purposes of this Agreement. The Employee hereby waives any requirement that the Employer submits proof of the economic value of any trade secret or posts a bond or other security.
- (viii) None of the foregoing obligations and restrictions applies to any part of the Confidential Information and/or Proprietary Information that the Employee demonstrates was or became generally available to the public other than as a result of a disclosure by the Employee.
- (ix) The Employee will not remove from the Employer's premises (except to the extent such removal is for purposes of the performance of the Employee's duties at home or while traveling, or except as otherwise specifically authorized by the Employer) any Proprietary Items. The Employee recognizes that, as between the Employer and the Employee, all of the Proprietary Items, whether or not developed by the Employee, are the exclusive property of the Employer. Upon termination of this Agreement by either party, or upon the request of the Employer during the employment of the Employee, the Employee will return to the Employer all of the Proprietary Items in the Employee's possession or subject to the Employee's control, and the Employee shall not retain any copies, abstracts, sketches, or other physical or electronic embodiment of any of the Proprietary Items.
- (x) During the Employee's employment with the Employer, the Employee will not improperly use or disclose any confidential information or trade secrets, if any, of any former employer or any other Person to whom the Employee has an obligation of confidentiality, and the Employee will not bring onto the premises of the Employer any unpublished documents or any property belonging to any former employer or any other Person to whom the Employee has an obligation of confidentiality unless consented to in writing by that former employer or Person.

#### (b) Employee Inventions

(i) Each Employee Invention will belong exclusively to the Employer. The Employee agrees that the Employer shall have sole and exclusive ownership rights in any conception, invention, trade secrets, information, ideas, improvement, substance, know-how, whether or not patentable, arising out of, resulting from, or derivative of: (1) the work or services of the Employee, or (2) within the scope of the duties of the Employee, or (3) using any materials,

compounds, devices, or monies of the Employer. Any resulting or derivative rights, including patent rights, shall become the exclusive property of the Employer and the Employer shall be entitled to the entire right, title and interest with respect hereto. The Employee agrees, without additional compensation, to convey, assign the entire right, title, and interest in and to any inventions for the United States and all foreign jurisdictions to the Employer arising out of, resulting from, or derivative of: (1) the work or services of the Employee, or (2) within the scope of the duties of the Employee, or (3) using any materials, compounds, devices, or monies.

- (ii) The Employer shall retain the entire right, title and interest in and to any and all Confidential Information and/or Proprietary Information provided by the Employer to the Employee and to any methods, compounds, improvements, substances, and compositions using or incorporating such Confidential Information and/or Proprietary Information.
- (iii) The Employee agrees that Confidential Information and/or Proprietary Information provided to the Employee by the Employer shall be used for work purposes only and shall not be used for any other uses, studies, experiments or tests.

- (iv) The Employee agrees that he will promptly disclose to the Employer, or any Persons designated by the Employer, all the Employee Inventions, made or conceived or reduced to practice or learned by him, either alone or jointly with others, during the employment of the Employee. The Employee further agrees to assist the Employer in every proper way (but at the Employer's expense) to obtain and from time to time enforce patents, copyrights or other rights on Employee Inventions in any and all countries, and to that end the Employee will execute all documents necessary: (a) to apply for, obtain and vest in the name of the Employer alone (unless the Employer otherwise directs) letters patent, copyrights or other analogues protection in any country throughout the world and when so obtained or vested to renew and restore the same; and (b) to defend (including the giving of testimony and rendering any other assistance) any opposition proceedings in respect of such applications and any opposition proceedings or petitions or applications for revocation of such letters patent, copyright or other analogous protection. The Employee's obligation to assist the Employer in obtaining and enforcing patents and copyrights for Employee Inventions in any and all countries shall continue beyond and after the termination of the Employee.
- (v) Any copyrightable work whether published or unpublished created by the Employee in connection with or during the performance of services below shall be considered a work made for hire, to the fullest extent permitted by law and all right, title and interest therein, including the worldwide copyrights, shall be the property of the Employer as the employer and party specially commissioning such work. In the event that any such copyrightable work or portion thereof shall not be legally qualified as a work made for hire, or shall

subsequently be so held, the Employee agrees to properly convey to the Employer, without additional compensation, the entire right, title and interest in and to such work or portion thereof, including but not limited to the worldwide copyrights, extensions of such copyrights, and renewal copyrights therein, and further including all rights to reproduce the copyrighted work in copies or phonorecords, to prepare derivative works based on the copyrighted work, to distribute copies of the copyrighted work, to perform the copyrighted work publicly, to display the copyrighted work publicly, and to register the claim of copyright therein and to execute any and all documents with respect hereto.

(vi) The Employee may not publish or disclose any Confidential Information and/or Proprietary Information relating to, arising from, derivative of, or as a result of his employment pursuant to this Agreement, including but not limited to: information, improvements, results, experiments, data, or methods that makes reference to any of the Confidential Information and/or Proprietary Information. Any work performed under, or arising from, or a result of his employment with the Employer shall not be published or disclosed in written, electronic, or oral form without the express written permission of the Employer.

## 7.3 <u>Disputes or Controversies</u>

The Employee recognizes that should a dispute or controversy arising from or relating to this Agreement be submitted for adjudication to any court, arbitration panel, or other third party, the preservation of the secrecy of Confidential Information and/or Proprietary Information may be jeopardized. All pleadings, documents, testimony, and records relating to any such adjudication will be maintained in secrecy and will be available for inspection by the Employer, the Employee, and their respective attorneys and experts, who will agree, in advance and in writing, to receive and maintain all such information in secrecy, except as may be limited by them in writing.

# 7.4 <u>Agreement on Condition of Employment</u>

As a condition of employment, the Employee agrees to execute and abide by the Employer's current form of Agreement on Condition of Employment, which may be amended by the parties from time to time without regard to this Agreement. The Agreement on Condition of Employment contains provisions that are intended by the parties to survive and do survive termination or expiration of this Agreement. In the event that the terms of this Agreement differ from or are in conflict with the Agreement on Condition of Employment, this Agreement shall control.

# 8. NON-COMPETITION

#### 8.1 Acknowledgments by the Employee

The Employee understands and recognizes that the Employee's services provided to the Employer are special, unique, unusual, extraordinary and intellectual in character. Subject to Section 8.4 below, the Employee agrees that, during the employment of the Employee and for

a period of two (2) years from the date of termination of the Employee's employment with the Employer, he will not in any manner, directly or indirectly, on behalf of himself or any Person, firm, partnership, joint venture, corporation or other business entity, engage or invest in, own, manage, operate, finance, control or participate in the ownership, management, operation, financing, or control of, be employed by, associated with, or in any manner connected with, lend the Employee's name or similar name to, lend the Employee's credit to or render services or advice to, enter into or engage in any Competing Business; *provided*, *however*, that the Employee may purchase or otherwise acquire up to (but not more than) one percent of any class of securities of any enterprise (but without otherwise participating in the activities of such enterprise) if such securities are listed on any national or regional securities exchange or have been registered under Section 12(g) of the Securities Exchange Act of 1934.

8.2 In consideration of the acknowledgements by the Employee, and in consideration of the compensation and benefits to be paid or provided to the Employee by the Employee, the Employee covenants that, subject to Section 8.4 below, he will not, directly or indirectly, whether for the Employee's own account or the account of any other Person (i) at any time during the employment of the Employee and for a period of two (2) years from the termination of the Employee's employment with the Employer, solicit, employ, or otherwise engage as an employee, independent contractor, or otherwise, any Person who is or was an employee of the Employer at any time during the Employee's employment with the Employer or in any manner induce or attempt to induce any employee of the Employer to terminate his employment with the Employer; or (ii) at any time during the employment of the Employee with the Employer and for two (2) years from the termination of the Employee's employment with the Employer, interfere with the Employer's relationship with any Person, including any Person who at any time during the Employee's employment with the Employer was an employee, contractor, supplier, or customer of the Employer.

- 8.3 In further consideration of these promises, the Employee agrees that he will not at any time during or after the Employee's employment with the Employer, disparage the Employer or any of its shareholders, directors, officers, employees, parents, subsidiaries, affiliates or agents in any manner likely to be harmful to them or their business, business reputation or personal reputation; *provided*, *however*, that the Employee may respond accurately and fully to any question, inquiry or request for information when required by legal process.
- 8.4 <u>Change of Control</u>. In the event of a Change of Control Termination, the Employee's obligations under Sections 8.1 and 8.2 above and the non-competition and non-solicitation provisions in the Agreement on Condition of Employment shall expire one (1) year from the date of termination of his employment with the Employer (or any entity acquiring the Employer as a result of a Change of Control).
- 8.5 If any covenant in Section 8 is held to be unreasonable, arbitrary, or against public policy, such covenant will be considered to be divisible with respect to scope, time, and geographic area, and such lesser scope, time, or geographic area, or all of them, as a court of competent jurisdiction may determine to be reasonable, not arbitrary, and not against public policy, will be effective, binding, and enforceable against the Employee.

The period of time applicable to any covenant in Section 8 will be extended by the duration of any violation by the Employee of such covenant.

The Employee will, while the covenants under Section 8 are in effect, give notice to the Employer, within ten days after accepting any other employment, of the identity of the Employee's employer. The Employer may notify such employer that the Employee is bound by this Agreement and, at the Employer's election, furnish such employer with a copy of this Agreement or relevant portions thereof.

## 9. TAX MATTERS

- 9.1 <u>Responsibility for Tax Obligations</u>. The Employee agrees that he is responsible for any applicable taxes of any nature (including any penalties or interest that may apply to such taxes) that the Employer reasonably determines apply to any payment or equity award made to the Employee hereunder (or any arrangement contemplated hereunder), that the Employee's receipt of any payment or benefit hereunder is conditioned on the Employee's satisfaction of any applicable withholding or similar obligations that apply to such payment or benefit, and that any cash payment owed to the Employee hereunder will be reduced to satisfy any such withholding or similar obligations that may apply thereto.
- Compliance with Section 409A. Any payments or benefits provided under this Agreement that constitute "deferred compensation" within the meaning of Section 409A of the Code and the regulations and other guidance thereunder and any state law of similar effect (collectively "Section 409A") shall not commence in connection with the Employee's termination of employment unless the Employee has also incurred a "separation from service," as such term is defined in Treasury Regulation Section 1.409A-1(h) (without regard to any permissible alternative definition thereunder) ("Separation from Service"). It is intended that each installment of the payments and benefits provided for in this Agreement is a separate "payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2)(i). For the avoidance of doubt, it is intended that payments of the amounts set forth in this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9). However, if the Employer determines that the payments and benefits provided under this Agreement constitute "deferred compensation" under Section 409A and the Employee is, on the date of the Employee's Separation from Service, a "specified employee" of the Employer or any successor entity thereto, as such term is defined in Section 409A(a)(2)(B)(i) of the Code, then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of any such payments or benefits shall be delayed as follows: on the earlier to occur of (i) the date that is six (6) months and one (1) day after the Employee's Separation from Service or (ii) the date of the Employee's death (such earlier date, the "Delayed Initial Payment Date"), the Employer shall (A) pay to the Employee a lump sum amount equal to the sum of the payments that the Employee would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the payments had not been so delayed pursuant to this Section 9.2 and (B) commence paying the balance of the payments in accordance with the applicable payment schedules set forth in this Agreement. If the Employer determines that any payments or benefits provided under this Agreement constitute "deferred compensation" under Section 409A and the Release could become effective in the calendar year following the calendar

year in which the Employee's Separation from Service occurs, the Release will not be deemed effective any earlier than the Release Deadline for purposes of determining the timing of payment of any such payments or benefits.

## 9.3 Parachute Payments

- (a) Notwithstanding anything in this Agreement to the contrary, if any payment or benefit the Employee will or may receive from the Employer or otherwise (a "280G Payment") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then any such 280G Payment pursuant to this Agreement (a "Payment") shall be equal to the Reduced Amount. The "Reduced Amount" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount (i.e., the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in the Employee's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "Reduction Method") that results in the greatest economic benefit for the Employee. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "Pro Rata Reduction Method").
- (b) Notwithstanding any provision of Section 9.3(a) to the contrary, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for the Employee as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (*e.g.*, being terminated without Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a

third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.

(c) If the Employee receives a Payment for which the Reduced Amount was determined pursuant to clause (x) of Section 9.3(a) and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, the Employee shall promptly return to the Employer a sufficient amount of the Payment (after reduction pursuant to clause (x) of Section 9.3(a)) so that no portion of the remaining Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) of Section 9.3(a), the Employee

shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

# 10. CLAWBACK/RECOVERY

Any amounts paid to the Employee by the Employer, whether or not under this Agreement or any incentive plan of the Employer, will be subject to recoupment in accordance with The Sarbanes-Oxley Act of 2002, The Dodd-Frank Wall Street Reform and Consumer Protection Act and any implementing regulations under these acts, any clawback policy adopted by the Employer, or as otherwise required by applicable law. In addition, in consideration of the Employee's continued employment with the Employer and in recognition of the Employee's position of trust and authority with the Employer, the Employee agrees to promptly consent to any clawback policy adopted by the Employer.

### 11. GENERAL PROVISIONS

#### 11.1 <u>Injunctive Relief and Additional Remedy</u>

The Employee acknowledges that the injury that would be suffered by the Employer as a result of a breach of the provisions of this Agreement (including any provision of Sections 7 and 8) would be irreparable and that an award of monetary damages to the Employer for such a breach would be an inadequate remedy. Consequently, the Employer will have the right, in addition to any other rights it may have, to obtain injunctive relief to restrain any breach or threatened breach or otherwise to specifically enforce any provision of this Agreement, and the Employer will not be obligated to post bond or other security in seeking such relief. Without limiting the Employer's rights under this Section 11 or any other remedies of the Employer, if the Employee breaches any of the provisions of Section 7 or 8, the Employer will have the right to cease making any payments otherwise due to the Employee under this Agreement.

# 11.2 Covenants of Sections 7 and 8 are Essential and Independent Covenants

The covenants by the Employee in Sections 7 and 8 are essential elements of this Agreement, and without the Employee's agreement to comply with such covenants, the Employer would not have entered into this Agreement or employed or continued the employment of the Employee. The Employer and the Employee have independently consulted their respective counsel and have been advised in all respects concerning the reasonableness and propriety of such covenants, with specific regard to the nature of the business conducted by the Employer. The Employee agrees that this Agreement does not prevent him from earning a living or pursuing his career and that he has the ability to secure other non-competitive employment using his marketable skills. The Employee agrees that the restrictions contained in this Agreement are reasonable, proper, and necessitated by the Employer's legitimate business interests, including without limitation, the Employer's Confidential and/or Proprietary Information and the goodwill of its customers.

The Employee's covenants in Sections 7 and 8 are independent covenants and the existence of any claim by the Employee against the Employer under this Agreement or otherwise will not excuse the Employee's breach of any covenant in Section 7 or 8.

If the Employee's employment hereunder is terminated by either party, this Agreement will continue in full force and effect as is necessary or appropriate to enforce the covenants and agreements of the Employee in Sections 7 and 8.

#### 11.3 Representations and Warranties by the Employee

The Employee represents and warrants to the Employer that the execution and delivery by the Employee of this Agreement do not, and the performance by the Employee of the Employee's obligations hereunder will not, with or without the giving of notice or the passage of time, or both:
(a) violate any judgment, writ, injunction, or order of any court, arbitrator, or governmental agency applicable to the Employee; or (b) conflict with, result in the breach of any provisions of or the termination of, or constitute a default under, any agreement to which the Employee is a party or by which the Employee is or may be bound.

### 11.4 Waiver

The rights and remedies of the parties to this Agreement are cumulative and not alternative. Neither the failure nor any delay by either party in exercising any right, power, or privilege under this Agreement will operate as a waiver of such right, power, or privilege, and no single or partial exercise of any such right, power, or privilege will preclude any other or further exercise of such right, power, or privilege or the exercise of any other right, power, or privilege. To the maximum extent permitted by applicable law, (a) no claim or right arising out of this Agreement can be discharged by one party, in whole or in part, by a waiver or renunciation of the claim or right unless in writing signed by the other party; (b) no waiver that may be given by a party will be applicable except in the specific instance for which it is given; and (c) no notice to or demand on one party will be deemed to be a waiver of any obligation of such party or of the right of the party giving such notice or demand to take further action without notice or demand as provided in this Agreement.

#### 11.5 Binding Effect; Delegation of Duties Prohibited

This Agreement shall inure to the benefit of, and shall be binding upon, the parties hereto and their respective successors, assigns, heirs, and legal representatives, including any entity with which the Employer may merge or consolidate or to which all or substantially all of its assets may be

transferred. The duties and covenants of the Employee under this Agreement, being personal, may not be delegated.

#### 11.6 Notices

All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when (a) delivered by hand (with written confirmation of receipt), (b) sent by facsimile (with written confirmation of receipt), provided that a copy is mailed by registered mail, return receipt requested, or (c) when received by the addressee, if sent by a nationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses and facsimile numbers set forth below (or to such other addresses and facsimile numbers as a party may designate by notice to the other parties):

If to the Employer: GTx, Inc.

175 Toyota Plaza, 7<sup>th</sup> Floor Memphis, Tennessee 38103

Attention: Vice President, Chief Legal Officer

Facsimile No.:901-844-8075

If to the Employee: Mark E. Mosteller

5064 Anchor Cove

Memphis, Tennessee 38117

The Employee shall notify the Employer in writing of any change of his address. Otherwise, the Employer shall send all notices to the Employee's address herein.

#### 11.7 Entire Agreement; Amendments

This Agreement, including the Agreement on Condition of Employment, contains the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral or written, between the parties hereto with respect to the subject matter hereof. The Employer and the Employee further acknowledge and agree that the provisions of this Agreement amend and supersede the Prior Employment Agreement, which shall be of no further force and effect. This Agreement may not be amended orally, but only by an agreement in writing signed by the Employee and a duly authorized officer or director of the Employer.

## 11.8 Governing Law

This Agreement will be governed by the laws of the State of Tennessee without regard to conflicts of laws principles.

# 11.9 Jurisdiction

Any action or proceeding seeking to enforce any provision of, or based on any right arising out of, this Agreement shall be brought against either of the parties in the courts of the State of Tennessee, County of Shelby, or, if it has or can acquire jurisdiction, in the United States District Court for the Western District of Tennessee, and each of the parties consents to the jurisdiction of such courts (and of the appropriate appellate courts) in any such action or proceeding and waives any objection to venue laid therein. Process in any action or proceeding referred to in the preceding sentence may be served on either party anywhere in the world.

# 11.10 Section Headings, Construction

The headings of Sections in this Agreement are provided for convenience only and will not affect its construction or interpretation. All references to "Section" or "Sections" refer to the corresponding Section or Sections of this Agreement unless otherwise specified. All words used in this Agreement will be construed to be of such gender or number as the circumstances require. Unless otherwise expressly provided, the word "including" does not limit the preceding words or terms.

# 11.11 Severability

If any provision of this Agreement is held invalid or unenforceable by any court of competent jurisdiction, the other provisions of this Agreement will remain in full force and effect. Any provision of this Agreement held invalid or unenforceable only in part or degree will remain in full force and effect to the extent not held invalid or unenforceable.

# 11.12 <u>Counterparts</u>

This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of this Agreement and all of which, when taken together, will be deemed to constitute one and the same agreement.

# 11.13 Waiver of Jury Trial

THE PARTIES HERETO HEREBY WAIVE A JURY TRIAL IN ANY LITIGATION WITH RESPECT TO THIS AGREEMENT, OR ARISING OUT OF OR CONCERNING THE EMPLOYEE'S EMPLOYMENT WITH THE EMPLOYER OR TERMINATION THEREOF.

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date above first written above.

# MARK E. MOSTELLER

/s/ Mark E. Mosteller

GTx, Inc.

By: /s/ Henry P. Doggrell

Name: Henry P. Doggrell
Title: Chief Legal Officer

# AMENDED AND RESTATED EMPLOYMENT AGREEMENT

This Amended and Restated Employment Agreement (this "Agreement") is made and entered into as of February 14, 2013 (the "Effective Date") by and between **GTx, Inc.**, located at 175 Toyota Plaza, 7<sup>th</sup> Floor, Memphis, Tennessee 38103 (the "Employer"), and **HENRY P. DOGGRELL** (the "Employee"), residing at 1657 Peabody Avenue, Memphis, Tennessee 38104.

WHEREAS, the Employee has been providing services to the Employer as Vice President, Chief Legal Officer and Secretary under the terms of an Amended and Restated Employment Agreement that was effective as of November 10, 2008 (the "Prior Employment Agreement"); and

WHEREAS, the Employer and the Employee wish to amend and restate the Prior Employment Agreement as set forth herein; and

WHEREAS, during the course of the Employee's employment with the Employer, the Employer will train and continue to train the Employee and to impart to the Employee proprietary, confidential, and/or trade secret information, data and/or materials of the Employer; and

WHEREAS, the Employer has a vital interest in maintaining its confidential information and trade secrets, as well as rights to inventions, since doing so allows the Employer to compete fairly and enhances the value of the Employer to shareholders and job security for employees; and

WHEREAS, the Employer desires to retain the services of the Employee and the Employee is willing to be employed and continue to be employed with the Employer upon the terms and subject to the conditions set forth in this Agreement;

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained in this Agreement, the employment and continued employment of the Employee in accordance with the terms and conditions of this Agreement, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties, intending to be legally bound, agree and covenant as follows:

#### 1. DEFINITIONS

For the purposes of this Agreement, the following terms have the meanings specified or referred to in this Section 1.

"Agreement" has the meaning set forth in first paragraph of this Agreement.

"Basic Compensation" means Salary and Benefits.

"Benefits" has the meaning stated in Section 3.1(b) of this Agreement.

"Board of Directors" means the Board of Directors of the Employer.

"CEO" has the meaning set forth in Section 2.2.

"Change of Control" means any of the following events: (a) the sale or other disposition of all or substantially all of the assets of the Employer in a single transaction or in a series of transactions (including, without limitation, any liquidation or dissolution of the Employer); (b) any Person or group becomes the beneficial owner, directly, or indirectly, of securities of the Employer representing more than fifty percent (50%) of the combined voting power of the Employer's then outstanding securities other than by virtue of a merger, consolidation or similar transaction (for such purposes, "voting stock" shall mean the capital stock of the Employer of any class or classes, the holders of which are ordinarily, in the absence of contingencies, entitled to vote for the election of members of the Board of Directors (or Persons performing similar functions) of the Employer); (c) a merger or consolidation of the Employer with or into any other entity, if immediately after giving effect to such transaction more than fifty percent (50%) of the issued and outstanding voting stock of the surviving entity of such transaction is held by Persons who were not holders (taking into account their individual and affiliated holdings) as of the Effective Date of at least fifty percent (50%) of the voting stock of the Employer; or (d) individuals who, on the Effective Date, are members of the Board of Directors (the "Incumbent Board") cease for any reason to constitute at least a majority of the members of the Board of Directors; provided, however, that if the appointment or election (or nomination for election) of any new member of the Board of Directors was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member will, for purposes of this Agreement, be considered as a member of the Incumbent Board. A Change of Control shall not include: (1) any transfer or issuance of stock of the Employer to one or more of the Employer's lenders (or to any agents or representatives thereof) in exchange for debt of the Employer owed to any such lenders; (2) any transfer of stock of the Employer to or by any Person or entity, including but not limited to one or more of the Employer's lenders (or to any agents or representatives thereof), pursuant to the terms of any pledge of said stock as collateral for any loans or financial accommodations to the Employer and/or its subsidiaries; (3) any transfer or issuance to any Person or entity, including but not limited to one or more of the Employer's lenders (or to any agents or representatives thereof), in connection with the workout or restructuring of the Employer's debts to any one of the Employer's lenders, including but not limited to the issuance of new stock in exchange for any equity contribution to the Employer in connection with the workout or restructuring of such debt; (4) any transfer of stock by a stockholder of the Employer which is a partnership or corporation to the partners or stockholders in such stockholder or any transfer of stock by a stockholder of the Employer to an entity affiliated with such stockholder or the immediate family of such stockholder or a trust or similar entity for the benefit of such family members; or (5) any transfer or issuance of stock in connection with an offering of the Employer's stock in a registered public transaction not involving a transaction described in Rule 145, promulgated under the Securities Act of 1933, as amended, provided that the Employer's officers and Board of Directors shall not materially change as a result thereof.

<u>"Change of Control Termination"</u> means (i) a Termination Without Cause of the Employee's employment by the Employer (other than for death or disability) within twelve (12)

months after a Change of Control or (ii) the Employee's resignation for Good Reason within twelve (12) months after a Change of Control.

"Competing Business" means any individual or entity, other than the Employer, that is engaging in, or proposes to engage in, the development, manufacture, distribution or sale of a Competing Product in North America, South America, Europe and Eastern Europe, and in the countries of Russia, Australia, Japan, China, Taiwan, South Korea and India; provided, however, that an entity that develops, manufactures, distributes or sells a Competing Product in a separate business unit than the business unit in which the Employee is then employed shall not be deemed a Competing Business unless the Employee provides Confidential Information and/or Proprietary Information to the business unit that is engaging in or proposes to engage in the development, manufacture, distribution or sale of a Competing Product.

"Competing Product" means any pharmaceutical or other compound, composition, formulation, method, process, product or material that is competitive with any product of the Employer under development, manufacture, distribution or commercialization at any time from and after October 1, 2003 (the effective date of the Employee's initial employment agreement with the Employer) through the date of termination of the Employee's employment, including, without limitation, small molecules that target androgen, estrogen, glucocorticoid, and/or other hormone receptors for purposes of treating, diagnosing, or imaging humans in health and disease, including treating cancer, osteoporosis and bone loss and muscle loss.

#### "Confidential Information and/or Proprietary Information" means any and all:

- (a) information disclosed to the Employee or known by the Employee as a consequence of, or through, the Employee's employment with the Employer since his initial date of employment on October 1, 2001 (including information conceived, originated, discovered, or developed in whole or in part by the Employee), not generally known in the relevant trade or industry, about the Employer's business, products, processes, and services; and trade secrets concerning the business and affairs of the Employer, product specifications, data, know-how, formulae, compositions, research, processes, designs, sketches, photographs, graphs, drawings, samples, inventions and ideas, past, current, and planned research and development, current and planned manufacturing or distribution methods and processes, customer lists, current and anticipated customer requirements, price lists, market studies, business plans, computer software and programs (including object code and source code), computer software and database technologies, systems, structures, and architectures (and related formulae, compositions, processes, improvements, devices, know-how, inventions, discoveries, concepts, ideas, designs, methods and information); and any other information, however documented, that is a trade secret within the meaning of Tenn. Code §39-14-138 or any other applicable law; and
- (b) information concerning the business and affairs of the Employer (which includes historical financial statements, financial projections and budgets, historical and projected sales, capital spending budgets and plans, the names and backgrounds of key personnel, personnel training and techniques and materials), however documented; and
- (c) intellectual property, inventions, methods, processes, techniques, computer programs, devices, products, services, compounds, gene therapy products, pharmaceuticals,

substances, vectors, enzymes, genes, concepts, discoveries, improvements, and designs, whether or not patentable in the United States or foreign countries, any trade secrets, information, procedures, technologies, data, results, conclusions, know-how or show-how and business information; and

- (d) notes, analysis, compilations, studies, summaries, and other material prepared by or for the Employer containing or based, in whole or in part, on any information included in the foregoing.
  - "Delayed Initial Payment Date" has the meaning stated in Section 9.2 of this Agreement.
  - "Effective Date" means the date stated in the first paragraph of this Agreement.
  - "Employee" has the meaning stated in the first paragraph of this Agreement.
- "Employee Invention" means any idea, invention, technique, modification, process, improvement (whether patentable or not), industrial design (whether registerable or not), work of authorship (whether or not copyright protection may be obtained for it), design, copyrightable work, discovery, trademark, copyright, trade secret, formula, device, method, compound, gene, prodrug, pharmaceutical, structure, product concept, marketing plan, strategy, customer list, technique, blueprint, sketch, record, note, drawing, know-how, data, patent application, continuation application, continuation-in-part application, file wrapper continuation application or divisional application, created, conceived, or developed by the Employee, either solely or in conjunction with others, during the Employee's employment, or a period that includes a portion of the Employee's employment, that relates in any way to, or is useful in any manner in, the business then being conducted or proposed to be conducted by the Employer, and any such item created by the Employee, either solely or in conjunction with others, following termination of the Employee's employment with the Employer, that is based upon or uses Confidential Information and/or Proprietary Information.
- "Employer" means GTx, Inc., its successors and assigns, and any of its current or future subsidiaries, or organizations controlled by, controlling, or under common control with it.
  - "Expenses" has the meaning stated in Section 4.1 of this Agreement.
  - "Good Reason" for termination means that the Employee voluntarily resigns from all positions he then holds with the Employer if and only if:
  - (a) one of the following actions have been taken without the Employee's express written consent:
- (i) following a Change of Control, an adverse change in the Employee's authority, duties or responsibilities (including reporting responsibilities) which, without the Employee's consent, represents a material reduction in or a material demotion of the Employee's authority, duties or responsibilities as in effect immediately prior to a Change of Control or the assignment to the Employee of any duties or responsibilities which are materially inconsistent with and materially adverse to such authority, duties or responsibilities;

- (ii) following a Change of Control, a material reduction in the then current Salary of the Employee;
- (iii) following a Change of Control, the relocation of the Employer's principal employee offices to a location that increases the Employee's one-way commute by more than twenty (20) miles;
- (iv) the failure of the Employer to obtain an agreement reasonably satisfactory to the Employee from any successor or assign of the Employer upon a Change of Control to assume and agree to perform this Agreement in all material respects following the Change of Control; or
- (v) the Employer materially breaches its obligations under this Agreement or any other then-effective agreement with the Employee (including any agreement or arrangement providing for incentive compensation or employee benefits, including the Benefits provided in this Agreement).
  - (b) the Employee provides written notice to the Board of Directors within the thirty (30) day period immediately following such action; and
  - (c) such action is not remedied by the Employer within thirty (30) days following the Employer's receipt of such written notice; and
  - (d) the Employee's resignation is effective not later than sixty (60) days after the expiration of such thirty (30)-day cure period.
- "Person" means any individual, corporation (including any non-profit corporation), general or limited partnership, limited liability company, joint venture, estate, trust, association, organization, or governmental body.
- <u>"Proprietary Items"</u> means any Proprietary and/or Confidential Information embodied in any document, record, recording, electronic media, formulae, notebook, plan, model, component, device, or computer software or code, whether embodied in a disk or in any other form.
- <u>"Release"</u> means a general release of claims in favor of the Employer, in a form acceptable to the Employer, which shall specifically relate to all of the Employee's rights and claims in existence at the time of such execution and shall confirm the Employee's continuing obligations to the Employer (including but not limited to obligations under Section 7 and Section 8 of this Agreement, the Agreement on Condition of Employment and any other confidentiality and/or non-competition agreement with the Employer).

<u>"Salary"</u> has the meaning stated in Section 3.1(a) of this Agreement.

"Section 409A" has the meaning stated in Section 9.2 of this Agreement.

"Termination Date" has the meaning stated in Section 6.1 of this Agreement.

<u>"Termination With Cause"</u> means the termination of the Employee's employment by act of the Board of Directors for any of the following reasons, any of which shall constitute "Cause" for purposes of this Agreement:

- (a) the Employee's conviction of a felony;
- (b) the Employee's theft, embezzlement, misappropriation of or intentional infliction of material damage to the Employer's property or business opportunities;
- (c) the Employee's breach of the provisions contained in Section 7 or Section 8 of this Agreement or the provisions in the Agreement on Condition of Employment regarding confidentiality, non-competition or non-solicitation; or
- (d) the Employee's ongoing willful neglect of or failure to perform his duties hereunder or his ongoing willful failure or refusal to follow any reasonable, unambiguous duly adopted written direction of the CEO that is not inconsistent with the description of the Employee's duties set forth in Section 2.3, if such willful neglect or failure is materially damaging or materially detrimental to the business and operations of the Employer; provided that, if curable, the Employee shall have received written notice of such neglect or failure and shall have continued to engage in such neglect or failure after 30 days following receipt of such notice from the CEO, which notice specifically identifies the manner in which the CEO believes that the Employee has engaged in such neglect or failure. For purposes of this subsection, no act, or failure to act, shall be deemed "willful" unless done, or omitted to be done, by the Employee not in good faith, and without reasonable belief that such action or omission was in the best interest of the Employer.

<u>"Termination Without Cause"</u> means the termination of the Employee's employment by the Employer for any reason other than (i) Termination With Cause, or (ii) a termination by the Employer due to the Employee's death or disability.

# 2. EMPLOYMENT TERMS AND DUTIES

# 2.1 <u>Employment</u>

The Employer hereby continues the employment of the Employee, and the Employee hereby accepts continued employment by the Employer, upon the terms and conditions set forth in this Agreement.

# 2.2 <u>Term</u>

Either the Employee or the Employer may terminate this Agreement and the Employee's employment and compensation with or without Cause or notice, at any time, at either the Employer's or the Employee's option. No officer or manager of the Employer has the authority to enter into any other agreement for employment for a specified period of time, or to modify or to make any agreement contrary to the foregoing, except by written amendment to this Agreement, dated and signed by the Chief Executive Officer ("CEO") or the President of the Employer.

#### 2.3 <u>Duties</u>

The Employee will continue to have such duties as are assigned or delegated to the Employee by the Board of Directors, the CEO or the President and will initially serve as Vice President, Chief Legal Officer and Secretary for the Employer. The Employee will devote his full time, attention, skill and energy to the business of the Employer, will use his best efforts to promote the success of the Employer's business, and will cooperate fully with the Board of Directors, the CEO and the President in the advancement of the best interest of the Employer. The Employee agrees to abide by all bylaws, policies, practices, procedures or rules of the Employer. The Employee may be reassigned or transferred to another management position, as designated by the Board of Directors, the CEO or the President, which may or may not provide the same level of responsibility as the initial assignment, in accordance with the terms and conditions of this Agreement.

#### 3. COMPENSATION

## 3.1 <u>Basic Compensation</u>

- (a) <u>Salary.</u> As of the Effective Date, the Employee will be paid for each of the twenty-six pay periods during the calendar year approximately \$13,983.69, which is the equivalent of \$363,576 per calendar year (the "Salary"), subject to review and adjustment from time to time by the CEO in his sole discretion.
- (b) <u>Benefits.</u> The Employee will, during his employment with the Employer, be permitted to participate in such life insurance, hospitalization, major medical, short term disability, long term disability, 401(k) plan and other employee benefit plans of the Employer that may be in effect from time to time, to the extent the Employee is eligible under the terms of those plans (collectively, the "Benefits"). All matters of eligibility for coverage or benefits under any such plan shall be determined in accordance with the provisions of such plan. The Employer reserves the right to change, alter, or terminate any such plan, in its sole discretion, subject to the terms of such plan.
- (c) The Employer may withhold from the Salary or Benefits payable to the Employee all federal, state, local, and other taxes and other amounts as permitted or required pursuant to law, rules or regulations.

#### 4. FACILITIES AND EXPENSES

#### 4.1 General

The Employer will furnish the Employee office space, equipment, supplies, and such other facilities and personnel as the Employer deems necessary or appropriate for the performance of the Employee's duties under this Agreement. The Employer will pay the Employee's dues in such professional societies and organizations as the CEO or President deems appropriate, and will pay on behalf of the Employee (or reimburse the Employee for) reasonable expenses incurred by the Employee at the request of, or on behalf of, the Employer in the performance of the Employee's duties pursuant to this Agreement, and in accordance with the Employer's employment policies, including reasonable expenses incurred by the Employee in

attending conventions, seminars, and other business meetings, in appropriate business entertainment activities, and for promotional expenses (the "Expenses"). To the extent that any reimbursements payable or in-kind benefits provided pursuant to this Agreement are subject to the provisions of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), any such reimbursements payable pursuant to this Agreement shall be paid no later than December 31 of the year following the year in which the expense was incurred, the amount of expenses reimbursed or in-kind benefits provided in one year shall not affect the amount eligible for reimbursement or in-kind benefits to be provided in any subsequent year, and the right to reimbursement or in-kind benefits under this Agreement will not be subject to liquidation or exchange for another benefit. The Employee must file expense reports with respect to such expenses in accordance with the Employer's policies.

#### 5. VACATIONS AND HOLIDAYS

The Employee will be eligible to accrue paid vacation each calendar year in accordance with the vacation policies of the Employer in effect from time to time. Under such policies of the Employer as of the Effective Date, the Employee is eligible to accrue up to four (4) weeks of paid vacation each calendar year. Vacation must be taken by the Employee at such time or times during the calendar year as approved by the CEO or President. Additionally, the Employee will be entitled to the paid holidays set forth in the Employer's policies. Any accrued vacation days and holidays that are not used by the Employee by the end of the calendar year in which they were accrued will be lost and may not be used in any subsequent calendar year; *provided*, *however*, that upon termination of the Employee's employment, the Employee will be paid the equivalent compensation attributable to any accrued vacation days which were accrued during the calendar year in which such termination occurs and are not otherwise used by the Employee as of the date of such termination.

#### 6. TERMINATION

- 6.1 <u>At-Will Employment</u>. The Employee's employment is at-will, which means that either the Employee or the Employer may terminate this Employment Agreement (with the exception of the provisions of Sections 7 and 8 which shall survive termination of this Agreement and the Employee's employment) with or without Cause or notice, at any time at either the Employee's or the Employer's option. Except as otherwise specifically set forth herein, or as provided in any plan documents governing any compensatory equity awards that have been or may be granted to the Employee from time to time in the sole discretion of the Employer or an affiliate, upon termination of the Employee's employment the Employer shall be released from any and all further obligations under this Agreement, except the Employer shall be obligated to pay the Employee his accrued but unpaid Basic Compensation and Expenses owing to the Employee through the day on which the Employee's employment is terminated (the "Termination Date"). The Employee's obligations under Sections 7 and 8 shall continue pursuant to the terms and conditions of this Agreement.
- 6.2 <u>Termination Upon Death</u>. The employment of the Employee shall terminate on the date of the Employee's death, in which event the Employee's accrued but unpaid Basic Compensation and Expenses, owing to the Employee through the date of the

Employee's death, shall be paid to his estate. The Employee's estate will not be entitled to any other compensation under this Agreement.

- 6.3 <u>Termination Related to a Change of Control</u>. As additional consideration for the covenants in Section 7 and Section 8, in the event of a Change of Control Termination, and provided that the Employee signs and allows to become effective a Release within the time period provided therein (but not later than the 60<sup>th</sup> day following the Termination Date, such latest permitted effective date is the "Release Deadline" for purposes of this Agreement), then subject to Section 9.2:
  - (a) The Employee shall receive as severance one (1) year of his Salary, payable in accordance with the Employer's then current payroll schedule over the one (1) year period following the Termination Date, less deductions required by law; *provided*, *however*, that if the Employee terminates his employment on account of a material reduction in his Salary, as provided in paragraph (a)(ii) of the definition of Good Reason, the amount of such severance shall be based on the Employee's Salary immediately prior to such reduction. Notwithstanding the foregoing payment schedule, no severance will be paid prior to the effective date of the Release. Subject to Section 9.2, on the first regular payroll pay day following the effective date of the Release, the Employer will pay the Employee the severance that the Employee would otherwise have received on or prior to such date but for the delay in payment related to the effectiveness of the Release, with the balance of the severance being paid as originally scheduled.
  - (the Employee timely elects group health insurance coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 (the COBRA), the Employer will pay the Employee's monthly COBRA premiums (including the cost of eligible dependent coverage, if any) through the earliest of the following (the "COBRA Payment Period"): (i) for twelve (12) months following the Termination Date; (ii) the date that the Employee becomes eligible for group health insurance coverage through a new employer; or (iii) the date that the Employee is no longer eligible for COBRA coverage. Notwithstanding the foregoing, if at any time the Employer determines, in its sole discretion, that its payment of the Employee's COBRA premiums would result in a violation of applicable law (including, without limitation, Section 105(h)(2) of the Code and Section 2716 of the Public Health Service Act), then in lieu of paying such COBRA premiums, the Employer will pay the Employee on the last day of each remaining month of the COBRA Payment Period a fully taxable cash payment equal to the COBRA premium for that month, subject to applicable tax withholding (such amount, the "Special Severance Payment"); provided, however, that any such Special Severance Payment will be made without regard to the Employee's payment of COBRA premiums and for purposes of any such Special Severance Payment, the "COBRA Payment Period" will be determined without regard to the expiration of the Employee's eligibility for continued coverage under COBRA.

## 7. NON-DISCLOSURE COVENANT; EMPLOYEE INVENTIONS

#### 7.1 <u>Acknowledgements by the Employee</u>

The Employee acknowledges and agrees that (a) during the course of his employment and as a part of his employment, the Employee will be afforded access to Confidential Information and/or Proprietary Information; (b) public disclosure of such Confidential Information and/or Proprietary Information could have an adverse effect on the Employer and its business; (c) because the Employee possesses substantial technical expertise and skill with respect to the Employer's business, the Employer desires to obtain exclusive ownership of each Employee Invention, and the Employer will be at a substantial competitive disadvantage if it fails to acquire exclusive ownership of each Employee Invention; and (d) the provisions of this Section 7 are reasonable and necessary to prevent the improper use or disclosure of Confidential Information and/or Proprietary Information and to provide the Employer with exclusive ownership of all Employee Inventions.

# 7.2 <u>Agreements of the Employee</u>

In consideration of the compensation and benefits to be paid or provided to the Employee by the Employer under this Agreement and otherwise, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Employee covenants and agrees as follows:

# (a) <u>Confidentiality</u>

- (i) That all of such Confidential Information and/or Proprietary Information is a unique asset of the business of the Employer, the disclosure of which would be damaging to the Employer.
- (ii) That the Employee will not at any time, whether during or after termination or cessation of the Employee's employment, except as authorized by the Employer and for its benefit, use, divulge or disclose (or enable anyone else to use, divulge or disclose) to any Person, association or entity any Confidential Information and/or Proprietary Information which the Employee presently possesses or which the Employee may obtain during the course of the Employee's employment with respect to the business, finances, customers or affairs of the Employer or trade secrets, developments, methods or other information and data pertaining to the Employer's business. The Employee shall keep strictly confidential all matters and information entrusted to the Employee and shall not use or attempt to use any such Confidential Information and/or Proprietary Information in any manner which may injure or cause loss or may be calculated to injure or cause loss, whether directly or indirectly, to the Employer.
- (iii) That during the course of this Agreement or at any time after termination, the Employee will keep in strictest confidence and will not disclose or make accessible to any other Person without the prior written consent of the Employer, the Confidential Information and/or Proprietary Information; the Employee agrees: (a) not to use any such Confidential Information and/or Proprietary Information for himself or others; and (b) not to take any such material or reproductions thereof from the Employer's facilities at any time

 $during \ his \ employment \ except, \ in \ each \ case, \ as \ required \ in \ connection \ with \ the \ Employee's \ duties \ to \ the \ Employer.$ 

(iv) The Employee agrees to hold in confidence, and not to distribute or disseminate to any Person or entity for any reason, any Confidential Information and/or Proprietary Information of the Employer under this Agreement, or information relating to

experiments or results obtained based on the duties of the Employee, except for information which: (a) is in or which becomes a part of the public domain not as a result of a breach of this Agreement, (b) is information lawfully received from a third party who had the right to disclose such information or (c) is required by legal process before a court of proper jurisdiction (by oral questions, deposition, interrogatories, requests for information or documents, subpoena, civil investigative domain or other similar process) to disclose all or any part of any Confidential Information and/or Proprietary Information, provided that the Employee will provide the Employer with prompt notice of such request or requirement, as well as notice of the terms and circumstances surrounding such request or requirements, so that the Employer may seek an appropriate protective order or waive compliance with the provisions of this Agreement. In such case, the parties will consult with each other on the advisability of pursuing any such order or other legal action or available step to resist or narrow such request or requirement. If, failing the entry of a protective order or the receipt of a waiver hereunder, the Employee is, in the opinion of counsel reasonably acceptable to the Employer, legally compelled to disclose Confidential Information and/or Proprietary Information, the Employee may disclose that portion of such information which counsel advises is necessary to disclose. The Employee will not oppose any action by the Employer to prevent disclosure pursuant to an appropriate protective order or to request other reliable assurances that confidential treatment will be accorded to the disclosure of such information.

- (v) Upon termination of this Agreement by either party or upon written notice by the Employer, the Employee shall promptly redeliver to the Employer, or, if requested by the Employer, promptly destroy all written Confidential Information and/or Proprietary Information and any other written material containing any information included in the Confidential Information and/or Proprietary Information (whether prepared by the Employer, the Employee, or a third party), and will not retain any copies, extracts or other reproductions in whole or in part of such written Confidential Information and/or Proprietary Information (and upon request certify such redelivery or destruction to the Employer in a written instrument reasonably acceptable to the Employer and its counsel).
- (vi) This Agreement and the terms and conditions recited herein are confidential and non-public, except as may be expressly permitted by the Employer. The Employee agrees not to disclose the contents of this Agreement to any Person or entity, including, but not limited to the press, other media, any

public body, or any competitor of the Employer, except to the Employee's legal counsel or as may be required by law.

- (vii) Any trade secrets of the Employer will be entitled to all of the protections and benefits of State of Tennessee law and any other applicable law. If any information that the Employer deems to be a trade secret is found by a court of competent jurisdiction not be to a trade secret for purposes of this Agreement, such information will, nevertheless, be considered Confidential Information and/or Proprietary Information for purposes of this Agreement. The Employee hereby waives any requirement that the Employer submits proof of the economic value of any trade secret or posts a bond or other security.
- (viii) None of the foregoing obligations and restrictions applies to any part of the Confidential Information and/or Proprietary Information that the Employee demonstrates was or became generally available to the public other than as a result of a disclosure by the Employee.
- (ix) The Employee will not remove from the Employer's premises (except to the extent such removal is for purposes of the performance of the Employee's duties at home or while traveling, or except as otherwise specifically authorized by the Employer) any Proprietary Items. The Employee recognizes that, as between the Employer and the Employee, all of the Proprietary Items, whether or not developed by the Employee, are the exclusive property of the Employer. Upon termination of this Agreement by either party, or upon the request of the Employer during the employment of the Employee, the Employee will return to the Employer all of the Proprietary Items in the Employee's possession or subject to the Employee's control, and the Employee shall not retain any copies, abstracts, sketches, or other physical or electronic embodiment of any of the Proprietary Items.
- (x) During the Employee's employment with the Employer, the Employee will not improperly use or disclose any confidential information or trade secrets, if any, of any former employer or any other Person to whom the Employee has an obligation of confidentiality, and the Employee will not bring onto the premises of the Employer any unpublished documents or any property belonging to any former employer or any other Person to whom the Employee has an obligation of confidentiality unless consented to in writing by that former employer or Person.

#### (b) Employee Inventions

(i) Each Employee Invention will belong exclusively to the Employer. The Employee agrees that the Employer shall have sole and exclusive ownership rights in any conception, invention, trade secrets, information, ideas, improvement, substance, know-how, whether or not patentable, arising out of, resulting from, or derivative of: (1) the work or services of the Employee, or (2) within the scope of the duties of the Employee, or (3) using any materials,

compounds, devices, or monies of the Employer. Any resulting or derivative rights, including patent rights, shall become the exclusive property of the Employer and the Employer shall be entitled to the entire right, title and interest with respect hereto. The Employee agrees, without additional compensation, to convey, assign the entire right, title, and interest in and to any inventions for the United States and all foreign jurisdictions to the Employee arising out of, resulting from, or derivative of: (1) the work or services of the Employee, or (2) within the scope of the duties of the Employee, or (3) using any materials, compounds, devices, or monies.

- (ii) The Employer shall retain the entire right, title and interest in and to any and all Confidential Information and/or Proprietary Information provided by the Employer to the Employee and to any methods, compounds, improvements, substances, and compositions using or incorporating such Confidential Information and/or Proprietary Information.
- (iii) The Employee agrees that Confidential Information and/or Proprietary Information provided to the Employee by the Employer shall be used for work purposes only and shall not be used for any other uses, studies, experiments or tests.

- (iv) The Employee agrees that he will promptly disclose to the Employer, or any Persons designated by the Employer, all the Employee Inventions, made or conceived or reduced to practice or learned by him, either alone or jointly with others, during the employment of the Employee. The Employee further agrees to assist the Employer in every proper way (but at the Employer's expense) to obtain and from time to time enforce patents, copyrights or other rights on Employee Inventions in any and all countries, and to that end the Employee will execute all documents necessary: (a) to apply for, obtain and vest in the name of the Employer alone (unless the Employer otherwise directs) letters patent, copyrights or other analogues protection in any country throughout the world and when so obtained or vested to renew and restore the same; and (b) to defend (including the giving of testimony and rendering any other assistance) any opposition proceedings in respect of such applications and any opposition proceedings or petitions or applications for revocation of such letters patent, copyright or other analogous protection. The Employee's obligation to assist the Employer in obtaining and enforcing patents and copyrights for Employee Inventions in any and all countries shall continue beyond and after the termination of the Employee.
- (v) Any copyrightable work whether published or unpublished created by the Employee in connection with or during the performance of services below shall be considered a work made for hire, to the fullest extent permitted by law and all right, title and interest therein, including the worldwide copyrights, shall be the property of the Employer as the employer and party specially commissioning such work. In the event that any such copyrightable work or portion thereof shall not be legally qualified as a work made for hire, or shall

subsequently be so held, the Employee agrees to properly convey to the Employer, without additional compensation, the entire right, title and interest in and to such work or portion thereof, including but not limited to the worldwide copyrights, extensions of such copyrights, and renewal copyrights therein, and further including all rights to reproduce the copyrighted work in copies or phonorecords, to prepare derivative works based on the copyrighted work, to distribute copies of the copyrighted work, to perform the copyrighted work publicly, to display the copyrighted work publicly, and to register the claim of copyright therein and to execute any and all documents with respect hereto.

(vi) The Employee may not publish or disclose any Confidential Information and/or Proprietary Information relating to, arising from, derivative of, or as a result of his employment pursuant to this Agreement, including but not limited to: information, improvements, results, experiments, data, or methods that makes reference to any of the Confidential Information and/or Proprietary Information. Any work performed under, or arising from, or a result of his employment with the Employer shall not be published or disclosed in written, electronic, or oral form without the express written permission of the Employer.

## 7.3 <u>Disputes or Controversies</u>

The Employee recognizes that should a dispute or controversy arising from or relating to this Agreement be submitted for adjudication to any court, arbitration panel, or other third party, the preservation of the secrecy of Confidential Information and/or Proprietary Information may be jeopardized. All pleadings, documents, testimony, and records relating to any such adjudication will be maintained in secrecy and will be available for inspection by the Employer, the Employee, and their respective attorneys and experts, who will agree, in advance and in writing, to receive and maintain all such information in secrecy, except as may be limited by them in writing.

# 7.4 Agreement on Condition of Employment

As a condition of employment, the Employee agrees to execute and abide by the Employer's current form of Agreement on Condition of Employment, which may be amended by the parties from time to time without regard to this Agreement. The Agreement on Condition of Employment contains provisions that are intended by the parties to survive and do survive termination or expiration of this Agreement. In the event that the terms of this Agreement differ from or are in conflict with the Agreement on Condition of Employment, this Agreement shall control.

# 8. NON-COMPETITION

#### 8.1 Acknowledgments by the Employee

The Employee understands and recognizes that the Employee's services provided to the Employer are special, unique, unusual, extraordinary and intellectual in character. Subject to Section 8.4 below, the Employee agrees that, during the employment of the Employee and for

a period of two (2) years from the date of termination of the Employee's employment with the Employer, he will not in any manner, directly or indirectly, on behalf of himself or any Person, firm, partnership, joint venture, corporation or other business entity, engage or invest in, own, manage, operate, finance, control or participate in the ownership, management, operation, financing, or control of, be employed by, associated with, or in any manner connected with, lend the Employee's name or similar name to, lend the Employee's credit to or render services or advice to, enter into or engage in any Competing Business; provided, however, that the Employee may purchase or otherwise acquire up to (but not more than) one percent of any class of securities of any enterprise (but without otherwise participating in the activities of such enterprise) if such securities are listed on any national or regional securities exchange or have been registered under Section 12(g) of the Securities Exchange Act of 1934.

8.2 In consideration of the acknowledgements by the Employee, and in consideration of the compensation and benefits to be paid or provided to the Employee by the Employee, the Employee covenants that, subject to Section 8.4 below, he will not, directly or indirectly, whether for the Employee's own account or the account of any other Person (i) at any time during the employment of the Employee and for a period of two (2) years from the termination of the Employee's employment with the Employer, solicit, employ, or otherwise engage as an employee, independent contractor, or otherwise, any Person who is or was an employee of the Employer at any time during the Employee's employment with the Employer or in any manner induce or attempt to induce any employee of the Employer to terminate his employment with the Employer; or (ii) at any time during the employment of the Employee with the Employer and for two (2) years from the termination of the Employee's employment with the Employer, interfere with the Employer's relationship with any Person, including any Person who at any time during the Employee's employment with the Employer was an employee, contractor, supplier, or customer of the Employer.

- 8.3 In further consideration of these promises, the Employee agrees that he will not at any time during or after the Employee's employment with the Employer, disparage the Employer or any of its shareholders, directors, officers, employees, parents, subsidiaries, affiliates or agents in any manner likely to be harmful to them or their business, business reputation or personal reputation; *provided*, *however*, that the Employee may respond accurately and fully to any question, inquiry or request for information when required by legal process.
- 8.4 <u>Change of Control</u>. In the event of a Change of Control Termination, the Employee's obligations under Sections 8.1 and 8.2 above and the non-competition and non-solicitation provisions in the Agreement on Condition of Employment shall expire one (1) year from the date of termination of his employment with the Employer (or any entity acquiring the Employer as a result of a Change of Control).
- 8.5 If any covenant in Section 8 is held to be unreasonable, arbitrary, or against public policy, such covenant will be considered to be divisible with respect to scope, time, and geographic area, and such lesser scope, time, or geographic area, or all of them, as a court of competent jurisdiction may determine to be reasonable, not arbitrary, and not against public policy, will be effective, binding, and enforceable against the Employee.

The period of time applicable to any covenant in Section 8 will be extended by the duration of any violation by the Employee of such covenant.

The Employee will, while the covenants under Section 8 are in effect, give notice to the Employer, within ten days after accepting any other employment, of the identity of the Employee's employer. The Employer may notify such employer that the Employee is bound by this Agreement and, at the Employer's election, furnish such employer with a copy of this Agreement or relevant portions thereof.

## 9. TAX MATTERS

- 9.1 <u>Responsibility for Tax Obligations</u>. The Employee agrees that he is responsible for any applicable taxes of any nature (including any penalties or interest that may apply to such taxes) that the Employer reasonably determines apply to any payment or equity award made to the Employee hereunder (or any arrangement contemplated hereunder), that the Employee's receipt of any payment or benefit hereunder is conditioned on the Employee's satisfaction of any applicable withholding or similar obligations that apply to such payment or benefit, and that any cash payment owed to the Employee hereunder will be reduced to satisfy any such withholding or similar obligations that may apply thereto.
- Compliance with Section 409A. Any payments or benefits provided under this Agreement that constitute "deferred compensation" 9.2 within the meaning of Section 409A of the Code and the regulations and other guidance thereunder and any state law of similar effect (collectively "Section 409A") shall not commence in connection with the Employee's termination of employment unless the Employee has also incurred a "separation from service," as such term is defined in Treasury Regulation Section 1.409A-1(h) (without regard to any permissible alternative definition thereunder) ("Separation from Service"). It is intended that each installment of the payments and benefits provided for in this Agreement is a separate "payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2)(i). For the avoidance of doubt, it is intended that payments of the amounts set forth in this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9). However, if the Employer determines that the payments and benefits provided under this Agreement constitute "deferred compensation" under Section 409A and the Employee is, on the date of the Employee's Separation from Service, a "specified employee" of the Employer or any successor entity thereto, as such term is defined in Section 409A(a)(2)(B)(i) of the Code, then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of any such payments or benefits shall be delayed as follows: on the earlier to occur of (i) the date that is six (6) months and one (1) day after the Employee's Separation from Service or (ii) the date of the Employee's death (such earlier date, the "Delayed Initial Payment Date"), the Employer shall (A) pay to the Employee a lump sum amount equal to the sum of the payments that the Employee would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the payments had not been so delayed pursuant to this Section 9.2 and (B) commence paying the balance of the payments in accordance with the applicable payment schedules set forth in this Agreement. If the Employer determines that any payments or benefits provided under this Agreement constitute "deferred compensation" under Section 409A and the Release could become effective in the calendar year following the calendar

year in which the Employee's Separation from Service occurs, the Release will not be deemed effective any earlier than the Release Deadline for purposes of determining the timing of payment of any such payments or benefits.

# 9.3 Parachute Payments

- (a) Notwithstanding anything in this Agreement to the contrary, if any payment or benefit the Employee will or may receive from the Employer or otherwise (a "280G Payment") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then any such 280G Payment pursuant to this Agreement (a "Payment") shall be equal to the Reduced Amount. The "Reduced Amount" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount (i.e., the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in the Employee's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "Reduction Method") that results in the greatest economic benefit for the Employee. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "Pro Rata Reduction Method").
- (b) Notwithstanding any provision of Section 9.3(a) to the contrary, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for the Employee as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future

events (*e.g.*, being terminated without Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.

(c) If the Employee receives a Payment for which the Reduced Amount was determined pursuant to clause (x) of Section 9.3(a) and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, the Employee shall promptly return to the Employer a sufficient amount of the Payment (after reduction pursuant to clause (x) of Section 9.3(a)) so that no portion of the remaining Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) of Section 9.3(a), the Employee

shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

### 10. CLAWBACK/RECOVERY

Any amounts paid to the Employee by the Employer, whether or not under this Agreement or any incentive plan of the Employer, will be subject to recoupment in accordance with The Sarbanes-Oxley Act of 2002, The Dodd-Frank Wall Street Reform and Consumer Protection Act and any implementing regulations under these acts, any clawback policy adopted by the Employer, or as otherwise required by applicable law. In addition, in consideration of the Employee's continued employment with the Employer and in recognition of the Employee's position of trust and authority with the Employer, the Employee agrees to promptly consent to any clawback policy adopted by the Employer.

#### 11. GENERAL PROVISIONS

## 11.1 <u>Injunctive Relief and Additional Remedy</u>

The Employee acknowledges that the injury that would be suffered by the Employer as a result of a breach of the provisions of this Agreement (including any provision of Sections 7 and 8) would be irreparable and that an award of monetary damages to the Employer for such a breach would be an inadequate remedy. Consequently, the Employer will have the right, in addition to any other rights it may have, to obtain injunctive relief to restrain any breach or threatened breach or otherwise to specifically enforce any provision of this Agreement, and the Employer will not be obligated to post bond or other security in seeking such relief. Without limiting the Employer's rights under this Section 11 or any other remedies of the Employer, if the Employee breaches any of the provisions of Section 7 or 8, the Employer will have the right to cease making any payments otherwise due to the Employee under this Agreement.

## 11.2 Covenants of Sections 7 and 8 are Essential and Independent Covenants

The covenants by the Employee in Sections 7 and 8 are essential elements of this Agreement, and without the Employee's agreement to comply with such covenants, the Employer would not have entered into this Agreement or employed or continued the employment of the Employee. The Employer and the Employee have independently consulted their respective counsel and have been advised in all respects concerning the reasonableness and propriety of such covenants, with specific regard to the nature of the business conducted by the Employer. The Employee agrees that this Agreement does not prevent him from earning a living or pursuing his career and that he has the ability to secure other non-competitive employment using his marketable skills. The Employee agrees that the restrictions contained in this Agreement are reasonable, proper, and necessitated by the Employer's legitimate business interests, including without limitation, the Employer's Confidential and/or Proprietary Information and the goodwill of its customers.

The Employee's covenants in Sections 7 and 8 are independent covenants and the existence of any claim by the Employee against the Employer under this Agreement or otherwise will not excuse the Employee's breach of any covenant in Section 7 or 8.

If the Employee's employment hereunder is terminated by either party, this Agreement will continue in full force and effect as is necessary or appropriate to enforce the covenants and agreements of the Employee in Sections 7 and 8.

# 11.3 Representations and Warranties by the Employee

The Employee represents and warrants to the Employer that the execution and delivery by the Employee of this Agreement do not, and the performance by the Employee of the Employee's obligations hereunder will not, with or without the giving of notice or the passage of time, or both:

(a) violate any judgment, writ, injunction, or order of any court, arbitrator, or governmental agency applicable to the Employee; or (b) conflict with, result in the breach of any provisions of or the termination of, or constitute a default under, any agreement to which the Employee is a party or by which the Employee is or may be bound.

# 11.4 Waiver

The rights and remedies of the parties to this Agreement are cumulative and not alternative. Neither the failure nor any delay by either party in exercising any right, power, or privilege under this Agreement will operate as a waiver of such right, power, or privilege, and no single or partial exercise of any such right, power, or privilege will preclude any other or further exercise of such right, power, or privilege or the exercise of any other right, power, or privilege. To the maximum extent permitted by applicable law, (a) no claim or right arising out of this Agreement can be discharged by one party, in whole or in part, by a waiver or renunciation of the claim or right unless in writing signed by the other party; (b) no waiver that may be given by a party will be applicable except in the specific instance for which it is given; and (c) no notice to or demand on one party will be deemed to be a waiver of any obligation of such party or of the right of the party giving such notice or demand to take further action without notice or demand as provided in this Agreement.

# 11.5 <u>Binding Effect; Delegation of Duties Prohibited</u>

This Agreement shall inure to the benefit of, and shall be binding upon, the parties hereto and their respective successors, assigns, heirs, and legal representatives, including any entity with which the Employer may merge or consolidate or to which all or substantially all of its assets may be

transferred. The duties and covenants of the Employee under this Agreement, being personal, may not be delegated.

#### 11.6 Notices

All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when (a) delivered by hand (with written confirmation of receipt), (b) sent by facsimile (with written confirmation of receipt), provided that a copy is mailed by registered mail, return receipt requested, or (c) when received by the addressee, if sent by a nationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses and facsimile numbers set forth below (or to such other addresses and facsimile numbers as a party may designate by notice to the other parties):

If to the Employer: GTx, Inc.

175 Toyota Plaza, 7<sup>th</sup> Floor Memphis, Tennessee 38103 Attention: Chief Executive Officer Facsimile No.: 901-844-8075

If to the Employee: Henry P. Doggrell

1657 Peabody Avenue Memphis, Tennessee 38104

The Employee shall notify the Employer in writing of any change of his address. Otherwise, the Employer shall send all notices to the Employee's address herein.

#### 11.7 Entire Agreement; Amendments

This Agreement, including the Agreement on Condition of Employment, contains the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral or written, between the parties hereto with respect to the subject matter hereof. The Employer and the Employee further acknowledge and agree that the provisions of this Agreement amend and supersede the Prior Employment Agreement, which shall be of no further force and effect. This Agreement may not be amended orally, but only by an agreement in writing signed by the Employee and a duly authorized officer or director of the Employer.

## 11.8 <u>Governing Law</u>

This Agreement will be governed by the laws of the State of Tennessee without regard to conflicts of laws principles.

# 11.9 <u>Jurisdiction</u>

Any action or proceeding seeking to enforce any provision of, or based on any right arising out of, this Agreement shall be brought against either of the parties in the courts of the State of Tennessee, County of Shelby, or, if it has or can acquire jurisdiction, in the United States District Court for the Western District of Tennessee, and each of the parties consents to the jurisdiction of such courts (and of the appropriate appellate courts) in any such action or proceeding and waives any objection to venue laid therein. Process in any action or proceeding referred to in the preceding sentence may be served on either party anywhere in the world.

# 11.10 <u>Section Headings, Construction</u>

The headings of Sections in this Agreement are provided for convenience only and will not affect its construction or interpretation. All references to "Section" or "Sections" refer to the corresponding Section or Sections of this Agreement unless otherwise specified. All words used in this Agreement will be construed to be of such gender or number as the circumstances require. Unless otherwise expressly provided, the word "including" does not limit the preceding words or terms.

# 11.11 Severability

If any provision of this Agreement is held invalid or unenforceable by any court of competent jurisdiction, the other provisions of this Agreement will remain in full force and effect. Any provision of this Agreement held invalid or unenforceable only in part or degree will remain in full force and effect to the extent not held invalid or unenforceable.

# 11.12 <u>Counterparts</u>

This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of this Agreement and all of which, when taken together, will be deemed to constitute one and the same agreement.

# 11.13 Waiver of Jury Trial

THE PARTIES HERETO HEREBY WAIVE A JURY TRIAL IN ANY LITIGATION WITH RESPECT TO THIS AGREEMENT, OR ARISING OUT OF OR CONCERNING THE EMPLOYEE'S EMPLOYMENT WITH THE EMPLOYER OR TERMINATION THEREOF.

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date above first written above.

# HENRY P. DOGGRELL

/s/ Henry P. Doggrell

GTx, Inc.

By: /s/ Marc S. Hanover

Name: Marc S. Hanover<br/>Title: President/COO

# AMENDED AND RESTATED EMPLOYMENT AGREEMENT

This Amended and Restated Employment Agreement (this "Agreement") is made and entered into as of February 14, 2013 (the "Effective Date") by and between **GTx, Inc.**, located at 175 Toyota Plaza, 7<sup>th</sup> Floor, Memphis, Tennessee 38103 (the "Employer"), and **JAMES T. DALTON** (the "Employee"), residing at 9896 Rue Bienville Place, Lakeland, TN 38002.

WHEREAS, Employee was previously a tenured professor of The Ohio State University ("OSU") and an employee of the Employer; and

WHEREAS, the Employee was providing services to the Employer under the terms of an Amended and Restated Employment Agreement that was effective as of November 10, 2008 (the "Prior Employment Agreement"); and

WHEREAS, the Employer and the Employee wish to amend and restate the Prior Employment Agreement as set forth herein; and

WHEREAS, during the course of the Employee's employment with the Employer, the Employer will train and continue to train the Employee and to impart to the Employee proprietary, confidential, and/or trade secret information, data and/or materials of the Employer; and

WHEREAS, the Employer has a vital interest in maintaining its confidential information and trade secrets, as well as rights to inventions, since doing so allows the Employer to compete fairly and enhances the value of the Employer to shareholders and job security for employees; and

WHEREAS, the Employer desires to retain the services of the Employee and the Employee is willing to be employed and continue to be employed with the Employer upon the terms and subject to the conditions set forth in this Agreement;

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained in this Agreement, the employment and continued employment of the Employee in accordance with the terms and conditions of this Agreement, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties, intending to be legally bound, agree and covenant as follows:

#### 1. DEFINITIONS

For the purposes of this Agreement, the following terms have the meanings specified or referred to in this Section 1.

"Agreement" has the meaning set forth in first paragraph of this Agreement.

"Basic Compensation" means Salary and Benefits.

"Benefits" has the meaning stated in Section 3.1(b) of this Agreement.

"Board of Directors" means the Board of Directors of the Employer.

"CEO" has the meaning set forth in Section 2.2.

"Change of Control" means any of the following events: (a) the sale or other disposition of all or substantially all of the assets of the Employer in a single transaction or in a series of transactions (including, without limitation, any liquidation or dissolution of the Employer); (b) any Person or group becomes the beneficial owner, directly, or indirectly, of securities of the Employer representing more than fifty percent (50%) of the combined voting power of the Employer's then outstanding securities other than by virtue of a merger, consolidation or similar transaction (for such purposes, "voting stock" shall mean the capital stock of the Employer of any class or classes, the holders of which are ordinarily, in the absence of contingencies, entitled to vote for the election of members of the Board of Directors (or Persons performing similar functions) of the Employer); (c) a merger or consolidation of the Employer with or into any other entity, if immediately after giving effect to such transaction more than fifty percent (50%) of the issued and outstanding voting stock of the surviving entity of such transaction is held by Persons who were not holders (taking into account their individual and affiliated holdings) as of the Effective Date of at least fifty percent (50%) of the voting stock of the Employer; or (d) individuals who, on the Effective Date, are members of the Board of Directors (the "Incumbent Board") cease for any reason to constitute at least a majority of the members of the Board of Directors; provided, however, that if the appointment or election (or nomination for election) of any new member of the Board of Directors was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member will, for purposes of this Agreement, be considered as a member of the Incumbent Board. A Change of Control shall not include: (1) any transfer or issuance of stock of the Employer to one or more of the Employer's lenders (or to any agents or representatives thereof) in exchange for debt of the Employer owed to any such lenders; (2) any transfer of stock of the Employer to or by any Person or entity, including but not limited to one or more of the Employer's lenders (or to any agents or representatives thereof), pursuant to the terms of any pledge of said stock as collateral for any loans or financial accommodations to the Employer and/or its subsidiaries; (3) any transfer or issuance to any Person or entity, including but not limited to one or more of the Employer's lenders (or to any agents or representatives thereof), in connection with the workout or restructuring of the Employer's debts to any one of the Employer's lenders, including but not limited to the issuance of new stock in exchange for any equity contribution to the Employer in connection with the workout or restructuring of such debt; (4) any transfer of stock by a stockholder of the Employer which is a partnership or corporation to the partners or stockholders in such stockholder or any transfer of stock by a stockholder of the Employer to an entity affiliated with such stockholder or the immediate family of such stockholder or a trust or similar entity for the benefit of such family members; or (5) any transfer or issuance of stock in connection with an offering of the Employer's stock in a registered public transaction not involving a transaction described in Rule 145, promulgated under the Securities Act of 1933, as amended, provided that the Employer's officers and Board of Directors shall not materially change as a result thereof.

"Change of Control Termination" means (i) a Termination Without Cause of the Employee's employment by the Employer (other than for death or disability) within twelve (12) months after a Change of Control or (ii) the Employee's resignation for Good Reason within twelve (12) months after a Change of Control.

"Competing Business" means any individual or entity, other than the Employer, that is engaging in, or proposes to engage in, the development, manufacture, distribution or sale of a Competing Product in North America, South America, Europe and Eastern Europe, and in the countries of Russia, Australia, Japan, China, Taiwan, South Korea and India; provided, however, that an entity that develops, manufactures, distributes or sells a Competing Product in a separate business unit than the business unit in which the Employee is then employed shall not be deemed a Competing Business unless the Employee provides Confidential Information and/or Proprietary Information to the business unit that is engaging in or proposes to engage in the development, manufacture, distribution or sale of a Competing Product.

"Competing Product" means any pharmaceutical or other compound, composition, formulation, method, process, product or material that is competitive with any product of the Employer under development, manufacture, distribution or commercialization at any time from and after January 1, 2005 (the effective date of the Employee's initial employment agreement with the Employer) through the date of termination of the Employee's employment, including, without limitation, small molecules that target androgen, estrogen, glucocorticoid, and/or other hormone receptors for purposes of treating, diagnosing, or imaging humans in health and disease, including treating cancer, osteoporosis and bone loss and muscle loss.

## "Confidential Information and/or Proprietary Information" means any and all:

- information disclosed to the Employee or known by the Employee as a consequence of, or through, the Employee's employment with the Employer since his initial date of employment on January 1, 2005 or pursuant to the Employee's prior relationship with the Employer either through his employment with OSU or under the Consulting Agreement (including information conceived, originated, discovered, or developed in whole or in part by the Employee), not generally known in the relevant trade or industry, about the Employer's business, products, processes, and services; and trade secrets concerning the business and affairs of the Employer, product specifications, data, know-how, formulae, compositions, research, processes, designs, sketches, photographs, graphs, drawings, samples, inventions and ideas, past, current, and planned research and development, current and planned manufacturing or distribution methods and processes, customer lists, current and anticipated customer requirements, price lists, market studies, business plans, computer software and programs (including object code and source code), computer software and database technologies, systems, structures, and architectures (and related formulae, compositions, processes, improvements, devices, know-how, inventions, discoveries, concepts, ideas, designs, methods and information); and any other information, however documented, that is a trade secret within the meaning of Tenn. Code §39-14-138 or any other applicable law; and
- (b) information concerning the business and affairs of the Employer (which includes historical financial statements, financial projections and budgets, historical and projected sales,

capital spending budgets and plans, the names and backgrounds of key personnel, personnel training and techniques and materials), however documented; and

- (c) intellectual property, inventions, methods, processes, techniques, computer programs, devices, products, services, compounds, gene therapy products, pharmaceuticals, substances, vectors, enzymes, genes, concepts, discoveries, improvements, and designs, whether or not patentable in the United States or foreign countries, any trade secrets, information, procedures, technologies, data, results, conclusions, know-how or show-how and business information; and
- (d) notes, analysis, compilations, studies, summaries, and other material prepared by or for the Employer containing or based, in whole or in part, on any information included in the foregoing.
  - "Delayed Initial Payment Date" has the meaning stated in Section 9.2 of this Agreement.
  - "Effective Date" means the date stated in the first paragraph of this Agreement.
  - "Employee" has the meaning stated in the first paragraph of this Agreement.

"Employee Invention" means any idea, invention, technique, modification, process, improvement (whether patentable or not), industrial design (whether registerable or not), work of authorship (whether or not copyright protection may be obtained for it), design, copyrightable work, discovery, trademark, copyright, trade secret, formula, device, method, compound, gene, prodrug, pharmaceutical, structure, product concept, marketing plan, strategy, customer list, technique, blueprint, sketch, record, note, drawing, know-how, data, patent application, continuation application, continuation-in-part application, file wrapper continuation application or divisional application, created, conceived, or developed by the Employee, either solely or in conjunction with others, during the Employee's employment, or a period that includes a portion of the Employee's employment, that relates in any way to, or is useful in any manner in, the business then being conducted or proposed to be conducted by the Employer, and any such item created by the Employee, either solely or in conjunction with others, following termination of the Employee's employment with the Employer, that is based upon or uses Confidential Information and/or Proprietary Information.

<u>"Employer"</u> means GTx, Inc., its successors and assigns, and any of its current or future subsidiaries, or organizations controlled by, controlling, or under common control with it.

- "Expenses" has the meaning stated in Section 4.1 of this Agreement.
- "Good Reason" for termination means that the Employee voluntarily resigns from all positions he then holds with the Employer if and only if:
- (a) one of the following actions have been taken without the Employee's express written consent:
- (i) following a Change of Control, an adverse change in the Employee's authority, duties or responsibilities (including reporting responsibilities) which, without the Employee's consent, represents a material reduction in or a material demotion of the Employee's authority,

duties or responsibilities as in effect immediately prior to a Change of Control or the assignment to the Employee of any duties or responsibilities which are materially inconsistent with and materially adverse to such authority, duties or responsibilities;

- (ii) following a Change of Control, a material reduction in the then current Salary of the Employee;
- (iii) following a Change of Control, the relocation of the Employer's principal employee offices to a location that increases the Employee's one-way commute by more than twenty (20) miles;
- (iv) the failure of the Employer to obtain an agreement reasonably satisfactory to the Employee from any successor or assign of the Employer upon a Change of Control to assume and agree to perform this Agreement in all material respects following the Change of Control; or
- (v) the Employer materially breaches its obligations under this Agreement or any other then-effective agreement with the Employee (including any agreement or arrangement providing for incentive compensation or employee benefits, including the Benefits provided in this Agreement).
  - (b) the Employee provides written notice to the Board of Directors within the thirty (30) day period immediately following such action; and
  - (c) such action is not remedied by the Employer within thirty (30) days following the Employer's receipt of such written notice; and
  - (d) the Employee's resignation is effective not later than sixty (60) days after the expiration of such thirty (30)-day cure period.

"Person" means any individual, corporation (including any non-profit corporation), general or limited partnership, limited liability company, joint venture, estate, trust, association, organization, or governmental body.

<u>"Proprietary Items"</u> means any Proprietary and/or Confidential Information embodied in any document, record, recording, electronic media, formulae, notebook, plan, model, component, device, or computer software or code, whether embodied in a disk or in any other form.

<u>"Release"</u> means a general release of claims in favor of the Employer, in a form acceptable to the Employer, which shall specifically relate to all of the Employee's rights and claims in existence at the time of such execution and shall confirm the Employee's continuing obligations to the Employer (including but not limited to obligations under Section 7 and Section 8 of this Agreement, the Agreement on Condition of Employment and any other confidentiality and/or non-competition agreement with the Employer).

<u>"Salary"</u> has the meaning stated in Section 3.1(a) of this Agreement.

"Section 409A" has the meaning stated in Section 9.2 of this Agreement.

"Termination Date" has the meaning stated in Section 6.1 of this Agreement.

<u>"Termination With Cause"</u> means the termination of the Employee's employment by act of the Board of Directors for any of the following reasons, any of which shall constitute "Cause" for purposes of this Agreement:

- (a) the Employee's conviction of a felony;
- (b) the Employee's theft, embezzlement, misappropriation of or intentional infliction of material damage to the Employer's property or business opportunities;
- (c) the Employee's breach of the provisions contained in Section 7 or Section 8 of this Agreement or the provisions in the Agreement on Condition of Employment regarding confidentiality, non-competition or non-solicitation; or
- (d) the Employee's ongoing willful neglect of or failure to perform his duties hereunder or his ongoing willful failure or refusal to follow any reasonable, unambiguous duly adopted written direction of the CEO that is not inconsistent with the description of the Employee's duties set forth in Section 2.3, if such willful neglect or failure is materially damaging or materially detrimental to the business and operations of the Employer; provided that, if curable, the Employee shall have received written notice of such neglect or failure and shall have continued to engage in such neglect or failure after 30 days following receipt of such notice from the CEO, which notice specifically identifies the manner in which the CEO believes that the Employee has engaged in such neglect or failure. For purposes of this subsection, no act, or failure to act, shall be deemed "willful" unless done, or omitted to be done, by the Employee not in good faith, and without reasonable belief that such action or omission was in the best interest of the Employer.

"Termination Without Cause" means the termination of the Employee's employment by the Employer for any reason other than (i) Termination With Cause, or (ii) a termination by the Employer due to the Employee's death or disability.

# 2. EMPLOYMENT TERMS AND DUTIES

# 2.1 <u>Employment</u>

The Employer hereby continues the employment of the Employee, and the Employee hereby accepts continued employment by the Employer, upon the terms and conditions set forth in this Agreement.

# 2.2 <u>Term</u>

Either the Employee or the Employer may terminate this Agreement and the Employee's employment and compensation with or without Cause or notice, at any time, at

either the Employer's or the Employee's option. No officer or manager of the Employer has the authority to enter into any other agreement for employment for a specified period of time, or to modify or to make any agreement contrary to the foregoing, except by written amendment to this Agreement, dated and signed by the Chief Executive Officer ("CEO") or the President of the Employer.

#### 2.3 <u>Duties</u>

The Employee will continue to have such duties as are assigned or delegated to the Employee by the Board of Directors, the CEO or the President and will initially serve as Vice President, Chief Scientific Officer for the Employer. The Employee will devote his full time, attention, skill and energy to the business of the Employer, will use his best efforts to promote the success of the Employer's business, and will cooperate fully with the Board of Directors, the CEO and the President in the advancement of the best interest of the Employer. The Employee agrees to abide by all bylaws, policies, practices, procedures or rules of the Employer. The Employee may be reassigned or transferred to another management position, as designated by the Board of Directors, the CEO or the President, which may or may not provide the same level of responsibility as the initial assignment, in accordance with the terms and conditions of this Agreement.

#### 3. COMPENSATION

#### 3.1 Basic Compensation

- (a) <u>Salary.</u> As of the Effective Date, the Employee will be paid for each of the twenty-six pay periods during the calendar year approximately \$16,560, which is the equivalent of \$430,560 per calendar year (the "Salary"), subject to review and adjustment from time to time by the CEO in his sole discretion.
- (b) <u>Benefits.</u> The Employee will, during his employment with the Employer, be permitted to participate in such life insurance, hospitalization, major medical, short term disability, long term disability, 401(k) plan and other employee benefit plans of the Employer that may be in effect from time to time, to the extent the Employee is eligible under the terms of those plans (collectively, the "Benefits"). All matters of eligibility for coverage or benefits under any such plan shall be determined in accordance with the provisions of such plan. The Employer reserves the right to change, alter, or terminate any such plan, in its sole discretion, subject to the terms of such plan.
- (c) The Employer may withhold from the Salary or Benefits payable to the Employee all federal, state, local, and other taxes and other amounts as permitted or required pursuant to law, rules or regulations.

#### 4. FACILITIES AND EXPENSES

#### 4.1 General

The Employer will furnish the Employee office space, equipment, supplies, and such other facilities and personnel as the Employer deems necessary or appropriate for the

performance of the Employee's duties under this Agreement, including sufficient capital equipment as determined by the CEO to support the needs of a preclinical research & development department. The Employer will pay on behalf of the Employee (or reimburse the Employee for) reasonable expenses incurred by the Employee at the request of, or on behalf of, the Employer in the performance of the Employee's duties pursuant to this Agreement, and in accordance with the Employer's employment policies, including reasonable expenses incurred by the Employee in attending conventions, seminars, and other business meetings, in appropriate business entertainment activities, and for promotional expenses (the "Expenses"). To the extent that any reimbursements payable or in-kind benefits provided pursuant to this Agreement are subject to the provisions of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), any such reimbursements payable pursuant to this Agreement shall be paid no later than December 31 of the year following the year in which the expense was incurred, the amount of expenses reimbursed or in-kind benefits provided in one year shall not affect the amount eligible for reimbursement or in-kind benefits to be provided in any subsequent year, and the right to reimbursement or in-kind benefits under this Agreement will not be subject to liquidation or exchange for another benefit. The Employee must file expense reports with respect to such expenses in accordance with the Employer's policies.

# 5. VACATIONS AND HOLIDAYS

The Employee will be eligible to accrue paid vacation each calendar year in accordance with the vacation policies of the Employer in effect from time to time. Under such policies of the Employer as of the Effective Date, the Employee is eligible to accrue up to four (4) weeks of paid vacation each calendar year. Vacation must be taken by the Employee at such time or times during the calendar year as approved by the CEO or President. Additionally, the Employee will be entitled to the paid holidays set forth in the Employer's policies. Any accrued vacation days and holidays that are not used by the Employee by the end of the calendar year in which they were accrued will be lost and may not be used in any subsequent calendar year; *provided*, *however*, that upon termination of the Employee's employment, the Employee will be paid the equivalent compensation attributable to any accrued vacation days which were accrued during the calendar year in which such termination occurs and are not otherwise used by the Employee as of the date of such termination.

#### 6. TERMINATION

6.1 At-Will Employment. The Employee's employment is at-will, which means that either the Employee or the Employer may terminate this Employment Agreement (with the exception of the provisions of Sections 7 and 8 which shall survive termination of this Agreement and the Employee's employment) with or without Cause or notice, at any time at either the Employee's or the Employer's option. Except as otherwise specifically set forth herein, or as provided in any plan documents governing any compensatory equity awards that have been or may be granted to the Employee from time to time in the sole discretion of the Employer or an affiliate, upon termination of the Employee's employment the Employer shall be released from any and all further obligations under this Agreement, except the Employer shall be obligated to pay the Employee his accrued but unpaid Basic Compensation and Expenses owing to the Employee through the day on which the Employee's employment is terminated (the

"Termination Date"). The Employee's obligations under Sections 7 and 8 shall continue pursuant to the terms and conditions of this Agreement.

- 6.2 <u>Termination Upon Death</u>. The employment of the Employee shall terminate on the date of the Employee's death, in which event the Employee's accrued but unpaid Basic Compensation and Expenses, owing to the Employee through the date of the Employee's death, shall be paid to his estate. The Employee's estate will not be entitled to any other compensation under this Agreement.
- 6.3 <u>Termination Related to a Change of Control</u>. As additional consideration for the covenants in Section 7 and Section 8, in the event of a Change of Control Termination, and provided that the Employee signs and allows to become effective a Release within the time period provided therein (but not later than the 60<sup>th</sup> day following the Termination Date, such latest permitted effective date is the "Release Deadline" for purposes of this Agreement), then subject to Section 9.2:
  - (a) The Employee shall receive as severance one (1) year of his Salary, payable in accordance with the Employer's then current payroll schedule over the one (1) year period following the Termination Date, less deductions required by law; *provided, however*, that if the Employee terminates his employment on account of a material reduction in his Salary, as provided in paragraph (a)(ii) of the definition of Good Reason, the amount of such severance shall be based on the Employee's Salary immediately prior to such reduction. Notwithstanding the foregoing payment schedule, no severance will be paid prior to the effective date of the Release. Subject to Section 9.2, on the first regular payroll pay day following the effective date of the Release, the Employer will pay the Employee the severance that the Employee would otherwise have received on or prior to such date but for the delay in payment related to the effectiveness of the Release, with the balance of the severance being paid as originally scheduled.
  - (b) If the Employee timely elects group health insurance coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA"), the Employer will pay the Employee's monthly COBRA premiums (including the cost of eligible dependent coverage, if any) through the earliest of the following (the "COBRA Payment Period"): (i) for twelve (12) months following the Termination Date; (ii) the date that the Employee becomes eligible for group health insurance coverage through a new employer; or (iii) the date that the Employee is no longer eligible for COBRA coverage. Notwithstanding the foregoing, if at any time the Employer determines, in its sole discretion, that its payment of the Employee's COBRA premiums would result in a violation of applicable law (including, without limitation, Section 105(h)(2) of the Code and Section 2716 of the Public Health Service Act), then in lieu of paying such COBRA premiums, the Employer will pay the Employee on the last day of each remaining month of the COBRA Payment Period a fully taxable cash payment equal to the COBRA premium for that month, subject to applicable tax withholding (such amount, the "Special Severance Payment"); provided, however, that any such Special Severance Payment will be made without regard to the Employee's payment of COBRA premiums and for purposes of any such Special Severance Payment, the "COBRA Payment Period" will be

determined without regard to the expiration of the Employee's eligibility for continued coverage under COBRA.

#### 7. NON-DISCLOSURE COVENANT; EMPLOYEE INVENTIONS

#### 7.1 <u>Acknowledgements by the Employee</u>

The Employee acknowledges and agrees that (a) during the course of his employment and as a part of his employment, the Employee will be afforded access to Confidential Information and/or Proprietary Information; (b) public disclosure of such Confidential Information and/or Proprietary Information could have an adverse effect on the Employer and its business; (c) because the Employee possesses substantial technical expertise and skill with respect to the Employer's business, the Employer desires to obtain exclusive ownership of each Employee Invention, and the Employer will be at a substantial competitive disadvantage if it fails to acquire exclusive ownership of each Employee Invention; and (d) the provisions of this Section 7 are reasonable and necessary to prevent the improper use or disclosure of Confidential Information and/or Proprietary Information and to provide the Employer with exclusive ownership of all Employee Inventions.

# 7.2 <u>Agreements of the Employee</u>

In consideration of the compensation and benefits to be paid or provided to the Employee by the Employer under this Agreement and otherwise, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Employee covenants and agrees as follows:

# (a) <u>Confidentiality</u>

- (i) That all of such Confidential Information and/or Proprietary Information is a unique asset of the business of the Employer, the disclosure of which would be damaging to the Employer.
- (ii) That the Employee will not at any time, whether during or after termination or cessation of the Employee's employment, except as authorized by the Employer and for its benefit, use, divulge or disclose (or enable anyone else to use, divulge or disclose) to any Person, association or entity any Confidential Information and/or Proprietary Information which the Employee presently possesses or which the Employee may obtain during the course of the Employee's employment with respect to the business, finances, customers or affairs of the Employer or trade secrets, developments, methods or other information and data pertaining to the Employer's business. The Employee shall keep strictly confidential all matters and information entrusted to the Employee and shall not use or attempt to use any such Confidential Information and/or Proprietary Information in any manner which may injure or cause loss or may be calculated to injure or cause loss, whether directly or indirectly, to the Employer.
- (iii) That during the course of this Agreement or at any time after termination, the Employee will keep in strictest confidence and will not

disclose or make accessible to any other Person without the prior written consent of the Employer, the Confidential Information and/or Proprietary Information; the Employee agrees: (a) not to use any such Confidential Information and/or Proprietary Information for himself or others; and (b) not to take any such material or reproductions thereof from the Employer's facilities at any time during his employment except, in each case, as required in connection with the Employee's duties to the Employer.

- (iv) The Employee agrees to hold in confidence, and not to distribute or disseminate to any Person or entity for any reason, any Confidential Information and/or Proprietary Information of the Employer under this Agreement, or information relating to experiments or results obtained based on the duties of the Employee, except for information which: (a) is in or which becomes a part of the public domain not as a result of a breach of this Agreement, (b) is information lawfully received from a third party who had the right to disclose such information or (c) is required by legal process before a court of proper jurisdiction (by oral questions, deposition, interrogatories, requests for information or documents, subpoena, civil investigative domain or other similar process) to disclose all or any part of any Confidential Information and/or Proprietary Information, provided that the Employee will provide the Employer with prompt notice of such request or requirement, as well as notice of the terms and circumstances surrounding such request or requirements, so that the Employer may seek an appropriate protective order or waive compliance with the provisions of this Agreement. In such case, the parties will consult with each other on the advisability of pursuing any such order or other legal action or available step to resist or narrow such request or requirement. If, failing the entry of a protective order or the receipt of a waiver hereunder, the Employee is, in the opinion of counsel reasonably acceptable to the Employer, legally compelled to disclose Confidential Information and/or Proprietary Information, the Employee may disclose that portion of such information which counsel advises is necessary to disclose. The Employee will not oppose any action by the Employer to prevent disclosure pursuant to an appropriate protective order or to request other reliable assurances that confidential treatment will be accorded to the disclosure of such information.
- (v) Upon termination of this Agreement by either party or upon written notice by the Employer, the Employee shall promptly redeliver to the Employer, or, if requested by the Employer, promptly destroy all written Confidential Information and/or Proprietary Information and any other written material containing any information included in the Confidential Information and/or Proprietary Information (whether prepared by the Employer, the Employee, or a third party), and will not retain any copies, extracts or other reproductions in whole or in part of such written Confidential Information and/or Proprietary Information (and upon request certify such redelivery or destruction to the Employer in a written instrument reasonably acceptable to the Employer and its counsel).
- (vi) This Agreement and the terms and conditions recited herein are confidential and non-public, except as may be expressly permitted by the Employer. The Employee agrees not to disclose the contents of this Agreement to any Person or entity, including, but not limited to the press, other media, any public body, or any competitor of the Employer, except to the Employee's legal counsel, or as may be required by law.
- (vii) Any trade secrets of the Employer will be entitled to all of the protections and benefits of State of Tennessee law and any other applicable law. If any information that the Employer deems to be a trade secret is found by a court of competent jurisdiction not be to a trade secret for purposes of this Agreement, such information will, nevertheless, be considered Confidential Information and/or Proprietary Information for purposes of this Agreement. The Employee hereby waives any requirement that the Employer submits proof of the economic value of any trade secret or posts a bond or other security.
- (viii) None of the foregoing obligations and restrictions applies to any part of the Confidential Information and/or Proprietary Information that the Employee demonstrates was or became generally available to the public other than as a result of a disclosure by the Employee.
- (ix) The Employee will not remove from the Employer's premises (except to the extent such removal is for purposes of the performance of the Employee's duties at home or while traveling, or except as otherwise specifically authorized by the Employer) any Proprietary Items. The Employee recognizes that, as between the Employer and the Employee, all of the Proprietary Items, whether or not developed by the Employee, are the exclusive property of the Employer. Upon termination of this Agreement by either party, or upon the request of the Employer during the employment of the Employee, the Employee will return to the Employer all of the Proprietary Items in the Employee's possession or subject to the Employee's control, and the Employee shall not retain any copies, abstracts, sketches, or other physical or electronic embodiment of any of the Proprietary Items.
- (x) During the Employee's employment with the Employer, the Employee will not improperly use or disclose any confidential information or trade secrets, if any, of any former employer or any other Person to whom the Employee has an obligation of confidentiality, and the Employee will not bring onto the premises of the Employer any unpublished documents or any property belonging to any former employer or any other Person to whom the Employee has an obligation of confidentiality unless consented to in writing by that former employer or Person.

#### (b) <u>Employee Inventions</u>

(i) Each Employee Invention will belong exclusively to the Employer. The Employee agrees that the Employer shall have sole and exclusive

ownership rights in any conception, invention, trade secrets, information, ideas, improvement, substance, know-how, whether or not patentable, arising out of, resulting from, or derivative of: (1) the work or services of the Employee, or (2) within the scope of the duties of the Employee, or (3) using any materials, compounds, devices, or monies of the Employer. Any resulting or derivative rights, including patent rights, shall become the exclusive property of the Employer and the Employer shall be entitled to the entire right, title and interest with respect hereto. The Employee agrees, without additional compensation, to convey, assign the entire right, title, and interest in and to any inventions for the United States and all foreign jurisdictions to the Employer arising out of, resulting from, or derivative of: (1) the work or services of the Employee, or (2) within the scope of the duties of the Employee, or (3) using any materials, compounds, devices, or monies.

- (ii) The Employer shall retain the entire right, title and interest in and to any and all Confidential Information and/or Proprietary Information provided by the Employee to the Employee and to any methods, compounds, improvements, substances, and compositions using or incorporating such Confidential Information and/or Proprietary Information.
- (iii) The Employee agrees that Confidential Information and/or Proprietary Information provided to the Employee by the Employer shall be used for work purposes only and shall not be used for any other uses, studies, experiments or tests.
- (iv) The Employee agrees that he will promptly disclose to the Employer, or any Persons designated by the Employer, all the Employee Inventions, made or conceived or reduced to practice or learned by him, either alone or jointly with others, during the employment of the Employee. The Employee further agrees to assist the Employer in every proper way (but at the Employer's expense) to obtain and from time to time enforce patents, copyrights or other rights on Employee Inventions in any and all countries, and to that end the Employee will execute all documents necessary: (a) to apply for, obtain and vest in the name of the Employer alone (unless the Employer otherwise directs) letters patent, copyrights or other analogues protection in any country throughout the world and when so obtained or vested to renew and restore the same; and (b) to defend (including the giving of testimony and rendering any other assistance) any opposition proceedings in respect of such applications and any opposition proceedings or petitions or applications for revocation of such letters patent, copyright or other analogous protection. The Employee's obligation to assist the Employer in obtaining and enforcing patents and copyrights for Employee Inventions in any and all countries shall continue beyond and after the termination of the Employee.
- (v) Any copyrightable work whether published or unpublished created by the Employee in connection with or during the performance of services below shall be considered a work made for hire, to the fullest extent permitted by

law and all right, title and interest therein, including the worldwide copyrights, shall be the property of the Employer as the employer and party specially commissioning such work. In the event that any such copyrightable work or portion thereof shall not be legally qualified as a work made for hire, or shall subsequently be so held, the Employee agrees to properly convey to the Employer, without additional compensation, the entire right, title and interest in and to such work or portion thereof, including but not limited to the worldwide copyrights, extensions of such copyrights, and renewal copyrights therein, and further including all rights to reproduce the copyrighted work in copies or phonorecords, to prepare derivative works based on the copyrighted work, to distribute copies of the copyrighted work, to perform the copyrighted work publicly, to display the copyrighted work publicly, and to register the claim of copyright therein and to execute any and all documents with respect hereto.

(vi) The Employee may not publish or disclose any Confidential Information and/or Proprietary Information relating to, arising from, derivative of, or as a result of his employment pursuant to this Agreement, including but not limited to: information, improvements, results, experiments, data, or methods that makes reference to any of the Confidential Information and/or Proprietary Information. Any work performed under, or arising from, or a result of his employment with the Employer shall not be published or disclosed in written, electronic, or oral form without the express written permission of the Employer.

#### 7.3 <u>Disputes or Controversies</u>

The Employee recognizes that should a dispute or controversy arising from or relating to this Agreement be submitted for adjudication to any court, arbitration panel, or other third party, the preservation of the secrecy of Confidential Information and/or Proprietary Information may be jeopardized. All pleadings, documents, testimony, and records relating to any such adjudication will be maintained in secrecy and will be available for inspection by the Employer, the Employee, and their respective attorneys and experts, who will agree, in advance and in writing, to receive and maintain all such information in secrecy, except as may be limited by them in writing.

# 7.4 <u>Agreement on Condition of Employment</u>

As a condition of employment, the Employee agrees to execute and abide by the Employee's current form of Agreement on Condition of Employment, which may be amended by the parties from time to time without regard to this Agreement. The Agreement on Condition of Employment contains provisions that are intended by the parties to survive and do survive termination or expiration of this Agreement. In the event that the terms of this Agreement differ from or are in conflict with the Agreement on Condition of Employment, this Agreement shall control.

#### 8. NON-COMPETITION

#### 8.1 <u>Acknowledgments by the Employee</u>

The Employee understands and recognizes that the Employee's services provided to the Employer are special, unique, unusual, extraordinary and intellectual in character. Subject to Section 8.4 below, the Employee agrees that, during the employment of the Employee and for a period of two (2) years from the date of termination of the Employee's employment with the Employer, he will not in any manner, directly or indirectly, on behalf of himself or any Person, firm, partnership, joint venture, corporation or other business entity, engage or invest in, own, manage, operate, finance, control or participate in the ownership, management, operation, financing, or control of, be employed by, associated with, or in any manner connected with, lend the Employee's name or similar name to, lend the Employee's credit to or render services or advice to, enter into or engage in any Competing Business; *provided, however*, that the Employee may purchase or otherwise acquire up to (but not more than) one percent of any class of securities of any enterprise (but without otherwise participating in the activities of such enterprise) if such securities are listed on any national or regional securities exchange or have been registered under Section 12(g) of the Securities Exchange Act of 1934.

8.2 In consideration of the acknowledgements by the Employee, and in consideration of the compensation and benefits to be paid or provided to the Employee by the Employer, the Employee covenants that, subject to Section 8.4 below, he will not, directly or indirectly, whether for the Employee's own account or the account of any other Person (i) at any time during the employment of the Employee and for a period of two (2) years from the termination of the Employee's employment with the Employer, solicit, employ, or otherwise engage as an employee, independent contractor, or otherwise,

any Person who is or was an employee of the Employer at any time during the Employee's employment with the Employer or in any manner induce or attempt to induce any employee of the Employer to terminate his employment with the Employer; or (ii) at any time during the employment of the Employee with the Employer and for two (2) years from the termination of the Employee's employment with the Employer, interfere with the Employer's relationship with any Person, including any Person who at any time during the Employee's employment with the Employer was an employee, contractor, supplier, or customer of the Employer.

- 8.3 In further consideration of these promises, the Employee agrees that he will not at any time during or after the Employee's employment with the Employer, disparage the Employer or any of its shareholders, directors, officers, employees, parents, subsidiaries, affiliates or agents in any manner likely to be harmful to them or their business, business reputation or personal reputation; *provided*, *however*, that the Employee may respond accurately and fully to any question, inquiry or request for information when required by legal process.
- 8.4 <u>Change of Control</u>. In the event of a Change of Control Termination, the Employee's obligations under Sections 8.1 and 8.2 above and the non-competition and non-solicitation provisions in the Agreement on Condition of Employment shall expire one (1) year from the date of termination of his employment with the Employer (or any entity acquiring the Employer as a result of a Change of Control).
- 8.5 If any covenant in Section 8 is held to be unreasonable, arbitrary, or against public policy, such covenant will be considered to be divisible with respect to scope,

time, and geographic area, and such lesser scope, time, or geographic area, or all of them, as a court of competent jurisdiction may determine to be reasonable, not arbitrary, and not against public policy, will be effective, binding, and enforceable against the Employee.

The period of time applicable to any covenant in Section 8 will be extended by the duration of any violation by the Employee of such covenant.

The Employee will, while the covenants under Section 8 are in effect, give notice to the Employer, within ten days after accepting any other employment, of the identity of the Employee's employer. The Employer may notify such employer that the Employee is bound by this Agreement and, at the Employer's election, furnish such employer with a copy of this Agreement or relevant portions thereof.

#### 9. TAX MATTERS

- 9.1 <u>Responsibility for Tax Obligations</u>. The Employee agrees that he is responsible for any applicable taxes of any nature (including any penalties or interest that may apply to such taxes) that the Employer reasonably determines apply to any payment or equity award made to the Employee hereunder (or any arrangement contemplated hereunder), that the Employee's receipt of any payment or benefit hereunder is conditioned on the Employee's satisfaction of any applicable withholding or similar obligations that apply to such payment or benefit, and that any cash payment owed to the Employee hereunder will be reduced to satisfy any such withholding or similar obligations that may apply thereto.
- within the meaning of Section 409A of the Code and the regulations and other guidance thereunder and any state law of similar effect (collectively "Section 409A") shall not commence in connection with the Employee's termination of employment unless the Employee has also incurred a "separation from service," as such term is defined in Treasury Regulation Section 1.409A-1(h) (without regard to any permissible alternative definition thereunder) ("Separation from Service"). It is intended that each installment of the payments and benefits provided for in this Agreement is a separate "payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2)(i). For the avoidance of doubt, it is intended that payments of the amounts set forth in this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9). However, if the Employer determines that the payments and benefits provided under this Agreement constitute "deferred compensation" under Section 409A and the Employee is, on the date of the Employee's Separation from Service, a "specified employee" of the Employer or any successor entity thereto, as such term is defined in Section 409A(a)(2)(B)(i) of the Code, then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of any such payments or benefits shall be delayed as follows: on the earlier to occur of (i) the date that is six (6) months and one (1) day after the Employee's Separation from Service or (ii) the date of the Employee's death (such earlier date, the "Delayed Initial Payment Date"), the Employer shall (A) pay to the Employee a lump sum amount equal to the sum of the payments that the Employee would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the payments had not been so delayed pursuant to

this Section 9.2 and (B) commence paying the balance of the payments in accordance with the applicable payment schedules set forth in this Agreement. If the Employer determines that any payments or benefits provided under this Agreement constitute "deferred compensation" under Section 409A and the Release could become effective in the calendar year following the calendar year in which the Employee's Separation from Service occurs, the Release will not be deemed effective any earlier than the Release Deadline for purposes of determining the timing of payment of any such payments or benefits.

# 9.3 <u>Parachute Payments</u>

(a) Notwithstanding anything in this Agreement to the contrary, if any payment or benefit the Employee will or may receive from the Employer or otherwise (a "280G Payment") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then any such 280G Payment pursuant to this Agreement (a "Payment") shall be equal to the Reduced Amount. The "Reduced Amount" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount (i.e., the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in the Employee's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "Reduction Method") that results in the greatest economic benefit for the Employee. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "Pro Rata Reduction Method").

- (b) Notwithstanding any provision of Section 9.3(a) to the contrary, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for the Employee as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (*e.g.*, being terminated without Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.
- (c) If the Employee receives a Payment for which the Reduced Amount was determined pursuant to clause (x) of Section 9.3(a) and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise

Tax, the Employee shall promptly return to the Employer a sufficient amount of the Payment (after reduction pursuant to clause (x) of Section 9.3(a)) so that no portion of the remaining Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) of Section 9.3(a), the Employee shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

#### 10. CLAWBACK/RECOVERY

Any amounts paid to the Employee by the Employer, whether or not under this Agreement or any incentive plan of the Employer, will be subject to recoupment in accordance with The Sarbanes-Oxley Act of 2002, The Dodd-Frank Wall Street Reform and Consumer Protection Act and any implementing regulations under these acts, any clawback policy adopted by the Employer, or as otherwise required by applicable law. In addition, in consideration of the Employee's continued employment with the Employer and in recognition of the Employee's position of trust and authority with the Employer, the Employee agrees to promptly consent to any clawback policy adopted by the Employer.

#### 11. GENERAL PROVISIONS

# 11.1 <u>Injunctive Relief and Additional Remedy</u>

The Employee acknowledges that the injury that would be suffered by the Employer as a result of a breach of the provisions of this Agreement (including any provision of Sections 7 and 8) would be irreparable and that an award of monetary damages to the Employer for such a breach would be an inadequate remedy. Consequently, the Employer will have the right, in addition to any other rights it may have, to obtain injunctive relief to restrain any breach or threatened breach or otherwise to specifically enforce any provision of this Agreement, and the Employer will not be obligated to post bond or other security in seeking such relief. Without limiting the Employer's rights under this Section 11 or any other remedies of the Employer, if the Employee breaches any of the provisions of Section 7 or 8, the Employer will have the right to cease making any payments otherwise due to the Employee under this Agreement.

#### 11.2 Covenants of Sections 7 and 8 are Essential and Independent Covenants

The covenants by the Employee in Sections 7 and 8 are essential elements of this Agreement, and without the Employee's agreement to comply with such covenants, the Employer would not have entered into this Agreement or employed or continued the employment of the Employee. The Employer and the Employee have independently consulted their respective counsel and have been advised in all respects concerning the reasonableness and propriety of such covenants, with specific regard to the nature of the business conducted by the Employer. The Employee agrees that this Agreement does not prevent him from earning a living or pursuing his career and that he has the ability to secure other non-competitive employment using his marketable skills. The Employee agrees that the restrictions contained in this Agreement are reasonable, proper, and necessitated by the Employer's legitimate business interests, including without limitation, the Employer's Confidential and/or Proprietary Information and the goodwill of its customers.

The Employee's covenants in Sections 7 and 8 are independent covenants and the existence of any claim by the Employee against the Employer under this Agreement or otherwise will not excuse the Employee's breach of any covenant in Section 7 or 8.

If the Employee's employment hereunder is terminated by either party, this Agreement will continue in full force and effect as is necessary or appropriate to enforce the covenants and agreements of the Employee in Sections 7 and 8.

# 11.3 <u>Representations and Warranties by the Employee</u>

The Employee represents and warrants to the Employer that the execution and delivery by the Employee of this Agreement do not, and the performance by the Employee of the Employee's obligations hereunder will not, with or without the giving of notice or the passage of time, or both:

(a) violate any judgment, writ, injunction, or order of any court, arbitrator, or governmental agency applicable to the Employee; or (b) conflict with, result in the breach of any provisions of or the termination of, or constitute a default under, any agreement to which the Employee is a party or by which the Employee is or may be bound.

### 11.4 Waiver

The rights and remedies of the parties to this Agreement are cumulative and not alternative. Neither the failure nor any delay by either party in exercising any right, power, or privilege under this Agreement will operate as a waiver of such right, power, or privilege, and no single or partial exercise of any such right, power, or privilege will preclude any other or further exercise of such right, power, or privilege or the exercise of any other right, power, or privilege. To the maximum extent permitted by applicable law, (a) no claim or right arising out of this Agreement can be discharged by one party, in whole or in part, by a waiver or renunciation of the claim or right unless in writing signed by the other party; (b) no waiver that may be given by a party will be applicable except in the specific instance for which it is given; and (c) no notice to or demand on one party will be deemed to be a waiver of any

obligation of such party or of the right of the party giving such notice or demand to take further action without notice or demand as provided in this Agreement.

#### 11.5 <u>Binding Effect; Delegation of Duties Prohibited</u>

This Agreement shall inure to the benefit of, and shall be binding upon, the parties hereto and their respective successors, assigns, heirs, and legal representatives, including any entity with which the Employer may merge or consolidate or to which all or substantially all of its assets may be transferred. The duties and covenants of the Employee under this Agreement, being personal, may not be delegated.

#### 11.6 Notices

All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when (a) delivered by hand (with written confirmation of receipt), (b) sent by facsimile (with written confirmation of receipt), provided that a copy is mailed by registered mail, return receipt requested, or (c) when received by the addressee, if sent by a nationally recognized overnight delivery service (receipt

requested), in each case to the appropriate addresses and facsimile numbers set forth below (or to such other addresses and facsimile numbers as a party may designate by notice to the other parties):

If to the Employer: GTx, Inc.

175 Toyota Plaza, 7<sup>th</sup> Floor Memphis, Tennessee 38103

Attention: Vice President, Chief Legal Officer

Facsimile No.: 901-844-8075

If to the Employee: James T. Dalton

9896 Rue Bienville Place Lakeland, Tennessee 38002

The Employee shall notify the Employer in writing of any change of his address. Otherwise, the Employer shall send all notices to the Employee's address herein.

# 11.7 <u>Entire Agreement; Amendments</u>

This Agreement, including the Agreement on Condition of Employment, contains the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral or written, between the parties hereto with respect to the subject matter hereof. The Employer and the Employee further acknowledge and agree that the provisions of this Agreement amend and supersede the Prior Employment Agreement, which shall be of no further force and effect. This Agreement may not be amended orally, but only by an agreement in writing signed by the Employee and a duly authorized officer or director of the Employer.

#### 11.8 Governing Law

This Agreement will be governed by the laws of the State of Tennessee without regard to conflicts of laws principles.

#### 11.9 Jurisdiction

Any action or proceeding seeking to enforce any provision of, or based on any right arising out of, this Agreement shall be brought against either of the parties in the courts of the State of Tennessee, County of Shelby, or, if it has or can acquire jurisdiction, in the United States District Court for the Western District of Tennessee, and each of the parties consents to the jurisdiction of such courts (and of the appropriate appellate courts) in any such action or proceeding and waives any objection to venue laid therein. Process in any action or proceeding referred to in the preceding sentence may be served on either party anywhere in the world.

# 11.10 <u>Section Headings, Construction</u>

The headings of Sections in this Agreement are provided for convenience only and will not affect its construction or interpretation. All references to "Section" or "Sections" refer to the corresponding Section or Sections of this Agreement unless otherwise specified. All

words used in this Agreement will be construed to be of such gender or number as the circumstances require. Unless otherwise expressly provided, the word "including" does not limit the preceding words or terms.

# 11.11 Severability

If any provision of this Agreement is held invalid or unenforceable by any court of competent jurisdiction, the other provisions of this Agreement will remain in full force and effect. Any provision of this Agreement held invalid or unenforceable only in part or degree will remain in full force and effect to the extent not held invalid or unenforceable.

#### 11.12 Counterparts

This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of this Agreement and all of which, when taken together, will be deemed to constitute one and the same agreement.

# 11.13 Waiver of Jury Trial

THE PARTIES HERETO HEREBY WAIVE A JURY TRIAL IN ANY LITIGATION WITH RESPECT TO THIS AGREEMENT, OR ARISING OUT OF OR CONCERNING THE EMPLOYEE'S EMPLOYMENT WITH THE EMPLOYER OR TERMINATION THEREOF.

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date above first written above.

# JAMES T. DALTON

/s/ James T. Dalton

GTx, Inc.

By: /s/ Henry P. Doggrell Name: Henry P. Doggrell Title:

VP, Chief Legal Officer

# 2013 Compensation Information for Registrant's Executive Officers

The table below provides information regarding (i) the base salary of each executive officer of GTx, Inc. (the "Company"), effective as of January 1, 2013, and (ii) the target cash bonus award for each of the Company's executive officers under the Company's Executive Bonus Compensation Plan for fiscal 2013, expressed as a percentage of applicable base salary:

	2013 Annual Base Salary	2013 Target Bonus
Title	(\$)	(%)
ief Executive Officer and Vice-Chairman of the Board	565,110	65
ce President, Chief Financial Officer and Treasurer	320,856	30
esident and Chief Operating Officer	491,646	55
ce President, Chief Scientific Officer	430,560	30
ce President, Chief Legal Officer and Secretary	363,576	30
	ief Executive Officer and Vice-Chairman of the Board re President, Chief Financial Officer and Treasurer resident and Chief Operating Officer re President, Chief Scientific Officer	Title Base Salary (\$)  ief Executive Officer and Vice-Chairman of the Board 565,110 the President, Chief Financial Officer and Treasurer 320,856 esident and Chief Operating Officer 491,646 the President, Chief Scientific Officer 430,560

#### GTX, INC.

#### **DIRECTORS' DEFERRED COMPENSATION PLAN**

# (AMENDED AND RESTATED EFFECTIVE FEBRUARY 14, 2013)

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#### **ARTICLE 1**

#### DEFINITIONS

- **1.1** "*Board*" shall mean the Board of Directors of GTx, Inc.
- **1.2** "Cash Account" shall mean the account created by the Company pursuant to Article III of this Plan in accordance with an election by a Director to receive deferred cash compensation under Article II hereof.
- **1.3** "Capitalization Adjustment" means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or to the number of shares of Common Stock credited to any Stock Account, without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, stock split, reverse stock split, combination of shares, exchange of shares, change in corporate structure, or any similar equity restructuring transaction, as that term is used in Statement of Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company will not be treated as a Capitalization Adjustment.
  - **1.4** "Common Stock" shall mean the Common Stock of the Company.
  - **1.5** "Company" means GTx, Inc.
- **1.6** "*Director*" shall mean a member of the Board of Directors of the Company who is not an employee of the Company or any of its subsidiaries.
  - 1.7 "Effective Date" means the date on which the Plan, as amended and restated, is approved by the Board.
  - **1.8** "Fees" shall mean amounts earned for serving as a member of the Board, including any committees of the Board.
  - **1.9** "*He*", "*Him*" or "*His*" shall apply equally to male and female members of the Board.
  - **1.10** *"Plan"* shall mean the GTx, Inc. Directors' Deferred Compensation Plan, as it may be amended from time to time.
- **1.11** *"Stock Account"* shall mean the account created by the Company pursuant to Article III of this Plan in accordance with an election by a Director to receive stock compensation under Article II hereof.
- **1.12** "Stock Value" shall mean, for any given day, the price per share equal to the consolidated closing bid price for the Common Stock on such day, or the immediately preceding Trading Day if such day is not a Trading Day; provided, however, that in the event the Common

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Stock is not then listed on a national securities exchange or admitted to unlisted trading privileges on any such exchange, the "Stock Value" shall be determined in good faith by the Board. The definition of "Stock Value" in this Section 1.12 is intended to comply with the definition of "Market Value" under the Listing Rules adopted by The NASDAQ Stock Market LLC ("NASDAQ") so that this Plan constitutes a plan or arrangement exempt from the requirement of shareholder approval under NASDAQ Listing Rule 5635(c)(2). Any ambiguities shall be construed and administered in a way that is in compliance with such requirements and rules.

- **1.13** "*Trading Day*" means any day on which the exchange(s) or market(s) on which shares of Common Stock are listed or quoted is open for trading.
  - **1.14** "Year" shall mean calendar year.

#### **ARTICLE 2**

#### **ELECTION TO DEFER**

- **2.1** A Director may elect, on or before December 31 of any Year, to defer payment of all or a specified part of all Fees earned during the Year following such election. Any person who shall become a Director during any Year, and who was not a Director of the Company on the preceding December 31, may elect, within thirty (30) days after becoming a Director, to defer payment of all or a specified part of such Fees earned during the remainder of such Year.
- **2.2** The election to participate in the Plan and defer payments under the Plan shall be designated by submitting a letter in the form attached hereto as Appendix A to the Secretary of the Company by the applicable date under Paragraph 2.3.
- 2.3 The election is irrevocable with respect to the Year to which it relates upon the submission of such election to the Secretary of the Company. The election first submitted by a Director shall remain effective with respect to Fees earned during subsequent Years, unless the Director terminates it by written request delivered to the Secretary of the Company prior to the commencement of the Year for which the termination is first effective.

#### **ARTICLE 3**

#### **DEFERRED COMPENSATION ACCOUNTS**

- **3.1** The Company shall maintain separate memorandum accounts for the Fees deferred by each Director. Each Director shall be fully vested at all times in any amounts credited to his Cash Account and Stock Account.
- 3.2 The Company shall credit, on the date Fees become payable, to the Cash Account of each Director the deferred portion of any Fees due the Director as to which an election to receive cash has been made. Fees deferred in the form of cash (and interest thereon) shall be held in the general funds of the Company.

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- 3.3 On the first day of each quarter, the Company shall credit the Cash Account of each Director with interest calculated on the basis of the balance in such account on the first day of each month of the preceding quarter at the prime rate of interest then in effect at First Horizon National Bank, Memphis, Tennessee, or if no such rate shall be available, then such rate of interest as is then published in the Wall Street Journal as the prevailing prime rate of interest.
- 3.4 The Company shall credit the Stock Account of each Director who has elected to receive deferred compensation in the form of Common Stock with the number of shares of Common Stock equal in value to (i) the deferred portion of any Fees due the Director as to which an election to receive Common Stock has been made, divided by the Stock Value on the date such Fees otherwise would have been paid, (ii) any cash dividends (or the fair market value of dividends paid in property other than dividends payable in Common Stock) payable on the number of shares of Common Stock represented in each Director's Stock Account, divided by the Stock Value on the date such cash dividends are paid, and (iii) any stock dividends payable on the number of shares of Common Stock represented in each Director's Stock Account, equal in value to the Stock Value of such stock dividends on the date such stock dividends are paid. Credits that are made to each Director's Stock Account pursuant to the preceding sentence shall be made, with respect to any Fees, on the date that such Fees become payable and, with respect to any dividends, on the date that such dividends are paid on Common Stock. If adjustments are made to the outstanding shares of Common Stock as a result of stock-splits, recapitalizations, mergers, consolidations and the like, an appropriate adjustment also will be made in the number of shares of Common Stock credited to the Director's Stock Account.
  - **3.5** Common Stock shall be computed to three decimal places.
- **3.6** The right to receive Common Stock at a later date shall not entitle any person to rights of a stockholder with respect to such Common Stock unless and until shares of Common Stock have been issued to such person pursuant to Article IV hereof.
- **3.7** The Company shall set aside a sufficient number of shares of Common Stock to meet the needs of the Plan, provided that the Company shall not be required to issue any fractional shares of Common Stock, and any fractional share amounts shall be paid in cash to the Director, at the time the shares of Common Stock are issued to such Director, based on the Stock Value of such Common Stock on the payment date.
- **3.8** Nothing contained herein shall be deemed to create a trust of any kind or any fiduciary relationship. To the extent that any person acquires a right to receive payments from the Company under the Plan, such right shall be no greater than the right of any unsecured general creditor of the Company.

#### **ARTICLE 4**

# PAYMENT OF DEFERRED COMPENSATION

4.1 Amounts credited to a Director's Cash Account and Stock Account shall be distributed in a single lump sum to the Director on the date, if any, selected by the Director pursuant to the Director's election (made pursuant to Paragraph 2.2 of Article II) (or as soon as

administratively practicable thereafter); provided, however, that if the Director has not selected a distribution date or the Director's selected distribution date is after his "separation from service" (as defined in Treasury Regulation Section 1.409A-1(h)), then distribution shall be made on the date of the "separation from service" in the form of a single lump sum. Notwithstanding the foregoing, if the Director is a "specified employee" (as such term is defined in Internal Revenue Code Section 409A(a)(2)(B)(i)) of the Company or any successor entity thereto upon his or her "separation from service", then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Code Section 409A as a result of the payment of deferred compensation upon his "separation from service", the distribution shall be delayed until the earlier to occur of (i) the date that is six months and one day after the date of the "separation from service" or (ii) the date of the Director's death. Amounts credited to a Director's Cash Account shall be paid in cash. Amounts credited to a Director's Stock Account shall be paid in shares of Common Stock, subject to Paragraph 3.7 hereof.

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

#### ARTICLE 5

#### ADMINISTRATION

- **5.1** The Company shall administer the Plan at its expense. The Company has the exclusive discretion and authority to construe and interpret the Plan, and to decide any and all questions of fact, interpretation, definition, computation or administration arising in connection with the operation of the Plan, including, without limitation, eligibility to participate in the Plan and amount of benefits to be paid under the Plan. The rules, interpretations, computations and other actions of the Company shall be final and binding on all parties.
- **5.2** Except to the extent required by law, the right of any Director or any beneficiary to any benefit or to any payment hereunder shall not be subject in any manner to attachment or other legal process for the debts of such Director or beneficiary; and any such benefit or payment shall not be subject to alienation, sale, transfer, assignment or encumbrance.

#### **ARTICLE 6**

#### AMENDMENT OF PLAN

**6.1** The Plan may be amended, suspended or terminated in whole or in part from time to time by the Board, except that no amendment, suspension, or termination shall apply to the payment to any Director or beneficiary of a deceased Director of any amounts previously

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credited to a Director's Cash Account or Stock Account without such Director's (or beneficiary's, if applicable) express written consent.

#### **ARTICLE 7**

## COMMON STOCK SUBJECT TO THE PLAN

7.1 The total number of shares of Common Stock reserved and available for issuance under the Plan is seven hundred fifty thousand (750,000) (the "Share Reserve"). For the sake of clarity, the Share Reserve consists of two hundred fifty thousand (250,000) shares of Common Stock that were previously reserved/set aside for purposes of this Plan prior to the Effective Date and five hundred thousand (500,000) additional shares of Common Stock that are reserved/set aside and available for issuance as of the Effective Date. Any shares of Common Stock issued hereunder may consist, in whole or in part, of authorized and unissued shares, treasury shares or shares purchased on the open market. In the event of a Capitalization Adjustment, the Board will appropriately and proportionately adjust the Share Reserve and the number of Shares of Common Stock credited to any Stock Account, in each case, as approved by the Board in its sole discretion.

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	APPENDIX A
	DATE:
Corporate Secretary	
GTx, Inc.	
Dear	

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

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

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

(a)% of the aggregate Director's fees shall be credited to my Cash Account (as defined in the Plan);			
<b>(b)</b> % of the aggregate Director's fees shall be credited to my Stock Account (as defined in the Plan);			
(c)% of the aggregate Director's fees shall not be deferred, but shall be paid to me directly as they accrue.			
Optional: I elect to receive a distribution of the amount credited to my Cash administratively practicable thereafter):	Account and Stock Account on the following date (or as soon as		
I understand that if I do not select a distribution date for the amount credited select is after my "separation from service" (as defined in Treasury Regulation Section amount credited to my Cash Account and Stock Account will be distributed to me on sum.	1.409A-1(h)), then notwithstanding my selected distribution date, the		
Notwithstanding the foregoing, if I am a "specified employee" (as such term Company or any successor entity thereto upon my "separation from service", then, so personal tax consequences under Code Section 409A as a result of the payment of			
Appendix A-1			
deferred compensation upon my "separation from service", the distribution shall be do day after the date of my "separation from service" or (ii) the date of my death.  In the event of my death prior to receipt of the amounts credited to my Cash beneficiary to receive the amounts so credited.			
Very	ruly yours,		
Signa	ure		
Print	Name		
Appendix A-2			
	_		

#### Non-Employee Director Compensation Policy of GTx, Inc. Effective Date: 2/14/2013

#### I. Purpose

This Policy sets forth guidelines pertaining to compensation for non-employee Directors of the GTx, Inc. Board of Directors ("Board").

#### II. Scope

This Policy applies to all non-employee members of the Board and is not applicable to employee members of the Board. This Policy shall remain in effect until it is revised or rescinded by further action of the Board.

#### III. Policy Statements

The Board sets non-employee Directors' compensation at the recommendation of the Nominating and Corporate Governance Committee and the Compensation Committee. Compensation for non-employee Directors is comprised of a mix of cash and equity-based compensation.

Periodically, at the direction of the Nominating and Corporate Governance Committee, the Company provides information from independent consultants and/or data management sources relating to Board compensation paid by companies comparable to the Company within the biotech and pharmaceutical industries. The Nominating and Corporate Governance Committee uses this information in making its recommendations to the Compensation Committee regarding any modifications to Board compensation. The Compensation Committee considers the information and recommendations provided by the Nominating and Corporate Governance Committee and makes its recommendations to the Board then sets the Directors' compensation taking into account the recommendations from the Committees. Cash compensation payments and equity awards shall be paid or be made, as applicable, automatically and without further action of the Board, unless such non-employee Director declines to receive such compensation or awards by written notice to the Company.

#### A. Cash Compensation

#### Annual Retainer

Each non-employee Director shall be eligible to receive an annual retainer, to be paid quarterly in advance as follows:

- · a \$32,500 annual retainer for service as a member of our Board of Directors;
- a supplemental annual retainer for the Chairs of the Board and each Board committee in the following amounts: \$15,000 for Chair of the Board; \$12,000 for Chair of the Audit Committee; \$8,000 for Chair of the Compensation Committee; \$6,000 for Chair of the Nominating and Corporate Governance Committee; and \$10,000 for Chair of the Scientific Advisory Committee; and
- · a supplemental annual retainer for each member of the following committees other than the Chairs, in the following amounts: \$6,000 for members of the Audit Committee; \$4,000 for members of the Compensation Committee; \$3,000 for members of the Nominating and Corporate Governance Committee; and \$7,500 for members of the Scientific Advisory Committee.

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#### Expense Reimbursement

The Company shall reimburse a non-employee Director for all of his or her reasonable expenses incurred to attend meetings of the Board or its committees. Any travel expenses shall be reimbursed in accordance with the Company's standard travel policy. The travel expenses will be reimbursed within thirty (30) days after receipt by the Company of an invoice together with originals or copies of receipts showing the payment of such expenses.

# **B. Directors' Deferred Compensation**

Each non-employee Director has the opportunity to defer all or a portion of his or her cash compensation under the Company's Directors' Deferred Compensation Plan. Deferrals can be made into a cash account, a stock unit account, or a combination of both. All distributions under the Directors' Deferred Compensation Plan will be made in the form of a single lump sum in cash (for amounts credited to cash accounts) or in shares of GTx common stock (for amounts credited to stock unit accounts), except that any fractional shares of GTx common stock will be distributed in cash valued at the then current fair market value of GTx common stock, all of which is more particularly set forth in the Directors' Deferred Compensation Plan.

## C. Equity-Based Compensation

The Company's 2004 Non-Employee Directors' Stock Option Plan, as amended (the "2004 Directors' Plan"), provides for the automatic grant of initial and annual nonstatutory stock options to GTx's non-employee Directors who do not own more than ten percent of the combined voting power of GTx's then outstanding securities. If the Company's 2013 Non-Employee Director Equity Incentive Plan (the "2013 Directors' Plan") is approved by the Company's stockholders at the Company's 2013 Annual Meeting of Stockholders, no additional stock options will be granted under the 2004 Directors' Plan and the following initial and annual grants automatically will be made under the 2013 Directors' Plan. If the 2013 Directors' Plan is not approved by Company's stockholders at the Company's 2013 Annual Meeting of Stockholders, the following initial and annual grants automatically will be made under the 2004 Directors' Plan.

# **Initial Award**

Any individual who first becomes a non-employee Director automatically will be granted an option to purchase shares of GTx's common stock. The number of shares subject to each initial option grant is 22,500 shares, provided that the number of shares subject to such options may be increased or decreased by the Board in its sole discretion.

#### Annual Awards

Any individual who is serving as a non-employee Director on the day following an annual meeting of GTx's stockholders automatically will be granted an option to purchase shares of GTx's common stock on that date; provided, however, that if the individual has not been serving as a non-employee Director for the entire period since the preceding annual meeting, the number of shares subject to such individual's annual grant will be reduced pro rata for each full month prior to the date of grant during which such individual did not serve as a non-employee Director. The number of shares subject to each annual option grant is 20,000 shares, provided that the number of shares subject to such options may be increased or decreased by the Board in its sole discretion.

#### Provisions Applicable to All Non-Employee Director Awards

The exercise price per share for the options granted under the 2004 Directors' Plan (or the 2013 Directors' Plan if it is approved by the Company's stockholders) will not be less than the fair market value of the Company's common stock on the date of grant. The options which are the subject of an initial grant and an annual grant will vest in a series of three successive equal annual installments measured from the date of grant, so that each initial grant and each annual grant will be fully vested three years after the date of grant.

In the event of specified corporate transactions, as defined in the 2004 Directors' Plan or the 2013 Directors' Plan, as applicable, all outstanding options under the 2004 Directors' Plan or the 2013 Directors' Plan (if it is approved by the Company's stockholders) may be assumed or substituted for by any surviving or acquiring entity. If the surviving or acquiring entity elects not to assume or substitute for such options, then (a) with respect to any such options that are held by optionees then performing services for GTx or its affiliates, the vesting and

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exercisability of such options will be accelerated in full and such options will be terminated if not exercised prior to the effective date of the corporate transaction, and (b) all other outstanding options will terminate if not exercised prior to the effective date of the corporate transaction.

If a specified "change of control" transaction occurs, as defined in the 2004 Directors' Plan, then the vesting and exercisability of the optionee's options under the 2004 Directors' Plan will be accelerated in full immediately prior to (and contingent upon) the effectiveness of the transaction. Under the 2004 Directors' Plan, if an optionee is required to resign his or her position as a non-employee Director as a condition of the transaction, the vesting and exercisability of the optionee's options will be accelerated in full immediately prior to the effectiveness of such resignation. Under the 2013 Directors' Plan (if it is approved by the Company's stockholders), if a specified "change of control" transaction occurs, as defined in the 2013 Directors' Plan, then all stock awards under the 2013 Directors' Plan held by individuals whose service with GTX or its affiliates has not terminated prior to the transaction will become fully vested and, if applicable, exercisable, immediately prior to the transaction. In addition, under the 2013 Directors' Plan, if a non-employee Director is required to resign his or her position as a non-employee Director as a condition of the transaction, all outstanding stock awards held by such individual will become fully vested and, if applicable, exercisable, as of immediately prior to such resignation.

#### IV. Related Documents / Information

A. Directors' Deferred Compensation Plan

B. 2004 Non-Employee Directors' Stock Option Plan (Amended)

C. 2013 Non-Employee Director Equity Incentive Plan

D. Finance Policy, Business Travel and Expense

### V. Policy Owner

For assistance with interpretation regarding this policy, or any questions relating to this policy, contact:

Henry P. Doggrell VP, Chief Legal Officer (901) 507-6916 hdoggrell@gtxinc.com

#### VI. Revision History

Original Policy — Effective 1/1/2009

(Adopted by the GTx, Inc. Compensation Committee of the Board of Directors on 11/4/2008)

Amended and restated by GTx's Board of Directors on 2/14/2013

# VII. Approval

The signature below indicates that this policy has been approved by the Legal Department as of the approval date set forth below.

/s/ Henry P. Doggrell February 14, 2013 Date

Vice President, Chief Legal Officer

Henry P. Doggrell

#### **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, and
- (5) Registration Statement (Form S-3 No. 333-174396) of GTx, Inc. and in the related Prospectus

of our reports dated March 5, 2013, 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, 2012.

/s/ Ernst & Young LLP Memphis, Tennessee March 5, 2013

#### 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 5, 2013

/s/ Mitchell S. Steiner

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

#### CHIEF FINANCIAL OFFICER CERTIFICATION

#### I, Mark E. Mosteller, certify that:

- 1. I have reviewed this 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 5, 2013

/s/ Mark E. Mosteller

Mark E. Mosteller, CPA

Vice President and Chief Financial Officer

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

In connection with the Annual Report of GTx, Inc. (the "Company") on Form 10-K for the year ended December 31, 2012, 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 5, 2013

/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.

# 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, 2012, 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 5, 2013

/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.