GTX INC /DE/
Form 10-K
March 16, 2015

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

FORM 10-K

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

For the fiscal year ended December 31, 2014

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission file number 000-50549

GTx, Inc.
(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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 ý

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 ý 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 ý 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. o

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

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

The aggregate market value of common stock held by non-affiliates of the registrant based on the closing sales price of the registrant's common stock on June 30, 2014 as reported on The NASDAQ Global Market was $50,111,518.

There were 140,325,643 shares of registrant's common stock issued and outstanding as of March 9, 2015.

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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 2015 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 implementation of our business strategies, including our ability to preserve or realize any significant value from our enobosarm (GTx-024) and GTx-758 (Capesaris®) programs;
- the therapeutic and commercial potential of our product candidates;
- our ability to establish and maintain potential new collaborative, partnering or other strategic arrangements for the development and commercialization of our product candidates;
- the anticipated progress of our clinical programs, including whether our ongoing and planned clinical trials of enobosarm and GTx-758 will achieve clinically relevant results;
- the timing, scope and anticipated initiation, enrollment and completion of our ongoing and planned clinical trials;
- the timing of potential regulatory discussions and submissions, and the anticipated timing, scope and outcome of related regulatory actions or guidance;
- 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;
- 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 and our expenses, capital requirements and need 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.

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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, including treatments for breast and prostate cancer, and other serious medical conditions.

We are developing selective androgen receptor modulators, or SARMs, a new class of drugs that we believe have the potential to be used as a hormonal therapy for the treatment of advanced breast cancer, as well as the potential to prevent and treat muscle wasting in patients with cancer and other musculoskeletal wasting or muscle loss conditions. Our lead product candidate, enobosarm (GTx-024), has to date been evaluated in 21 completed or ongoing clinical trials enrolling approximately 1,554 subjects, including in three Phase 2 and two Phase 3 clinical trials. 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. Our current strategy is focused on the further development of enobosarm in two breast cancer indications targeting the androgen receptor, or AR. We are also evaluating opportunities for the use of enobosarm in other medical conditions. Additionally, we are also continuing our Phase 2 clinical trial of GTx-758 (Capesaris®) as a secondary hormonal treatment for men with castration resistant prostate cancer, or CRPC.

We announced during the second quarter of 2014 positive results from an ongoing Phase 2 proof-of-concept, open-label clinical trial evaluating enobosarm 9 mg oral daily for the treatment of patients with estrogen receptor, or ER, positive and AR positive metastatic breast cancer who have previously responded to hormonal therapy. Based on the positive results of our Phase 2 proof-of-concept clinical trial in patients with ER positive and AR positive metastatic breast cancer, as well as positive data reported in medical literature regarding the use of androgens for the treatment of breast cancer and our preclinical data demonstrating tumor growth inhibition with enobosarm in animal models of disease, we believe enobosarm has the potential to be an effective treatment alternative with a favorable side effect profile for women with ER positive and AR positive advanced breast cancer, as well as for women with advanced AR positive triple-negative breast cancer, or TNBC.

Subject to the receipt of necessary regulatory approvals, we plan to initiate a Phase 2 proof-of-concept clinical trial of enobosarm in the second quarter of 2015 that is designed to evaluate the efficacy and safety of enobosarm in patients with advanced AR positive TNBC. This planned open-label clinical trial will enroll up to approximately 55 patients, who will be administered an 18 mg oral daily dose of enobosarm, and clinical benefit will be assessed at four months of treatment. We plan to conduct this clinical trial using a Simon's two-stage design, pursuant to which we will enroll approximately half of the patients in the first stage, and, assuming a certain pre-specified minimal response rate is achieved, we will proceed with enrollment of the second stage. Subject to the receipt of necessary regulatory approvals, we also plan to initiate a second Phase 2 clinical trial in the third quarter of 2015 evaluating enobosarm in patients with ER positive and AR positive advanced breast cancer. This second planned open-label clinical trial is designed to enroll up to approximately 118 patients whose cancer treatment has shown prior response to hormonal therapy but has subsequently progressed. This second planned open-label clinical trial will randomize patients to either a 9 mg or 18 mg oral daily dose of enobosarm, again using a Simon's two-stage design, and will assess clinical benefit at six months of treatment. For each of these two Phase 2 clinical trials, clinical benefit is defined as a complete response, partial response or stable disease. We currently have sufficient funding through the end of 2016 to allow us to obtain the results from at least patients enrolled in stage one of

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each clinical trial, but our ability to enroll patients to stage two of the clinical trials and complete these clinical trials likely will require us to seek sufficient additional funding.

We announced in August 2013 that the POWER 1 (platinum plus taxane chemotherapy) and POWER 2 (platinum plus non-taxane chemotherapy) (Prevention and treatment Of muscle Wasting in patients with cancER) Phase 3 clinical trials evaluating enobosarm 3 mg daily for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer, or NSCLC, failed to meet the statistical criterion for the co-primary endpoints of lean body mass and physical function that were assessed using responder analyses as pre-specified for the United States Food and Drug Administration, or FDA. However, efficacy data from the studies demonstrated enobosarm's consistent effect on maintaining or improving lean body mass compared to placebo.

Enobosarm 3 mg demonstrated a statistically significant effect versus placebo on the primary endpoint of physical function through Day 84 in the POWER 1 clinical trial as assessed by continuous variable analysis, as pre-specified in our statistical analysis plan for the European Medicines Agency, or EMA. Based upon input from representatives of the FDA and from member countries to the EMA, we believe that the data from the POWER trials is not sufficient to support the filing and approval of a new drug application in the United States or a marketing authorization application in the European Union for enobosarm 3 mg for the prevention and treatment of muscle wasting in patients with advanced NSCLC. Our strategy does not currently include further development of enobosarm 3 mg for this indication in the U.S. or in Europe unless such development is part of a collaborative arrangement or strategic partnership. However, we are evaluating opportunities for the use of enobosarm in other medical conditions.

We are also developing 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 secondary hormonal treatment for advanced prostate cancer used in combination with androgen deprivation therapy, or ADT. We believe GTx-758 has the potential to reduce testosterone to levels lower than those attainable with ADT alone while ameliorating estrogen deficiency side effects, such as bone loss and hot flashes, which are common with current androgen deprivation therapies for prostate cancer.

We are currently conducting a Phase 2 open-label clinical trial in men who have developed metastatic or high risk non-metastatic CRPC while on ADT. GTx-758 has previously demonstrated the ability to increase the production of a protein called sex hormone binding globulin, or SHBG, that binds testosterone and thereby reduces 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 2 clinical trial is the proportion of subjects with a greater than or equal to 50% decline from baseline in serum PSA by day 90. Other key endpoints include serum SHBG and total and free testosterone levels in the study subjects. In addition, the clinical trial is evaluating the ability of GTx-758 to treat certain estrogen deficiency side effects associated with luteinizing hormone releasing hormone agonists such as hot flashes and bone loss. The Phase 2 clinical trial is designed to allow us to assess the safety and tolerability of GTx-758 in these subjects, including the incidence of venous thromboembolic events (blood clots), or VTEs. Enrollment of the 38 patients in the 125 mg arm has been completed without any occurrence of VTEs, and, during the first quarter of 2015, we met our enrollment goal of 38 subjects in the 250 mg arm. Based on the safety and efficacy data observed in the 125 mg arm and there being no unexpected side effects observed in the first ten metastatic patients enrolled in the 250 mg arm, enrollment of the 250 mg arm was opened to individuals with metastatic or high risk non-metastatic CRPC. To date, there has been one reported incidence of a VTE in a patient enrolled in the 250 mg arm, resulting in the patient's discontinuation from active treatment. The study is ongoing and primary efficacy data from all patients in the study is expected

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early in the third quarter of 2015. After receipt of data from this clinical trial, we will evaluate potential next steps in the clinical development of GTx-758, including potentially seeking a partnering or collaborative arrangement in order to fund additional clinical development.

Scientific Background on Estrogen and Androgen Hormones,
Selective Hormone Receptor Modulators, and ER Alpha Agonists

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. 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 typically 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 principally 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. Hair growth, acne and masculinization are also of concern in women who are exposed to exogenous testosterone. 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. 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 may be utilized in place of androgens for various medical conditions while avoiding the unwanted androgenic effects in the prostate in men or skin and hair in men and women. In previous studies, SARMs have been shown to decrease bone breakdown and increase muscle mass. In addition to the potential beneficial effects in muscle and bone,

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SARMs may provide a therapeutic option for some women with breast cancer. 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:

- androgen receptor positive breast cancer;
- muscle loss conditions of chronic diseases, such as cancer, AIDS, chronic kidney disease, end-stage renal disease, and neurodegenerative disorders;
- muscle loss of acute conditions such as trauma, burns, and rehabilitation;
- muscle loss conditions associated with aging such as frailty and chronic sarcopenia;
- the prevention and/or treatment of osteoporosis;
- disorders of the central nervous system, such as low libido in both men and women;
- low testosterone conditions, such as primary and secondary hypogonadism; and
- disorders of male reproductive functions, such as infertility and erectile dysfunction.

A selective ER alpha agonist is a nonsteroidal compound with the ability to preferentially bind and activate ER alpha as opposed to ER beta. The selectivity for ER alpha is important in that ER beta is the form of the receptor predominantly expressed on platelets and agents that bind to ER beta can result in platelet aggregation, i.e. blood clots. GTx-758, a selective ER 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 is capable of passively diffusing into prostate cancer cells or is available to target tissues for androgen action. We believe that GTx-758 has the potential to further lower testosterone levels in men on androgen deprivation therapies for prostate cancer, including luteinizing hormone releasing hormone, or LHRH, agonist and antagonists that do not achieve castrate levels of testosterone. We believe that GTx-758 may have the ability to treat men with advanced prostate cancer by lowering serum testosterone concentrations along with decreasing the incidences of hot flashes, bone loss or other side effects related to LHRH agonists and antagonists.

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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 Treatment of women with advanced AR positive TNBC (18 mg)	SARM	Phase 2	Plan to initiate a Phase 2 open-label proof-of-concept clinical trial evaluating enobosarm in patients with advanced AR positive TNBC in the second quarter of 2015, subject to receipt of necessary regulatory approvals.
Enobosarm Treatment of women with ER positive and AR positive advanced breast cancer (9 mg and 18 mg)	SARM	Phase 2	Plan to initiate a Phase 2 open-label clinical trial evaluating enobosarm in patients with ER positive and AR positive advanced breast cancer in the third quarter of 2015, subject to receipt of necessary regulatory approvals.
GTx-758 Secondary hormonal therapy in men with metastatic and non-metastatic CRPC	Selective ER alpha agonist	Phase 2	Completed enrollment of the 125 mg arm of an ongoing Phase 2 clinical trial for secondary hormonal therapy in men with metastatic CRPC and met the enrollment goal for the 250 mg arm in both metastatic and high risk non-metastatic CRPC during the first quarter of 2015.

SARMs

Overview of the Treatment of Breast Cancer

The treatment of breast cancer is one of the earliest examples of a targeted approach for cancer therapy. The development of therapeutic agents targeting the ER in breast cancer has served as a model for the development of other targeted therapies in oncology. The treatment for invasive breast cancer is guided, in part, by the characterization of receptor status in the tumor tissue which includes the presence or absence of ER, progesterone receptor, or PR, and human epidermal growth factor receptor 2, or HER2. Studies investigating the prevalence of receptor status in invasive breast cancer have demonstrated that 75-85% of tumors are ER positive and/or PR positive and 15-20% are HER2 positive. If there is a lack of expression of each of these three receptors, the breast cancer is known as TNBC, which is a more aggressive type of breast cancer with a worse prognosis than the receptor positive cancers.

Since the majority of breast cancers are receptor positive, historically, advances in the treatment for breast cancer were focused on targeting the ER through hormonal manipulation with selective ER modulators including ER antagonists, which block the proliferative action of estrogen, and aromatase inhibitors, which decrease the synthesis of estrogen in postmenopausal women.

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Unfortunately, as effective targeted approaches are not available for the treatment of TNBC, treatment is limited to cytotoxic chemotherapy.

Recent research has focused on identifying new potential therapeutic targets in both hormone receptor positive breast cancers and TNBC for several reasons. In ER positive patients, resistance to endocrine therapies is a clinical and scientific challenge leading researchers to investigate other targets that are linked to the ER function. In TNBC, therapeutic targets need to be identified to potentially improve outcomes for patients with this aggressive form of breast cancer either as first line therapy after chemotherapy or in conjunction with chemotherapy. One such target that has been identified in both ER positive and TNBCs is the AR. In fact, the AR is the most commonly expressed steroid receptor in breast cancer with up to 90% of ER positive breast cancers and up to 50% of TNBCs expressing AR. Recent small studies have demonstrated that targeting the AR may be a viable treatment approach for advanced breast cancer.

Enobosarm Clinical Trial History

Enobosarm has been evaluated in 21 completed or ongoing clinical trials enrolling approximately 1,554 subjects, including in three Phase 2 and two Phase 3 clinical trials. In our Phase 2 proof-of-concept clinical trial in the U.S., we enrolled 22 postmenopausal women with ER positive metastatic breast cancer who have previously responded to hormonal therapy to assess clinical benefit at six months of enobosarm 9 mg once daily treatment, which was defined as those patients receiving treatment who have demonstrated (i) a complete response (disappearance of all targeted lesions), (ii) a partial response (at least a 30 percent decrease in the sum of the longest diameters of the targeted lesions), or (iii) stable disease (no disease progression from baseline). The primary endpoint was assessed in 17 AR positive patients, including one patient who had AR status determined outside the protocol specified window. Six of these 17 patients demonstrated clinical benefit at six months, including the aforementioned patient, exceeding the pre-defined statistical threshold requiring that at least three of 14 patients with an AR positive metastatic lesion demonstrate clinical benefit. Seven patients in total (one patient with indeterminate AR status) achieved clinical benefit at six months as stable disease. The results also demonstrated that, after a median duration on study of 81 days, 41 percent of all patients (9/22) achieved clinical benefit as best response and also had increased PSA which appears to be an indicator of AR activity. No confirmed complete or partial responses have been observed in the study, although one patient with liver metastases had a 27% reduction in a target tumor, and one patient currently remains on study with stable disease. Enobosarm was well tolerated. The most common adverse events, or AEs, reported were pain, fatigue, nausea, hot flash/night sweats, and arthralgia. The majority of AEs were Grade 1. There were two serious adverse events, or SAEs, reported during the study. One of the SAEs, bone pain of the chest cage, was assessed as possibly related to enobosarm.

Based on the positive results from our Phase 2 proof-of-concept clinical trial in patients with ER positive and AR positive metastatic breast cancer, as well as positive data reported in medical literature regarding the use of androgens for the treatment of breast cancer and our preclinical data demonstrating tumor growth inhibition with enobosarm in animal models of disease, we plan to initiate two open-label Phase 2 clinical trials in 2015 designed to evaluate the efficacy and safety of enobosarm in patients with AR positive advanced breast cancer, subject to receipt of necessary regulatory approvals.

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Enobosarm for the Treatment of Women with Advanced AR Positive TNBC

Scientific Overview. Although the majority of breast cancers are determined to be hormone receptor positive (expressing ER, PR or HER2), up to 20% of women diagnosed with breast cancer will have TNBC which is characterized by a lack of expression of ER, PR or HER2. TNBC occurs more frequently in younger patients (less than 50 years of age) and generally exhibits a more aggressive pattern of progression along with lower survival rates. For those patients with advanced TNBC, standard treatment options are limited to cytotoxic chemotherapy. However, even after an initial response to chemotherapy, the duration of the response may be short and there may be a higher likelihood of visceral metastases, rapidly progressing disease, and inferior survival compared to hormone receptor positive breast cancer. Therefore, there is an emphasis on research focused towards identifying therapeutic targets in TNBC. One such target is the AR. Historically, the AR has been considered to be anti-proliferative and beneficial in hormone receptor positive breast cancers. In TNBC, data from peer-reviewed literature indicates that the presence of the AR and androgen synthesizing enzymes is associated with lower proliferation, lower tumor grade, better overall survival, and more favorable clinical outcomes, as compared to those patients with TNBC not expressing AR. The general consensus in current literature also suggests that the AR biomarker, PSA, is a favorable prognostic marker in breast cancer. Based on these findings, research is focusing on the AR as a potential therapeutic target. We have studied SARMs in preclinical TNBC cell and animal models. This preclinical data suggests that the growth of TNBC cells expressing AR was inhibited by AR agonists, but not by the AR antagonist bicalutamide, suggesting that using an AR agonist may be a potentially viable approach for the treatment of advanced AR positive TNBC. We believe that this data, coupled with the early clinical success of androgens in breast cancer, supports the clinical evaluation of enobosarm as a novel targeted therapy to treat advanced AR positive TNBC.

Potential Market. Breast cancer is the most commonly diagnosed cancer in women with one in eight women developing invasive breast cancer during their lifetime. As of January 1, 2014, it is estimated there were more than 3.1 million women with a history of invasive breast cancer living in the United States. In 2014, an estimated 233,000 new cases of breast cancer were diagnosed in women in the United States with TNBC accounting for up to 20% of these newly diagnosed breast cancers each year. Up to 50% of TNBC will express the AR, which accounts for approximately 23,000 patients per year. To date, treatment of TNBC has been limited to chemotherapy due to the lack of expression of known therapeutic targets on these tumors. Although first line chemotherapy is effective initially for the treatment of TNBC, patients eventually relapse and second line therapies are needed. While this market is smaller than ER positive breast cancer, it is currently underserved and represents an unmet medical need.

Clinical Trials. In the second quarter of 2015, we plan to initiate a Phase 2 clinical trial designed to evaluate the efficacy and safety of enobosarm in patients with advanced AR positive TNBC. This planned open-label proof-of-concept clinical trial will enroll up to approximately 55 patients, who will be administered an 18 mg oral daily dose of enobosarm, and clinical benefit will be assessed at four months of treatment. Clinical benefit is defined as a complete response, partial response or stable disease. We plan to conduct this clinical trial using a Simon's two-stage design, pursuant to which we will enroll approximately half of the patients in the first stage, and, assuming a certain pre-specified minimal response rate is achieved, we will proceed with enrollment of the second stage.

We currently have sufficient funding though the end of 2016 to allow us to obtain the results from at least patients enrolled in stage one of this clinical trial, but our ability to enroll patients to stage two of the clinical trial and complete the clinical trial likely will require us to seek sufficient additional funding.

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Enobosarm for the Treatment of Women with ER Positive and AR Positive Advanced Breast Cancer

Scientific Overview. Prior to the ability to characterize receptor status and the introduction of targeted therapies directed at the ER, it was known that hormonal manipulation through ovarian ablation, along with alterations of pituitary and adrenal function could lead to tumor responses in some patients with breast cancer. Hormonal manipulation with steroidal androgens was also used with success as a first line treatment prior to the introduction of tamoxifen but also after disease progression with tamoxifen. However, androgen treatment had limitations due to the virilizing side effects including body and facial hair growth, acne and deepening of voice. Presently, ER targeted therapies are the mainstay of treatment for hormone receptor positive breast cancer with androgens reserved for use after failure of anti-estrogen therapies. However, the virilizing side effects are still a major limitation for patient compliance and acceptance. Based on the historical success of androgens for the treatment of breast cancer along with our preclinical data demonstrating tumor growth inhibition in ER positive breast cancer, we initiated a proof-of-concept Phase 2 clinical trial to evaluate enobosarm in postmenopausal women with ER positive and AR positive metastatic breast cancer. Due to the positive results from this proof-of-concept clinical trial, our preclinical data demonstrating tumor growth inhibition with enobosarm in animal models of disease, the extensive experience we have with enobosarm in over 1,500 clinical trial patients, and its favorable safety profile, we believe enobosarm has the potential to be an effective treatment alternative for women with ER positive and AR positive advanced breast cancer.

Potential Market. Breast cancer is the most commonly diagnosed cancer in women with one in eight women developing invasive breast cancer during their lifetime. As of January 1, 2014, it is estimated there were more than 3.1 million women with a history of invasive breast cancer living in the United States. In 2014, an estimated 233,000 new cases of breast cancer were diagnosed in women in the United States with approximately 6% to 8% of these women having metastatic disease at time of diagnosis. As studies investigating the prevalence of receptor status in invasive breast cancer have demonstrated that 75-85% of tumors are ER positive, anti-estrogen therapy has been noted to have the greatest global impact than any other treatment intervention in oncology. However, despite the widespread use and success of ER targeted therapies, there is no cure for metastatic breast cancer and eventually approximately 20-30% of women diagnosed with invasive breast cancer will have a recurrence.

Clinical Trials. In the third quarter of 2015, we plan to initiate a second Phase 2 clinical trial designed to enroll up to approximately 118 patients whose cancer treatment has shown prior response to hormonal therapy but has subsequently progressed. This second planned open-label clinical trial will randomize patients to either a 9 mg or 18 mg oral daily dose of enobosarm, and clinical benefit will be assessed at six months of treatment. Clinical benefit is defined as a complete response, partial response or stable disease. We plan to conduct this clinical trial using a Simon's two-stage design, pursuant to which we will enroll approximately half of the patients in the first stage, and, assuming a certain pre-specified minimal response rate is achieved, we will proceed with enrollment of the second stage.

We currently have sufficient funding through the end of 2016 to allow us to obtain the results from at least patients enrolled in stage one of this clinical trial, but our ability to enroll patients to stage two of the clinical trial and complete the clinical trial likely will require us to seek sufficient additional funding.

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Selective ER Alpha Agonist

GTx-758 for the Secondary Hormonal Treatment of CRPC

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 more commonly 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 GTx-758 has the potential to reduce free testosterone without also causing certain estrogen deficiency side effects, such as bone loss and hot flashes, which are common with current androgen deprivation therapies for prostate cancer.

Potential Market. We are developing GTx-758 for secondary hormonal therapy in men with metastatic and non-metastatic CRPC, and, potentially, as a secondary hormonal treatment for advanced prostate cancer used in combination with ADT. We believe that GTx-758 may be effective, in combination with ADT, as a secondary hormonal 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® and XTANDI® are currently the only drugs 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 non-metastatic hormone sensitive prostate cancer and approximately 60,000 new cases are diagnosed each year. For hormone sensitive advanced 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 GTx-758 as an effective secondary hormonal therapy for men with metastatic and non-metastatic CRPC or potentially, as a secondary hormonal 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 GTx-758 in healthy male volunteers in two Phase 1 clinical trials, including a ten day multiple ascending dose study in 61 subjects where GTx-758 demonstrated the ability to increase serum SHBG and to reduce serum total and free testosterone. In September 2010, we announced that in a Phase 2, open label, pharmacokinetic and pharmacodynamic clinical trial

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in young healthy male volunteers, GTx-758 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 GTx-758 who achieved medical castration was comparable to rates of castration observed with LHRH agonists or antagonists therapies. In May 2011, we completed a Phase 1 clinical trial of GTx-758 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 GTx-758 doses given orally each day.

We designed two Phase 2 clinical trials to identify an appropriate dose of GTx-758 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 2 maintenance dose finding clinical trial evaluating GTx-758 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 2 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 GTx-758, 2000 mg or 1000 mg, until Day 360. We were also conducting a second line hormonal therapy Phase 2 clinical trial evaluating GTx-758 2000 mg once-a-day dose in 25 men with CRPC. The objective of this trial was to determine the ability of GTx-758 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 GTx-758, 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 GTx-758 at the doses being studied in the trials (1000 mg and higher per day). There were two deaths in subjects treated with GTx-758 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 GTx-758.

In May 2012, we announced that the FDA had removed its full clinical hold on our IND for GTx-758. Based upon feedback from the FDA in connection with the removal of the full clinical hold, in the third quarter of 2012 we initiated a Phase 2 clinical trial to evaluate the safety and efficacy of three lower doses of GTx-758 as secondary hormonal therapy in men with metastatic CRPC.

We are currently conducting a Phase 2 open-label clinical trial in men who have developed metastatic or high risk non-metastatic CRPC while on ADT. GTx-758 has previously demonstrated the ability to increase the production of a protein called SHBG that binds testosterone and thereby reduces free testosterone. By reducing free testosterone, we believe serum PSA will be reduced in men with CRPC. The primary endpoint of the current Phase 2 clinical trial is the proportion of subjects with a greater than or equal to 50% decline from baseline in serum PSA by day 90. Other key endpoints include serum SHBG and total and free testosterone levels in the study subjects. In addition, the clinical trial is evaluating the ability of GTx-758 to treat certain estrogen deficiency side effects associated with luteinizing hormone releasing hormone agonists such as hot flashes and bone loss. The Phase 2 clinical trial is designed to allow us to assess the safety and tolerability of GTx-758 in these subjects, including the incidence of VTEs. The original trial design provided for 75 total subjects to be enrolled in three sequential dosing arms, with the first 25 subjects in the study being enrolled in the GTx-758 125 mg dosing arm. Assuming that an acceptable incidence of VTEs was observed when the last subject enrolled in the GTx-758 125 mg dosing arm completed one 30 day cycle of therapy, enrollment of the next 25 subjects would commence in the GTx-758 250 mg dosing arm. Similarly, the GTx-758 500 mg dosing arm was to have commenced enrollment of the final 25 subjects when the last subject enrolled in the 250 mg dose arm completed one 30 day cycle of therapy, assuming an acceptable incidence of VTEs had been observed in both of the lower dosage arms and management

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had decided to continue testing at the next higher dose. After reviewing data collected from the GTx-758 125 mg dosing arm indicating the ability of the drug to substantially increase SHBG and lower free testosterone without any unexpected side effects occurring, the clinical trial protocol was amended in the third quarter of 2013 to eliminate the 500 mg dosing arm and to increase the number of subjects to be enrolled in the 125 mg and the 250 mg dosing arms to 38 patients per arm. Enrollment in the 125 mg arm has been completed without any occurrence of VTEs, and, during the first quarter of 2015, we met our enrollment goal of 38 subjects in the 250 mg arm. Based on the safety and efficacy data observed in the 125 mg arm and there being no unexpected side effects observed in the first ten metastatic patients enrolled in the 250 mg arm, enrollment of the 250 mg arm was opened to individuals with metastatic or high risk non-metastatic CRPC. To date, there has been one reported incidence of a VTE in a patient enrolled in the 250 mg arm, resulting in the patient's discontinuation from active treatment. The study is ongoing and primary efficacy data from all patients in the study is expected early in the third quarter of 2015.

Our Strategy

Our objective is to discover, develop and commercialize small molecules for the treatment of cancer, including treatments for prostate and breast cancer, and other serious medical conditions. Key elements of our strategy to achieve these objectives are to:

Pursue Clinical Development of Enobosarm. Our current strategy is focused on further development of enobosarm, our lead product candidate, in two breast cancer indications targeting the androgen receptor. Subject to the receipt of necessary regulatory approvals, we plan to initiate a Phase 2 open-label, proof of concept clinical trial, which is designed to enroll patients with advanced AR positive TNBC beginning in the second quarter of 2015. We also plan to initiate a second Phase 2 clinical trial in the third quarter of 2015 designed to enroll patients with ER positive and AR positive advanced breast cancer.

Pursue Clinical Development of GTx-758. Upon the completion of our ongoing Phase 2 clinical trial to evaluate the safety and efficacy of lower doses of GTx-758 as secondary hormonal therapy in men with metastatic and non-metastatic CRPC, we will evaluate potential next steps in the clinical development of GTx-758, including potentially seeking a partnering or collaborative arrangement in order to fund additional clinical development.

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 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

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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. 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 GTx-758. The active ingredient in GTx-758 is manufactured using a three-step synthetic process that uses commercially available starting materials for each step. GTx-758 drug product is manufactured using conventional manufacturing technology without the use of novel excipients. We rely on third-party vendors for the manufacture of GTx-758 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

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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 Treatment of Women with Advanced AR Positive TNBC

There are other SARM product candidates in development that may compete with enobosarm and any future SARM product candidates, if approved for commercial sale. We plan to advance the development of enobosarm for the treatment of women with advanced AR positive TNBC. There are no currently approved therapies for this subset of patients, beyond chemotherapy. However, a number of approaches for the treatment of TNBC are currently under investigation. Agents also targeting the androgen axis include XTANDI® (enzalutamide) being developed by Medivation and Astellas Pharma, orteronel (TAK-700) being developed by Takeda, and CR-1447 being developed by Curadis. Only a subset of the total TNBC population is AR positive; therefore, agents targeting TNBC as a whole may also compete with enobosarm if approved for commercial sale. These agents include: PI3K/AKT inhibitors (BKM120 being developed by Novartis), IL6/JAK/Stat inhibitors (ruxolitinib being developed by Incyte), mTOR inhibitors (Neratinib being developed by Puma), and PARP inhibitors (Velaparib being developed by AbbVie), PD-1 inhibitors (pembrolizumab) being developed by Merck & Co. and MPDL3280A being developed by Roche.

Enobosarm for the Treatment of Women with ER Positive and AR Positive Advanced Breast Cancer

We also plan to advance the development of enobosarm for the treatment of patients with ER positive and AR positive advanced breast cancer. To our knowledge, no other SARMs are currently in development for the ER positive and AR positive metastatic breast cancer indication; although SARMs in development for muscle wasting and cachexia could enter into a breast cancer program in the future. For example, Radius Health, Inc. has stated that it may test its SARM compound, RAD140, in a breast cancer indication in the future. A number of other compounds targeting the androgen axis in breast cancer could compete with enobosarm if one or more are approved for commercial sale in the indications for which enobosarm is being developed. These compounds fall into two categories, androgen synthesis inhibitors, or ASIs, and androgen receptor antagonists, or ARAs. ASIs in development include orteronel being developed by Takeda Pharmaceuticals and Zytiga® being developed by Janssen Pharmaceuticals. ARAs in development include XTANDI® (enzalutamide) being developed by Medivation and Astellas Pharma, and generic bicalutamide. Agents targeting pathways outside of the androgen axis also may compete with enobosarm in breast cancer as they are directed towards similar patient populations that may benefit from enobosarm.

GTx-758 for the Secondary Hormonal Treatment of CRPC

There are various products approved or under clinical development to treat men with advanced prostate cancer who have metastatic CRPC which may compete with GTx-758. Provenge®, which was recently acquired by Valeant Pharmaceuticals, is an autologous cellular immunotherapy for the treatment of asymptomatic or minimally symptomatic metastatic CRPC. Medivation and Astellas Pharma market XTANDI® (enzalutamide), an oral androgen receptor antagonist, that is approved for the treatment of men with metastatic CRPC in men previously treated with docetaxel as well as those that have not yet received chemotherapy. Zytiga®, sold by Johnson & Johnson, has been approved for the treatment of metastatic CRPC in patients who have received prior chemotherapy and recently received approval for the treatment of metastatic CRPC prior to chemotherapy. Johnson & Johnson acquired Aragon Pharmaceuticals, Inc., which developed a second generation anti-androgen (ARN-509) that is currently being evaluated in Phase 2 studies in men with progressive, advanced prostate cancer. Bayer HealthCare and Orion Corporation are currently performing a Phase 3 study of ODM-201 in

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men with CRPC without metastases and with a rising PSA examining safety and efficacy by measuring metastatic free survival. Millennium: The Takeda Oncology Company is developing TAK-700 for the treatment of men with metastatic CRPC prior to chemotherapy.

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 and 2034. We have issued patents in the United States and pending applications in countries outside the United States for enobosarm and certain other SARM compounds as a feed composition for animals. The patents in the United States will expire in 2025. The patent applications which are pending outside the United States will expire in 2031, if the patents are issued.

We have our own issued and pending patent applications in the United States, Canada, Australia, Europe, Japan, China and other countries in Asia, as well as in certain other countries outside those regions, related to solid forms of enobosarm. Issued patents covering solid forms of enobosarm in the United States will expire in 2028. Patents issued from pending patent applications in countries outside of the United States will expire in 2028. We have our own pending patent applications in the United States and as an International Application related to methods of treating breast cancer using our SARM compounds. Such patent applications, if issued, would expire in 2033 in the United States and outside of the United States.

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 GTx-758 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

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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 GTx-758 in the United States will expire in 2029, and pending patent applications in the United Sates covering GTx-758 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 pending 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. 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.

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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, or NDA. 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 has 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 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 1 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 2 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 3 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 3 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.

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Product Formulation and Manufacture

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

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

New Drug Application Process

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

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

If the FDA evaluations of the NDA and the manufacturing facilities are favorable, the FDA may issue an approval letter authorizing commercial marketing of the drug candidate for specified indications. The FDA could also issue a "complete response" letter at the end of the review period. A "complete response" letter will be issued to let a company know that the review period for a drug is complete and that the application is not yet ready for approval. The letter will describe specific deficiencies and, when possible, will outline recommended actions the applicant might take to get the application ready for approval.

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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.

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 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.

Approval Outside of the United States

In order to market any product outside of the United States, we must comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales and distribution of our products, which broadly reflect the issues addressed by the FDA above. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may negatively impact the regulatory process in other countries.

As in the United States, the marketing approval process in Europe and in other countries is a lengthy, challenging and inherently uncertain process. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of marketing approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. Generally the development and approval procedures are harmonized throughout the European Union: however, there is limited harmonization in relation to national pricing and reimbursement practices.

Under European Union regulatory systems, a company may not market a medicinal product without marketing authorization. There are three procedures for submitting a MAA in the EU: (1) the

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mutual recognition procedure (MRP); (2) the decentralized procedure (DCP) and (3) the centralized procedure (CP). The submission strategy for a given product will depend on the nature of the product, the target indication(s), the history of the product, and the marketing plan. The centralized procedure is compulsory for medicinal products which are produced by biotechnology processes, advanced therapy medicinal products and orphan drugs. Besides the products falling under the mandatory scope, the centralized procedure is also open for other innovative products that are new active substances or other medicinal products that constitute a significant therapeutic, scientific or technical innovation.

The centralized procedure leads to approval of the product in all 27 EU member states and in Norway, Iceland and Liechtenstein. Submission of one MAA thus leads to one assessment process and one authorization that allows access to all applicable markets within the entire EU. The process of the centralized procedure is triggered when the applicant sends the letter announcing the intent to submit a MAA (letter of intent). The letter of intent also initiates the assignment of the Rapporteur and Co-Rapporteur, who are the two appointed members of the Committee for Human Medicinal Products, or CHMP, representing two EU member states.

When using the MRP or DCP, the applicant must select which and how many EU member states in which to seek approval. In the case of an MRP, the applicant must initially receive national approval in one EU member state. This will be the so-called reference member state (RMS) for the MRP. Then, the applicant seeks approval for the product in other EU member states, the so-called concerned member states (CMS) in a second step: the mutual recognition process. For the DCP, the applicant will approach all chosen member states at the same time. To do so, the applicant will identify the RMS that will assess the submitted MAA and provide the other selected member states with the conclusions and results of the assessment.

When the application for marketing authorization is made, the competent authority responsible for granting a marketing authorization must verify whether the application complies with the relevant requirements, including compliance with the agreed pediatric investigational plan, or PIP. Assuming it does, the marketing authorization may be granted and the relevant results are included in the summary of product characteristics (SmPC) for the product, along with a statement indicating compliance with the agreed PIP. It is not necessary for the product actually to be indicated for use in the pediatric population (for example, if the results show that that would not be appropriate).

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.

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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

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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 issued by the FDA, and essentially codified under the 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

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.

If we obtain appropriate approval in the future to market any of our oral drug product candidates, those products could potentially be covered by various government health benefit programs as well as purchased by federal agencies. The participation in such programs or the sale of products to such agencies is subject to regulation. 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.

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. Oral drugs may be covered under 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.

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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 Public Health Service (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.

Although we currently have no products approved for commercial sale, we marketed FARESTON® through September 30, 2012 and the product was covered under various government health benefit programs as well as purchased by federal agencies. We could be subject to liability under federal laws regulating our participation in such programs or the sale of our product to such agencies if we failed to comply with applicable requirements, including reporting prices for our products or offering products for sale at certain prices.

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®, which we sold to a third party in 2012, 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

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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 prior reporting (when we marketed FARESTON®) or any future reporting (if we obtain approval and/or reimbursement from federal healthcare programs for our product candidates) 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 $20.9 million for the year ended December 31, 2014, $32.3 million for the year ended December 31, 2013, and $38.9 million for the year ended December 31, 2012. As a result of the October 2013 reduction in our workforce, we are no longer conducting in-house drug discovery activities and are focusing our research and development activities on clinical development of our current product candidates.

Employees

As of December 31, 2014, we had 25 employees, 6 of whom were Pharm.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.

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Management

The following table sets forth information about our executive officers and other key medical, clinical and regulatory officers as of March 9, 2015.

Name	Age	Position(s)
Executive Officers		
Marc S. Hanover	52	Chief Executive Officer
Robert J. Wills, Ph.D	61	Executive Chairman
Henry P. Doggrell	66	Vice President, Chief Legal Officer and Secretary
Jason T. Shackelford	39	Senior Director, Accounting and Corporate Controller, and Principal Financial and Accounting Officer
Other Key Medical, Clinical and Regulatory Officers		
Jeffrey G. Hesselberg	56	Vice President, Regulatory Affairs, Corporate Quality, and Drug Safety
Mary Ann Johnston, PharmD	43	Vice President, Medical Affairs and Clinical Operations

Executive Officers of the Registrant

Marc S. Hanover*,* a co-founder of GTx and our Chief Executive Officer, served as our President and Chief Operating Officer from our inception in September 1997 until his appointment as our permanent Chief Executive Officer in February 2015, and served as our acting Principal Financial Officer from December 31, 2013 until his appointment as our interim Chief Executive Officer on April 3, 2014. Mr. Hanover also previously served as a member of our Board of Directors from our inception until August 2011, and was again elected to our Board of Directors on April 3, 2014. 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.

Robert J. Wills, Ph.D., joined GTx as Executive Chairman and as a member of our Board of Directors on March 2, 2015. Dr. Wills served as Vice President, Alliance Manager for Johnson & Johnson, or J&J, and was responsible for managing strategic alliances for J&J's Pharmaceutical Group worldwide since 2002. Prior to this, Dr. Wills spent 22 years in pharmaceutical drug development, 12 of which were at J&J and 10 of which were at Hoffmann-La Roche Inc. Before assuming his alliance management role at J&J, Dr. Wills served as Senior Vice President Global Development at J&J where he was responsible for its late stage development pipeline and was a member of several internal commercial and research and development operating boards. Dr. Wills holds a B.S. in Biochemistry and a M.S. in Pharmaceutics from the University of Wisconsin and a Ph.D. in Pharmaceutics from the University of Texas.

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

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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.

Jason T. Shackelford currently serves as our Senior Director, Accounting and Corporate Controller, after joining GTx in July 2007 as Director, Accounting and Corporate Controller, and has served as our principal accounting officer since December 31, 2013 and as our principal financial and accounting officer since April 3, 2014. Prior to joining GTx, Mr. Shackelford was a Senior Audit Manager at KPMG LLP. Mr. Shackelford is a Certified Public Accountant and holds a Bachelor of Business Administration and Master of Accountancy from the University of Mississippi.

Other Key Medical, Clinical and Regulatory Officers of the Registrant

Jeffrey G. Hesselberg was appointed Vice President, Regulatory Affairs, Corporate Quality, and Drug Safety in August 2013. Previously, he had served as the Vice President, Regulatory Affairs since 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 and Clinical Operations in February 2014. Previously, she served as the Vice President, Medical Affairs since November 2012. Before that, 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, 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.

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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, 2014, we had an accumulated deficit of $494.8 million. Our net loss for the year ended December 31, 2014 was $39.4 million. We expect to incur significant operating losses for the foreseeable future as we continue our clinical development activities and potentially seek regulatory approval of our product candidates. 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 (GTx-024) and GTx-758 (Capesaris®), will require significant additional clinical development, financial resources and personnel in order to obtain necessary regulatory approvals for these product candidates and to develop them into commercially viable products. A substantial portion of our efforts and expenditures have been devoted to enobosarm 3 mg, which was the subject of our POWER 1 and POWER 2 Phase 3 clinical trials for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer, or NSCLC. The failure of the POWER trials to meet the primary statistical criterion for the co-primary endpoints agreed upon with the U.S. Food and Drug Administration, or FDA, significantly depressed our stock price and has harmed our future prospects. Although we evaluated the potential submission of a marketing authorization application, or MAA, to the European Medicines Agency, or EMA, seeking marketing approval of enobosarm 3 mg in the European Union, or EU, for the prevention and treatment of muscle wasting in patients with advanced NSCLC, based on input from the Medicines and Healthcare Products Regulatory Agency, or MHRA, we believe that the data from the POWER trials is not sufficient to support the filing and approval of a MAA without confirmatory data from another Phase 3 clinical trial of enobosarm 3 mg. As a result of this input, we do not intend to submit a MAA in the absence of such confirmatory data. In addition, since data from the two POWER trials failed to meet the primary statistical criterion pre-specified for the co-primary endpoints of lean body mass and physical function, the FDA will not accept a new drug application, or NDA, for enobosarm 3 mg for the prevention and treatment of muscle wasting in patients with advanced NSCLC. Accordingly, our strategy does not currently include further development of enobosarm for this indication in the U.S. or in Europe unless such development is part of a collaborative arrangement or strategic partnership. Moreover, our current strategy is focused on the further development of enobosarm for the treatment of patients with androgen receptor, or AR, positive advanced breast cancer. However, the development of enobosarm for the treatment of patients with AR positive advanced breast cancer is at an early stage and is subject to the substantial risk of failure inherent in the development of early-stage product candidates.

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. In addition, we do not expect to obtain FDA or EMA approval, or any other

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regulatory approvals, to market any of our product candidates, including enobosarm, for the foreseeable future, and it is possible that none of our product candidates will ever receive any regulatory approvals.

We have funded our operations primarily through public offerings and private placements of our securities, 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 collaborators are unable to develop and commercialize enobosarm or GTx-758, if development is further delayed or is eliminated, or if sales revenue from enobosarm or GTx-758 upon receiving marketing approval, if ever, 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 delay, reduce or eliminate our product development programs and could cause us to discontinue our operations.

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.

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 through the end of 2016 (during which time we expect, at a minimum, to obtain results from patients enrolled in stage one of each of our planned open-label Phase 2 clinical trials of enobosarm in patients with AR positive advanced breast cancer, using a Simon's two-stage clinical trial design). While we estimate that our current cash, cash equivalents and short-term investments are sufficient to fund our operations through 2016, we will need to obtain substantial additional funding to commence and complete stage two of both of our planned open-label Phase 2 clinical trials of enobosarm in patients with AR positive advanced breast cancer and to otherwise seek regulatory approval for enobosarm in patients with AR positive advanced breast cancer. In addition, if we decide to undertake any further development of GTx-758 and/or enobosarm beyond our ongoing and currently-planned clinical trials, we would need to obtain additional funding for such development, either through financing or by entering into collaborative arrangements or partnerships with third parties for such further development.

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

- the scope, rate of progress and cost of our clinical development programs, including our ongoing, planned and any future clinical trials of our product candidates;

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- the terms and timing of any potential collaborative, licensing and other strategic arrangements that we may establish;
- the amount and timing of any licensing fees, milestone payments and royalty payments from potential collaborators, if any;
- future clinical trial results, if any;
- 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 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.

While we have been able to fund our operations to date, we currently have no ongoing collaborations for the development and commercialization of our product candidates and no source of revenue, nor do we expect to generate revenue for the foreseeable future. We also do not have any commitments for future external funding. Until we can generate a sufficient amount of product revenue, which we may never do, we expect to finance future cash needs through potential collaboration, partnering or other strategic arrangements, as well as through public or private equity offerings or debt financings, or a combination of the foregoing. In October 2013, following our announcement that the POWER trials failed to achieve the results required by the FDA for us to submit a NDA for enobosarm, we announced and implemented a workforce reduction of approximately 60%. 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 use to meet our cash requirements, and they may negatively affect our business and growth prospects.

To the extent that we raise additional funds through potential collaboration, partnering or other strategic 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, any of which could result in the stockholders of GTx having little or no continuing interest in our enobosarm and/or GTx-758 programs as stockholders or otherwise. To the extent we raise additional funds by issuing equity securities, our stockholders may experience significant dilution, particularly given our currently depressed stock price, and debt financing, if available, may involve restrictive covenants. For example, we completed a private placement of common stock and warrants in March 2014, which was substantially dilutive, and completed a subsequent private placement in November 2014 that represented even greater dilution, and our stockholders may experience additional, perhaps substantial, dilution should we again raise additional funds by issuing equity securities. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Our ability to raise additional funds and the terms upon which we are able to raise such funds have been severely harmed by the failure of the two enobosarm Phase 3 clinical trials to meet both of the co-primary endpoints agreed upon with the FDA, and may in the future be adversely impacted by the uncertainty regarding the prospects of our planned development of enobosarm for the treatment of patients with AR positive advanced breast cancer and our ability to advance the development of enobosarm and GTx-758, if at all. Our ability to raise additional funds and the terms upon which we are able to raise such funds may also be adversely affected by the uncertainties regarding our financial condition, the sufficiency of our capital resources, our ability to maintain the listing of our common stock on the NASDAQ Global Market or another

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market tier of the NASDAQ Stock Market and recent and potential future management turnover. 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 enobosarm and GTx-758 programs, or conduct additional workforce or other expense reductions, any of which could have a material adverse effect on our business and our prospects.

Risks Related to Development of Product Candidates

We are substantially dependent on the success of enobosarm and our failure to advance the development of enobosarm or to obtain regulatory approval of enobosarm would significantly harm our prospects.

Our current strategy is focused on the further development of enobosarm for the treatment of patients with AR positive advanced breast cancer. However, the development of enobosarm for the treatment of patients with AR positive advanced breast cancer is at an early stage and is subject to the significant risk of failure inherent in the development of early-stage product candidates. Moreover, we still have only limited data from our preclinical models of breast cancer and our ongoing Phase 2 proof-of-concept clinical trial of enobosarm in women with ER positive and AR positive metastatic breast cancer. As a result, we will need to conduct additional clinical trials of enobosarm for the treatment of patients with AR positive advanced breast cancer to determine whether enobosarm is an effective treatment for patients with advanced AR positive TNBC and ER positive and AR positive advanced breast cancer. Additionally, if it is determined that enobosarm treatment is not superior to existing approved therapies for advanced breast cancer, or has an unacceptable safety profile, any regulatory approval of enobosarm could be denied or significantly delayed in this patient population.

Preclinical studies, including studies of SARMs in animal models of disease, may not accurately predict the results of subsequent human clinical trials of enobosarm, including the results our two planned Phase 2 clinical trials of enobosarm in patients with AR positive advanced breast cancer. Furthermore, the positive results from our ongoing Phase 2 proof-of-concept clinical trial of enobosarm in women with ER positive and AR positive metastatic breast cancer does not ensure that our two planned Phase 2 clinical trials will be successful or that any later trials will be successful. A number of companies in the pharmaceutical industry, including us and those with greater resources and experience than we have, have suffered significant setbacks in Phase 3 and later-stage clinical trials, even after receiving encouraging results in earlier clinical trials. Due to the uncertain and time-consuming clinical development and regulatory approval process, we may not be successful in developing enobosarm for the treatment of patients with AR positive advanced breast cancer, or in developing any of our product candidates, and it is possible that none of our current product candidates will ever become commercial products.

A substantial portion of our efforts and expenditures have been devoted to enobosarm 3 mg, which was the subject of our POWER 1 and POWER 2 Phase 3 clinical trials evaluating enobosarm 3 mg for the prevention and treatment of muscle wasting in patients with advanced NSCLC. We announced in August 2013 that these two Phase 3 clinical trials failed to meet the co-primary endpoints of lean body mass and physical function that were assessed statistically using responder analyses as required by the FDA. The failure of the POWER trials to meet the primary statistical criterion for the co-primary endpoints agreed upon with the FDA significantly depressed our stock price and has harmed our future prospects. Although we evaluated the potential submission of a MAA to the EMA seeking marketing approval of enobosarm 3 mg in the EU for the prevention and treatment of muscle wasting in patients with advanced NSCLC, based on recent input from the MHRA, we believe that the data from the POWER trials is not sufficient to support the filing and approval of a MAA without confirmatory data

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from another Phase 3 clinical trial of enobosarm 3 mg. As a result of this input, we do not intend to submit a MAA in the absence of such confirmatory data. In addition, since data from the two POWER trials failed to meet the primary statistical criterion pre-specified for the co-primary endpoints of lean body mass and physical function, the FDA will not accept a NDA for enobosarm 3 mg for the prevention and treatment of muscle wasting in patients with advanced NSCLC. Accordingly, our strategy does not currently include further development of enobosarm for this indication in the U.S. or in Europe unless such development is part of a collaborative arrangement or strategic partnership.

We and any potential 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 clinical 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 August 2013 that our POWER 1 and POWER 2 Phase 3 clinical trials evaluating enobosarm for the prevention and treatment of muscle wasting in patients with advanced NSCLC failed to meet the co-primary endpoints of lean body mass and physical function that were assessed statistically using responder analyses as agreed upon with the FDA. Although we evaluated the potential submission of a MAA to the EMA seeking marketing approval of enobosarm 3 mg in the EU for the prevention and treatment of muscle wasting in patients with advanced NSCLC, based on recent input from the MHRA, we believe that the data from the POWER trials is not sufficient to support the filing and approval of a MAA without confirmatory data from another Phase 3 clinical trial of enobosarm 3 mg. As a result of this input, we do not intend to submit a MAA in the absence of such confirmatory data. In addition, since data from the two POWER trials failed to meet the primary statistical criterion pre-specified for the co-primary endpoints of lean body mass and physical function, the FDA will not accept a NDA for enobosarm 3 mg for the prevention and treatment of muscle wasting in patients with advanced NSCLC. Accordingly, our strategy does not currently include further development of enobosarm for this indication in the U.S. or in Europe unless such development is part of a collaborative arrangement or strategic partnership.

Significant delays in clinical testing could materially impact our product development costs. We do not know whether planned clinical trials will begin on time, or whether ongoing clinical trials will need to be restructured or will be completed on schedule, if at all. For example, we have not yet received the necessary regulatory approvals to initiate our two planned Phase 2 clinical trials of enobosarm in patients with AR positive advanced breast cancer and it is possible that the initiation of these planned Phase 2 clinical trials may be delayed, perhaps substantially, or precluded altogether as a result of our inability to obtain these approvals. In this regard, we are planning to evaluate a higher dose of enobosarm than the previously evaluated 9 mg dose in both of the planned Phase 2 clinical trials. Accordingly, regulatory authorities, including the FDA, may require us to provide additional preclinical or clinical data prior to initiating the planned Phase 2 clinical trials, which could substantially increase our costs and delay the initiation of these trials. Moreover, both of the planned Phase 2 clinical trials are designed to be conducted using a Simon's two-stage design, pursuant to which we plan to enroll approximately half of the patients in the first stage, and, upon achievement of a pre-specified minimal response rate, we plan to proceed with enrollment of the second stage. However, even if we achieve the pre-specified minimal response rate, our ability to proceed with enrollment of and to complete the

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second stage in both trials is subject to our ability to obtain additional funding, which we may be unable to do. In any event, we or any potential 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 collaborators' ability to commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us or any potential 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 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 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 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 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 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 2 clinical trials of GTx-758, which we discontinued in February 2012, we observed venous thromboembolic events, or blood clots, in subjects treated with GTx-758 at the doses then being studied in these clinical trials (1000 mg and higher per day) and reported those events to the FDA. There were two deaths in subjects treated with GTx-758 and two deaths in subjects treated with Lupron Depot®. In February 2012, the FDA placed all of our then ongoing clinical studies of GTx-758 on full clinical hold, and we suspended further enrollment into these studies and notified clinical sites to discontinue treatment of subjects with GTx-758. In May 2012, the FDA notified us that it had removed the full clinical hold on GTx-758. In the third quarter of 2012, we initiated a Phase 2 clinical trial to evaluate GTx-758, at doses lower than those which were previously being tested in our discontinued Phase 2 clinical trials, as secondary hormonal therapy in men with metastatic castration resistant prostate cancer, or CRPC. Although our current Phase 2 clinical trial is evaluating GTx-758 at doses

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lower than those which were previously being tested in our discontinued Phase 2 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 2 clinical trial. In this regard, there has been one reported incidence of a VTE in a patient enrolled in the 250 mg arm of our ongoing Phase 2 clinical trial of GTx-758, resulting in his discontinuation from active treatment, and we cannot assure you that we will not observe an unacceptable incidence of VTEs in this trial. Our ability to develop GTx-758 as an effective secondary hormonal therapy for men with metastatic CRPC or, potentially, as a secondary hormonal treatment for advanced prostate cancer used in combination with ADT, is dependent on both our ability to obtain additional funding and 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 2 clinical trial of GTx-758, we may be required to abandon our development of GTx-758, in which case, we would not receive any return on our investment in that product candidate.

In our Phase 2 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, or HDL, have also been observed in subjects treated with enobosarm. Lower levels of HDL could lead to increased risk of adverse cardiovascular events. In addition, in our ongoing Phase 2 proof-of-concept clinical trial evaluating enobosarm in a 9 mg daily dose for the treatment of patients with ER positive and AR positive metastatic breast cancer, a serious adverse event, bone pain of the chest cage, was assessed as possibly related to enobosarm. Bone pain could be attributed to tumor flare, which is an increase in tumor activity usually seen with endocrine therapies. Although doses up to 30 mg have been evaluated in short duration studies, doses higher than the 9 mg dose currently being tested in our Phase 2 clinical trials may increase the risk or incidence of known potential side effects of SARMs including elevations in hepatic enzymes and further reductions in HDL, in addition to the emergence of side effects that have not been seen to date. Although no evidence of virilization has been seen to date with any dose of enobosarm, higher doses for longer duration may increase the risk of hair growth and masculinization in some women.

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 collaborators may conduct in the future or after any of our product candidates are approved and marketed:

- we or any potential 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.

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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, delay or abandon 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. For example, we may have to cease further development of our enobosarm 3 mg and GTx-758 programs if we are unable to raise sufficient funding for any additional clinical development of these product candidates through new collaborative arrangements with third parties or other financing alternatives. In this regard, if we decide to undertake any further development of GTx-758 and/or enobosarm beyond our ongoing and currently-planned clinical trials, we would need to obtain additional funding for such development, either through financing or by entering into collaborative arrangements or partnerships with third parties for any such further development. Moreover, both of the planned Phase 2 clinical trials of enobosarm are designed to be conducted using a Simon's two-stage design, pursuant to which we plan to enroll approximately half of the patients in the first stage, and, upon achievement of a pre-specified minimal response rate, we plan to proceed with enrollment of the second stage. However, even if we achieve the pre-specified minimal response rate, our ability to proceed with enrollment of and to complete the second stage in both trials is subject to our ability to obtain additional funding, which we may be unable to do. There can be no assurances that we will be successful in obtaining additional funding in any event. If we do not have sufficient funds, we will not be able to advance the development of our product candidates or otherwise 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 collaborative arrangements may place the development and commercialization of our product candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

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. We may not be able to locate third-party collaborators to develop and market our product candidates, and we lack the capital and resources necessary to develop our product candidates alone.

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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 collaborators may devote to our product candidates;
- potential 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 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 GTx-758 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 GTx-758, 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.

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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 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, or CROs, 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.

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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 business.

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, including enobosarm, 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 material and 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, including in those jurisdictions in which we have no patent protection.

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.

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 in those jurisdictions in which we have no patent protection. Even if patents are issued to us

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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 development and manufacturing 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 take many months to publish and 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 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.

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Risks Related to Regulatory Approval of Our Product Candidates

If we or any potential 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, including the EMA. Failure to obtain regulatory approval for a product candidate will prevent us or any potential 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, EMA or any other regulatory approvals to market any of our product candidates for the foreseeable future, if at all. The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved.

Changes in the regulatory approval policy during the development period, changes in or the enactment of additional regulations or statutes, or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. Even if the FDA or the EMA 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. Any FDA 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 and EMA 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, the EMA and other foreign regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is 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. Although we evaluated the potential submission of a MAA to the EMA seeking marketing approval of enobosarm 3 mg in the EU for the prevention and treatment of muscle wasting in patients with advanced NSCLC, based on recent input from the MHRA, we believe that the data from the POWER trials is not sufficient to support the filing and approval of a MAA without confirmatory data from another Phase 3 clinical trial of enobosarm 3 mg. As a result of this input, we do not intend to submit a MAA in the absence of such confirmatory data. In addition, since data from the two POWER trials failed to meet the primary statistical criterion pre-specified for the co-primary endpoints of lean body mass and physical function, the FDA will not accept a NDA for enobosarm 3 mg for the prevention and treatment of muscle wasting in patients with advanced NSCLC. Accordingly, our strategy does not

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currently include further development of enobosarm for this indication in the U.S. or in Europe unless such development is part of a collaborative arrangement or strategic partnership.

Additionally, there can be no assurance that the FDA will determine that the data from our ongoing, planned or potential future clinical trials of enobosarm for the treatment of patients with AR positive advanced breast cancer or GTx-758 will be sufficient for approval of these product candidates in any indications. For example, we may observe an unacceptable incidence of adverse events in our ongoing, planned or potential clinical trials of enobosarm or GTx-758, 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, the EMA and other foreign regulatory authorities for marketing approval of a product candidate, it may not result in any marketing approvals.

We do not expect to receive regulatory approval for the commercial sale of any of our product candidates that are in development for the foreseeable future, if at all. The inability to obtain approval from the FDA, the EMA and other foreign regulatory authorities for our product candidates would prevent us or any potential collaborators from commercializing these product candidates in the United States, the EU, 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.

Risks Related to Commercialization

The commercial success of any products that we and/or any potential 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 collaborators may develop, including enobosarm, may not gain market acceptance for its stated indication 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.

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For example, if we are able to raise sufficient funding for any additional clinical development of enobosarm 3 mg through new collaborative arrangements with third parties or other financing alternatives and a MAA is submitted to the EMA for the marketing approval of enobosarm 3 mg in the EU for the more narrow indication of the prevention and treatment of muscle wasting in patients with advanced NSCLC treated with platinum plus taxane chemotherapy and marketing approval is obtained, we anticipate that the commercial prospects for enobosarm 3 mg could be diminished as a result of this more limited product indication.

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 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 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 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

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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 collaborators may develop or sell. These cost-control initiatives could decrease the price we might establish for products that we or any potential 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 EU, 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 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 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 EU 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 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 collaborators receive for any products that we and/or any potential 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.

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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 $25 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 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 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 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. We plan to advance the development of enobosarm for the treatment of patients with AR positive advanced breast cancer. To our knowledge, no other SARMs are currently in development for this indication; although SARMs in development for muscle wasting and cachexia could enter into a breast cancer program in the future. For example, Radius Health, Inc. has stated that it may test its

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SARM compound, RAD140, in a breast cancer indication in the future. A number of other compounds targeting the androgen axis in breast cancer could compete with enobosarm if one or more are approved for commercial sale in the indications for which enobosarm is being developed. These compounds fall into two categories, androgen synthesis inhibitors, or ASIs, and androgen receptor antagonists, or ARAs. ASIs in development include orteronel being developed by Takeda Pharmaceuticals and Zytiga® being developed by Janssen Pharmaceuticals. ARAs in development include XTANDI® (enzalutamide) being developed by Medivation and Astellas Pharma, and generic bicalutamide. Agents targeting pathways outside of the androgen axis also may compete with enobosarm in breast cancer as they are directed towards similar patient populations that may benefit from enobosarm. Additionally, we plan to initiate a proof of concept study in advanced AR positive TNBC patients for which there are no currently approved therapies, beyond chemotherapy. However, a number of approaches for the treatment of TNBC are currently under investigation. Agents also targeting the androgen axis include XTANDI® (enzalutamide) being developed by Medivation and Astellas Pharma, orteronel (TAK-700) being developed by Takeda, and CR-1447 being developed by Curadis. Only a subset of the total TNBC population is AR positive; therefore, agents targeting TNBC as a whole may also compete with enobosarm if approved for commercial sale. These agents include: PI3K/AKT inhibitors (BKM120 being developed by Novartis), IL6/JAK/Stat inhibitors (ruxolitinib being developed by Incyte), mTOR inhibitors (Neratinib being developed by Puma), and PARP inhibitors (Velaparib being developed by AbbVie), PD-1 inhibitors (pembrolizumab) being developed by Merck & Co. and MPDL3280A being developed by Roche.

We are developing GTx-758 for secondary hormonal therapy in men with CRPC, and, potentially, as a secondary hormonal 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 GTx-758. Provenge®, which was recently acquired by Valeant Pharmaceuticals, is an autologous cellular immunotherapy for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer. Medivation and Astellas Pharma market XTANDI® (enzalutamide), an oral androgen receptor antagonist, for the treatment of metastatic castration-resistant prostate cancer in men previously treated with docetaxel as well as those that have not yet received chemotherapy. Zytiga®, sold by Johnson & Johnson, has been approved for the treatment of metastatic CRPC in patients who have received prior chemotherapy and recently received approval for the treatment of metastatic castrate resistant prostate cancer prior to chemotherapy. Johnson & Johnson acquired Aragon Pharmaceuticals, Inc., which developed a second generation anti-androgen (ARN-509) that is currently being evaluated in Phase 2 studies in men with progressive, advanced prostate cancer. Bayer HealthCare and Orion Corporation are currently performing a Phase 3 study of ODM-201 in men with CRPC without metastases and with a rising PSA examining safety and efficacy by measuring metastatic free survival. Millennium: The Takeda Oncology Company is developing TAK-700 for the treatment of men with metastatic CRPC prior to chemotherapy.

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.

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Risks Related to Employees, Growth and Other Aspects of Operations

Management transition creates uncertainties and could harm our business.

We have recently had significant changes in executive leadership, and more could occur. Effective December 31, 2013, Mark Mosteller resigned as our Chief Financial Officer. In connection with Mr. Mosteller's resignation, Marc S. Hanover, who was then serving as our President and Chief Operating Officer, was appointed as our acting principal financial officer and Jason T. Shackelford, who was then serving as our Corporate Controller and Director of Accounting, was appointed as our principal accounting officer. On April 3, 2014, Mitchell S. Steiner resigned as our Vice Chairman and Chief Executive Officer. On April 3, 2014, Mr. Hanover was appointed as our interim Chief Executive Officer and on February 12, 2015, Mr. Hanover was appointed as our permanent Chief Executive Officer. Upon the appointment of Mr. Hanover as interim Chief Executive Officer, Mr. Hanover ceased to perform the duties of our principal financial officer, which duties were assigned to Mr. Shackelford. Additionally, James T. Dalton, our former Chief Scientific Officer, resigned effective August 31, 2014. Finally, on March 2, 2015, Robert J. Wills was appointed as our Executive Chairman.

As a result of the recent changes in our management team, Messrs. Hanover and Shackelford have taken on substantially more responsibility for the management of our business and of our financial reporting which has resulted in greater workload demands and could divert their attention away from certain key areas of our business. For instance, Mr. Hanover has taken on the role of our Chief Executive Officer in addition to the role he served when functioning as our President and Chief Operating Officer, positions that were previously occupied by two persons. In addition, while Dr. Wills' role as our Executive Chairman is, in part, to support Mr. Hanover in his role as our permanent Chief Executive Officer, the position of Executive Chairman is new to us and it may be some time before we can assess how much assistance he will provide to Mr. Hanover. Also, while we have retained Dr. Dalton as a consultant to GTx following his employment end date, we no longer have regular access to Dr. Dalton's key scientific expertise, which could materially and adversely impact our product candidate development efforts. Disruption to our organization as a result of executive management transition may have a detrimental impact on our ability to implement our strategy and could have a material adverse effect on our business, financial condition and results of operations.

Changes to company strategy, which can often times occur with the appointment of new executives, can create uncertainty, may negatively impact our ability to execute quickly and effectively, and may ultimately be unsuccessful. In addition, executive leadership transition periods are often difficult as the new executives gain detailed knowledge of our operations, and friction can result from changes in strategy and management style. Management transition inherently causes some loss of institutional knowledge, which can negatively affect strategy and execution. Until we integrate new personnel, and unless they are able to succeed in their positions, we may be unable to successfully manage and grow our business, and our results of operations and financial condition could suffer as a result.

Our internal computer and information technology systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, or could otherwise face serious disruptions, which could result in a material disruption of our product development efforts.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, and telecommunication and electrical failures. Such events could cause interruptions of our operations. For instance, the loss of preclinical data or data from our ongoing, planned and potential future clinical trials involving our product candidates could result in delays in our development and regulatory filing efforts and significantly increase our costs. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the

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development of our product candidates could be delayed. In addition, our information technology and other internal infrastructure systems, including corporate firewalls, servers, leased lines and connection to the Internet, face the risk of systemic failure that could disrupt our operations. A significant disruption in the availability of our information technology and other internal infrastructure systems could cause delays in our research and development work and could otherwise adversely affect our business.

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, 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.

In October 2013, we announced a reduction of approximately 60% of our workforce following our announcement that our POWER trials failed to achieve the results required by the FDA to file a NDA for enobosarm 3 mg for the prevention and treatment of muscle wasting in patients with advanced NSCLC. In addition, since our October 2013 workforce reduction, our former Chief Executive Officer, former Chief Financial Officer and former Chief Scientific Officer have resigned. Primarily as a result of our October 2013 workforce reduction, only 25 employees remained as employees of GTx as of December 31, 2014. Accordingly, we have been and are operating with a shortage of resources and may not be able to effectively conduct our operations with this limited number of employees. In addition, we announced past workforce reductions in each of December 2009 and June 2011, and our history of implementing workforce reductions, along with the potential for future workforce reductions, may negatively affect our ability to retain or attract talented employees. Further, to the extent we experience additional management transition, competition for top management is high and it may take many months to find a candidate that meets our requirements. If we are unable to attract and retain qualified management personnel, our business could suffer.

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

As of December 31, 2014, we had only 25 employees, and we will need to hire experienced personnel to develop and commercialize our product candidates and to otherwise grow our business, and we will need to expand the number of our managerial, operational, financial and other employees to support that growth. Competition exists for qualified personnel in the biotechnology field.

Future growth, if any, 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 develop and commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

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Risks Related to Our Common Stock

If we fail to meet continued listing standards of The NASDAQ Stock Market LLC, our common stock may be delisted. Delisting could adversely affect the liquidity of our common stock and the market price of our common stock could decrease, and our ability to obtain sufficient additional capital to fund our operations and to continue as a going concern would be substantially impaired.

Our common stock is currently listed on The NASDAQ Global Market. The NASDAQ Stock Market LLC, or NASDAQ, has minimum requirements that a company must meet in order to remain listed on The NASDAQ Global Market. These requirements include maintaining a minimum closing bid price of $1.00 per share. On October 2, 2014, we received a letter from NASDAQ notifying us that for the previous 30 consecutive business days, the closing bid price for our common stock was below the minimum $1.00 per share requirement for continued listing on The NASDAQ Global Market, or the Bid Price Requirement. In accordance with NASDAQ listing rules, we were afforded 180 calendar days, or until March 31, 2015, to regain compliance with the Bid Price Requirement. In anticipation of not meeting the Bid Price Requirement by March 31, 2015, we applied to transfer the listing of our common stock to The NASDAQ Capital Market on March 13, 2015. If our transfer application is approved and we are able meet certain initial listing criteria for listing on The NASDAQ Capital Market on April 1, 2015, we expect to be afforded an additional 180 calendar day compliance period to regain compliance with the Bid Price Requirement (as applied to listing on The NASDAQ Capital Market); however, we cannot assure you that we will in fact be afforded an additional 180 calendar day compliance period, in part since NASDAQ retains discretion to not afford us an additional compliance period irrespective of our meeting these initial listing criteria, in which case, our common stock will be subject to delisting. If our transfer application is approved and we are afforded an additional 180 calendar day compliance period on April 1, 2015, we would have until September 28, 2015 in order to regain compliance with the Bid Price Requirement. In this regard, we have provided written notice to NASDAQ of our intention to cure the Bid Price Requirement deficiency during this second 180 calendar day compliance period by effecting a reverse stock split, if necessary. If our transfer application is approved and we are afforded an additional 180 day compliance period but we do not regain compliance by September 28, 2015, then NASDAQ will provide written notice that our common stock will be subject to delisting from The NASDAQ Capital Market. To regain compliance, our common stock must close at or above the $1.00 minimum bid price for at least 10 consecutive days or more at the discretion of NASDAQ. If we are not afforded an additional 180 day compliance period our common stock would be subject to immediate delisting. In either of those events, we may appeal the decision to a NASDAQ Listing Qualifications Panel, but there can be no assurance that any such appeal would be successful. In addition, we may be unable to meet other applicable NASDAQ listing requirements, including maintaining minimum levels of stockholders' equity or market values of our common stock in which case, our common stock could be delisted notwithstanding our ability to demonstrate compliance with the Bid Price Requirement.

If our common stock is delisted, we would expect our common stock to be traded in the over-the-counter market, which could adversely affect the liquidity of our common stock. Additionally, we could face significant material adverse consequences, including:

a limited availability of market quotations for our common stock;

a reduced amount of news and analyst coverage for us;

a decreased ability to issue additional securities and a concomitant substantial impairment in our ability to obtain sufficient additional capital to fund our operations and to continue as a going concern;

reduced liquidity for our stockholders;

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potential loss of confidence by employees and potential future partners or collaborators; and

loss of institutional investor interest and fewer business development opportunities.

The market price of our common stock has been volatile and may continue to be volatile in the future. This volatility may cause our stock price and the value of your investment to decline.

The market prices for securities of biotechnology companies, including ours, have been highly volatile and may continue to be so in the future. In this regard, the market price for our common stock has varied between a high of $2.35 on January 17, 2014 and a low of $0.41 on October 14, 2014 in the twelve-month period ended December 31, 2014. The market price of our common stock is likely to continue to be volatile and subject to significant price and volume fluctuations. 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 and/or completion of our ongoing, planned and any future clinical trials of enobosarm and GTx-758, or negative, inconclusive or mixed results reported in any of our ongoing, planned and any future clinical trials of enobosarm and GTx-758;

our ability to raise additional capital in the future to carry through with our clinical development plans, including to commence and complete stage two of both of our planned Phase 2 clinical trials of enobosarm, as well as our current and future operations, and the terms of any related financing arrangements;

reports of unacceptable incidences of adverse events observed in any of our ongoing and planned clinical trials of enobosarm and GTx-758;

announcements regarding further cost-cutting initiatives or restructurings;

uncertainties created by our past and potential future management turnover;

our ability to enter into new collaborative, licensing or other strategic arrangements with respect to our product candidates;

the terms and timing of any future collaborative, licensing or other arrangements that we may establish;

the timing of achievement of, or failure to achieve, our and any potential 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 our clinical trials, including regulatory actions requiring or leading to a delay or stoppage of our ongoing or planned clinical trials;

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 collaborators, or our competitors, and the timing of these introductions or announcements;

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market conditions for equity investments in general, or the biotechnology or pharmaceutical industries in particular;

announcements regarding our ability to comply with the minimum listing requirements of The NASDAQ Stock Market LLC;

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;

the trading volume of our common stock;

changes in accounting principles; and

additional losses of any of our key scientific or management personnel.

In addition, the stock markets in general, and the markets for biotechnology stocks in particular, have experienced significant volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock.

In the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs, which would hurt our financial condition and results of operations and divert management's attention and resources, which could result in delays of our clinical trials or commercialization efforts.

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

As of December 31, 2014, our executive officers, directors and holders of 5% or more of our outstanding common stock, including their affiliated or associated entities, held approximately 75.7% of our outstanding common stock, and our executive officers and directors alone, including their affiliated or associated entities, held approximately 35.8% of our outstanding common stock as well as warrants to purchase up to an additional 29.9 million shares of common stock. As a result, these stockholders, acting together, 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.

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Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change taxable income or taxes may be limited. Although we have recently completed a study to determine whether any Section 382 limitations exist and we do not believe that any Section 382 limitations exist at this time, Section 382 of the Internal Revenue Code is an extremely complex provision with respect to which there are many uncertainties and we have not established whether the IRS agrees with our determination. In any event, changes in our stock ownership, some of which are outside of our control, could in the future result in an ownership change and an accompanying Section 382 limitation. If a limitation were to apply, utilization of a portion of our domestic net operating loss and tax credit carryforwards could be limited in future periods and a portion of the carryforwards could expire before being available to reduce future income tax liabilities.

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, 2014, the average daily trading volume of our common stock on The NASDAQ Global Market was 432,274 shares. As a result, future sales of a

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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, 2014, we had 140,325,643 shares of common stock outstanding. In addition, as a result of the relatively low trading volume of our common stock, the trading of relatively small quantities of shares by our stockholders may disproportionately influence the market price of our common stock in either direction. The price for our shares could, for example, decline significantly in the event that a large number of our common shares are sold on the market without commensurate demand, as compared to an issuer with a higher trading volume that could better absorb those sales without an adverse impact on its stock price.

In November 2014, we completed a private placement 64.3 million shares of our common stock and warrants to purchase 64.3 million shares of our common stock. Similarly, in March 2014 we completed a private placement of 12.0 million shares of our common stock and warrants to purchase 10.2 million shares of our common stock. Pursuant to the terms of a registration rights agreement we entered into in connection with the March 2014 private placement, we filed a registration statement under the Securities Act registering the resale of the 12.0 million shares of common stock we issued to the investors in the March 2014 private placement, which include J.R. Hyde, III, our largest stockholder, as well as the 10.2 million shares of common stock underlying the warrants we issued to those investors. Likewise, pursuant to the terms of the securities purchase agreement we entered into in connection with the November 2014 private placement, we filed a registration statement under the Securities Act registering the resale of the 64.3 million shares of common stock we issued to the investors in the November 2014 private placement, which included J.R. Hyde, III, and we also agreed to file one or more registration statements covering the resale of the 64.3 million shares of common stock subject to the warrants we issued to the investors in the November 2014 private placement. Moreover, J.R. Hyde, III and certain of his affiliates, have rights under a separate registration rights agreement with us to require us to file resale registration statements covering an additional 7.9 million shares of common stock held in the aggregate or to include these shares in registration statements that we may file for ourselves or other stockholders. If Mr. Hyde or his affiliates or any of our other significant stockholders, including the other investors in our 2014 private placements, 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 office space located at 175 Toyota Plaza, Memphis, Tennessee, under an operating lease which expires on April 30, 2015. We believe that our facilities are currently adequate to meet our needs.

ITEM 3. LEGAL PROCEEDINGS

We are not currently involved in any material legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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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.

	2014		2013	
	High	Low	High	Low
First Quarter	$ 2.35	$ 1.47	$ 5.41	$ 4.15
Second Quarter	1.70	1.26	7.24	3.85
Third Quarter	1.49	0.69	7.14	1.31
Fourth Quarter	0.98	0.41	2.09	1.41

On March 9, 2015, the closing price of our common stock as reported on The NASDAQ Global Market was $0.80 per share and there were approximately 77 holders of record of our common stock.

Performance Graph[1]

The rules of the SEC require that we include in our annual report to stockholders a line-graph presentation comparing cumulative stockholder returns on our common stock with a broad equity market index that includes companies whose equity securities are traded on the NASDAQ and either a published industry or line-of-business standard index or an index of peer companies selected by us. We have elected to use The NASDAQ Composite Index (which tracks the aggregate price performance of equity securities of companies traded on NASDAQ Stock Market) and The NASDAQ Biotechnology Index (consisting of a group of approximately 150 companies in the biotechnology sector) 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, 2009 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, 2014 as reported on The NASDAQ Global Market was $0.73.

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.

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COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

Among GTx Inc., the NASDAQ Composite Index, and the NASDAQ Biotechnology Index

*$100 invested on 12/31/09 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

[1] The material in this section is not "soliciting material," is not deemed filed with the SEC and is not to be incorporated by reference in any filing of GTx, Inc. under the Securities Act of 1933 or the Securities Exchange Act of 1934 whether made before or after the date hereof and irrespective of any general incorporation language in such filing.

Dividend Policy

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

Sales of Unregistered Securities and Issuer Repurchases of Securities

Other than the sales of common stock and warrants in our March 2014 and November 2014 private placements, as disclosed by us in prior current reports on Form 8-K, we did not make any unregistered sales of equity securities in 2014. In addition, we did not repurchase any of our equity securities during the fourth quarter of 2014.

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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. Historical results are not indicative of the results to be expected in the future.

	Years Ended December 31,				
	2014	2013	2012	2011	2010
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenues:					
Collaboration revenue	$ -	$ -	$ -	$ 8,066	$ 56,786
Expenses:					
Research and development expenses	20,870	32,318	38,887	31,938	28,495
General and administrative expenses	9,478	11,281	10,845	12,027	13,194
Total expenses	30,348	43,599	49,732	43,965	41,689
(Loss) income from operations	(30,348)	(43,599)	(49,732)	(35,899)	15,097
Other (expense) income, net	(259)	1,488	(19)	398	1,363
Loss on change in fair value of warrant liability (a)	(8,804)	-	-	-	-
(Loss) income from operations before income taxes	(39,411)	(42,111)	(49,751)	(35,501)	16,460
Income tax benefit	-	-	8,821	886	-
Net (loss) income from continuing operations	(39,411)	(42,111)	(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 (loss) income from discontinued operations	-	-	13,855	1,321	(1,166)
Net (loss) income	$ (39,411)	$ (42,111)	$ (27,075)	$ (33,294)	$ 15,294
Net (loss) income per share basic and diluted:					
Net (loss) income from continuing operations	$ (0.48)	$ (0.67)	$ (0.65)	$ (0.60)	$ 0.42
Net (loss) income from discontinued operations	-	-	0.22	0.02	(0.03)
Net (loss) income per share	$ (0.48)	$ (0.67)	$ (0.43)	$ (0.58)	$ 0.39

	As of December 31,				
	2014	2013	2012	2011	2010
	(in thousands)				

Balance Sheet Data:					
Cash, cash equivalents and short-term investments (b)	$ 49,295	$ 14,729	$ 56,089	$ 74,440	$ 58,631
Working capital	17,359	10,604	47,320	71,015	55,149
Total assets	50,651	15,605	57,774	78,656	64,583
Accumulated deficit	(494,771)	(455,360)	(413,249)	(386,174)	(352,880)
Total stockholders' equity	17,829	10,684	47,701	71,874	51,727

(a)

The loss on the change in fair value of warrant liability is related to the private placement of warrants completed in November 2014. See Note 6, *Stockholders' Equity*, for further information.

(b)

Cash, cash equivalents and short-term investments for the year ended December 31, 2014 includes the net proceeds of $21.1 million and $42.8 million received from the private placements of common stock and warrants completed in March and November 2014, respectively. See Note 6, *Stockholders' Equity*, for further information.

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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, including treatments for breast and prostate cancer, and other serious medical conditions.

We are developing selective androgen receptor modulators, or SARMs, a new class of drugs that we believe have the potential to be used as a hormonal therapy for the treatment of advanced breast cancer, as well as the potential to prevent and treat muscle wasting in patients with cancer and other musculoskeletal wasting or muscle loss conditions. Our lead product candidate, enobosarm (GTx-024), has to date been evaluated in 21 completed or ongoing clinical trials enrolling approximately 1,554 subjects, including in three Phase 2 and two Phase 3 clinical trials. 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.

Our current strategy is focused on the further development of enobosarm in two breast cancer indications targeting the androgen receptor, or AR. We are also evaluating opportunities for the use of enobosarm in other medical conditions. Additionally, we are also continuing our Phase 2 clinical trial of GTx-758 (Capesaris®) as a secondary hormonal treatment for men with castration resistant prostate cancer, or CRPC.

We announced during the second quarter of 2014 positive results from an ongoing Phase 2 proof-of-concept, open-label clinical trial evaluating enobosarm 9 mg oral daily for the treatment of patients with estrogen receptor, or ER, positive and AR positive metastatic breast cancer who have previously responded to hormonal therapy. Based on the positive results of the Phase 2 proof-of-concept clinical trial in patients with ER positive and AR positive metastatic breast cancer, as well as positive data reported in medical literature regarding the use of androgens for the treatment of breast cancer and our preclinical data demonstrating tumor growth inhibition with enobosarm in animal models of disease, we believe enobosarm has the potential to be an effective treatment alternative with a favorable side effect profile for women with ER positive and AR positive advanced breast cancer, as well as for women with advanced AR positive triple-negative breast cancer, or TNBC.

Subject to the receipt of necessary regulatory approvals, we plan to initiate a Phase 2 proof-of-concept clinical trial of enobosarm in the second quarter of 2015 that is designed to evaluate the efficacy and safety of enobosarm in patients with advanced AR positive TNBC. This planned open-label clinical trial will enroll up to approximately 55 patients, who will be administered an 18 mg oral daily dose of enobosarm, and clinical benefit will be assessed at four months of treatment. We plan to conduct this clinical trial using a Simon's two-stage design, pursuant to which we will enroll

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approximately half of the patients in the first stage, and, assuming a certain pre-specified minimal response rate is achieved, we will proceed with enrollment of the second stage. Subject to the receipt of necessary regulatory approvals, we also plan to initiate a second Phase 2 clinical trial in the third quarter of 2015 evaluating enobosarm in patients with ER positive and AR positive advanced breast cancer. This second planned open-label clinical trial is designed to enroll up to approximately 118 patients whose cancer treatment has shown prior response to hormonal therapy but has subsequently progressed. This second planned open-label clinical trial will randomize patients to either a 9 mg or 18 mg oral daily dose of enobosarm, again using a Simon's two-stage design, and will assess clinical benefit at six months of treatment. For each of these two Phase 2 clinical trials, clinical benefit is defined as a complete response, partial response or stable disease. We currently have sufficient funding through the end of 2016 to allow us to obtain the results from at least patients enrolled in stage one of each clinical trial, but our ability to enroll patients to stage two of the clinical trials and complete these clinical trials likely will require us to seek sufficient additional funding.

We announced in August 2013 that the POWER 1 (platinum plus taxane chemotherapy) and POWER 2 (platinum plus non-taxane chemotherapy) (Prevention and treatment Of muscle Wasting in patients with cancER) Phase 3 clinical trials evaluating enobosarm 3 mg daily for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer, or NSCLC, failed to meet the statistical criterion for the co-primary endpoints of lean body mass and physical function that were assessed using responder analyses as pre-specified for the United States Food and Drug Administration, or FDA. However, efficacy data from the studies demonstrated enobosarm's consistent effect on maintaining or improving lean body mass compared to placebo.

Enobosarm 3 mg demonstrated a statistically significant effect versus placebo on the primary endpoint of physical function through Day 84 in the POWER 1 clinical trial as assessed by continuous variable analysis, as pre-specified in our statistical analysis plan for the European Medicines Agency, or EMA. Based upon input from representatives of the FDA and from member countries to the EMA, we believe that the data from the POWER trials is not sufficient to support the filing and approval of a new drug application in the United States or a marketing authorization application in the European Union for enobosarm 3 mg for the prevention and treatment of muscle wasting in patients with advanced NSCLC. Our strategy does not currently include further development of enobosarm 3 mg for this indication in the U.S. or in Europe unless such development is part of a collaborative arrangement or strategic partnership. However, we are evaluating opportunities for the use of enobosarm in other medical conditions.

Additionally, we are developing 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 secondary hormonal treatment for advanced prostate cancer used in combination with androgen deprivation therapy, or ADT. We believe GTx-758 has the potential to reduce testosterone to levels lower than those attainable with ADT alone while ameliorating estrogen deficiency side effects, such as bone loss and hot flashes, which are common with current androgen deprivation therapies for prostate cancer.

We are currently conducting a Phase 2 open-label clinical trial in men who have developed metastatic or high risk non-metastatic CRPC while on ADT. GTx-758 has previously demonstrated the ability to increase the production of a protein called sex hormone binding globulin, or SHBG, that binds testosterone and thereby reduces 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 2 clinical trial is the proportion of subjects with a greater than or equal to 50% decline from baseline in serum PSA by day 90. Other key endpoints include serum SHBG and total and free testosterone levels in the study subjects. In addition, the clinical trial is evaluating the ability

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of GTx-758 to treat certain estrogen deficiency side effects associated with luteinizing hormone releasing hormone agonists such as hot flashes and bone loss. The Phase 2 clinical trial is designed to allow us to assess the safety and tolerability of GTx-758 in these subjects, including the incidence of venous thromboembolic events (blood clots), or VTEs. Enrollment of the 38 patients in the 125 mg arm has been completed without any occurrence of VTEs, and, during the first quarter of 2015, we met our enrollment goal of 38 subjects in the 250 mg arm. Based on the safety and efficacy data observed in the 125 mg arm and there being no unexpected side effects observed in the first ten metastatic patients enrolled in the 250 mg arm, enrollment of the 250 mg arm was opened to individuals with metastatic or high risk non-metastatic CRPC. To date, there has been one reported incidence of a VTE in a patient enrolled in the 250 mg arm, resulting in the patient's discontinuation from active treatment. The study is ongoing and primary efficacy data from all patients in the study is expected early in the third quarter of 2015. After receipt of data from this clinical trial, we will evaluate potential next steps in the clinical development of GTx-758, including potentially seeking a partnering or collaborative arrangement in order to fund additional clinical development.

Financial Overview

Our net loss for the year ended December 31, 2014 was $39.4 million. The net loss for the year ended December 31, 2014 included a non-cash loss of $8.8 million due to revaluation of our warrant liability at December 31, 2014, which warrant liability resulted from the issuance of common stock and warrants in our November 2014 private placement discussed below. We expect to incur significant operating losses for the foreseeable future as we continue our clinical development activities and potentially seek regulatory approval of our product candidates. We have funded our operations primarily through the sale of equity securities, collaboration and license agreements, and prior to September 2012, product revenue from sales of FARESTON®, the rights to which we sold to a third party in the third quarter of 2012. We currently have no ongoing collaborations for the development and commercialization of our product candidates and no source of revenue, nor do we expect to generate revenue for the foreseeable future. We do not expect to obtain FDA or EMA approval, or any other regulatory approvals, to market any of our product candidates, including enobosarm, for the foreseeable future, and it is possible that none of our product candidates will ever receive any regulatory approvals.

At December 31, 2014, we had cash, cash equivalents and short-term investments of $49.3 million compared to $14.7 million at December 31, 2013. On March 6, 2014, we completed a private placement of units consisting of 12.0 million shares of common stock and warrants to purchase 10.2 million shares of our common stock for net proceeds to us approximately $21.1 million, after deducting offering expenses. On November 14, 2014, we completed a separate private placement of units consisting of an aggregate of 64.3 million shares of our common stock and warrants to purchase an aggregate of 64.3 million shares of our common stock for net proceeds to us of $42.8 million, after deducting offering expenses.

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 through the end of 2016 (during which time we expect, at a minimum, to obtain results from patients enrolled in stage one of each of our planned open-label Phase 2 clinical trials of enobosarm in patients with AR positive advanced breast cancer, using a Simon's two-stage clinical trial design). While we estimate that our current cash, cash equivalents and short-term investments are sufficient to fund our operations through 2016, we will need to obtain substantial additional funding to commence and complete stage two of both of our planned open-label Phase 2 clinical trials of enobosarm in patients with AR positive advanced breast cancer and to otherwise seek regulatory approval for enobosarm in patients with AR positive advanced breast cancer. In addition, if we decide to undertake any further development of

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GTx-758 and/or enobosarm beyond our ongoing and currently-planned clinical trials, we would need to obtain additional funding for such development, either through financing or by entering into collaborative arrangements or partnerships with third parties for such further development.

While we have been able to fund our operations to date, we currently have no ongoing collaborations for the development and commercialization of our product candidates and no source of revenue, nor do we expect to generate revenue for the foreseeable future. We also do not have any commitments for future external funding. Until we can generate a sufficient amount of product revenue, which we may never do, we expect to finance future cash needs through potential collaboration, partnering or other strategic arrangements, as well as through public or private equity offerings or debt financings, or a combination of the foregoing. Our ability to raise additional funds and the terms upon which we are able to raise such funds have been severely harmed by the failure of the two enobosarm Phase 3 clinical trials to meet both of the co-primary endpoints agreed upon with the FDA, and may in the future be adversely impacted by the uncertainty regarding the prospects of our planned development of enobosarm for the treatment of patients with AR positive advanced breast cancer and our ability to advance the development of enobosarm and GTx-758, if at all. Our ability to raise additional funds and the terms upon which we are able to raise such funds may also be adversely affected by the uncertainties regarding our financial condition, the sufficiency of our capital resources, our ability to maintain the listing of our common stock on the NASDAQ Global Market or another market tier of the NASDAQ Stock Market and recent and potential future management turnover. 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 enobosarm and GTx-758 programs, or conduct additional workforce or other expense reductions, any of which could have a material adverse effect on our business and our prospects.

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. As a result of the October 2013 reduction in our workforce, we are no longer conducting in-house drug discovery activities and we are focusing our research and development activities on the ongoing clinical development of our current product candidates.

We expect that our research and development expenses for fiscal year 2015 will increase as compared to fiscal year 2014 due to our plan to initiate two Phase 2 clinical trials of enobosarm in two different breast cancer indications targeting the androgen receptor.

There is a substantial risk that any development program may not produce revenue. Moreover, because of uncertainties inherent in drug 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.

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

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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:

- the scope, rate of progress and cost of our clinical development programs, including our ongoing and any future clinical trials of enobosarm and GTx-758;
- the terms and timing of any potential collaborative, licensing and other strategic arrangements that we may establish;
- the amount and timing of any licensing fees, milestone payments and royalty payments from potential 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 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 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 2015 to be relatively consistent with fiscal year 2014.

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, valuation of warrants, 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

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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.

Warrant Liability

On November 14, 2014, we issued warrants to purchase 64.3 million shares of our common stock in a private placement to certain investors. We classify the warrants as a liability on our balance sheet since these warrants contain certain terms that could require us (or our successor) to purchase the warrants for cash in an amount equal to the value (as calculated utilizing a contractually-agreed Black-Scholes option pricing formula) of the unexercised portion of the warrants in connection with certain change of control transactions occurring on or prior to December 31, 2016, with such cash payment capped at an amount equal to $0.125 per unexercised share underlying each warrant. In addition, each warrant is subject to net cash settlement if, at the time of any exercise, there are then an insufficient number of authorized and reserved shares of common stock to effect a share settlement of the warrant. As of December 31, 2014, we did not have a sufficient number of authorized and reserved shares of common stock to effect the share settlement of all of these warrants; however, these warrants were not exercisable at December 31, 2014.

As a result of the foregoing provisions, we are required to account for these warrants as a liability at fair value, which is calculated using the Black-Scholes-Merton pricing valuation model. The Black-Scholes-Merton pricing valuation model requires that we use significant assumptions and judgment to determine appropriate inputs to the model. Some of the assumptions that we rely on include the volatility of the our common stock over the life of the warrant and risk-free interest rate. Our warrant liability is influenced by these assumptions and the price of our common stock as of the balance sheet date. The estimated warrant liability is required to be revalued at each balance sheet date until the earlier of the exercise of the warrants or, assuming stockholder approval is obtained for the authorization of additional common stock, the expiration of the provision on December 31, 2016 that could require cash settlement upon certain change of control transactions. Upon the exercise of the warrants or, assuming stockholder approval is obtained for the authorization of additional common stock, the expiration of the provision on December 31, 2016 that could require cash settlement upon certain change of control transactions, the fair value of the warrants will be reclassified from a liability to stockholders' equity on our balance sheets and no further adjustment to the fair value would be made in subsequent periods.

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.

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Share-Based Compensation

We have stock option and equity incentive plans that provide for the purchase or acquisition of our common stock by certain of our employees and non-employees. 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 stock options 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.

Share-based compensation also includes restricted stock units, or RSUs, granted to employees. We estimate the fair value of RSUs using the closing price of our stock on the grant date. All of our outstanding RSUs vested during the second quarter of 2014 and no RSUs were outstanding as of December 31, 2014. The fair value of RSUs was amortized on a straight-line basis over the requisite service period of the awards.

The following table summarizes share-based compensation expense included within the statements of operations for the years ended December 31, 2014, 2013 and 2012:

	Years ended December 31,		
	2014	2013	2012
	(in thousands)		
Research and development expenses	$ 2,512	$ 1,875	$ 1,046
General and administrative expenses	2,041	1,993	1,771
Total share-based compensation	$ 4,553	$ 3,868	$ 2,817

Share-based compensation expense recorded in the statement of operations as general and administrative expense for the years ended December 31, 2014, 2013 and 2012 included share-based compensation expense related to deferred compensation arrangements for our non-employee directors of $125,000, $135,000 and $169,000, respectively. At December 31, 2014, the total compensation cost related to non-vested stock options not yet recognized was approximately $4.0 million with a weighted average expense recognition period of 3.94 years.

Income Taxes

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

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Accordingly, at December 31, 2014 and 2013, net of the valuation allowance, the net deferred tax assets were reduced to zero.

We have recognized the tax effect of discontinued operations in the statement of operations in accordance with the intra-period accounting rules for the year ended December 31, 2012. An offsetting tax benefit was recorded in continuing operations for the year ended December 31, 2012 in relation to the tax expense that was recognized for discontinued operations.

Revenue Recognition

Our revenues for the year ended December 31, 2012 consisted of product sales of FARESTON®, which is included in income from discontinued operations before income taxes.

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, 2014 and December 31, 2013, our accrual for product returns, was $141,000 and $918,000, respectively. For the year ended December 31, 2014, we recorded a benefit of $576 as general and administrative expenses in the statement of operations for adjustments to our accrual for product returns related to the closure of the return period for a portion of the previously sold inventory.

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board issued Accounting Standard Update 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The new guidance is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern within one year of the date the financial statements are issued and to provide related footnote disclosure. This new guidance is effective for the first annual period ending after December 15, 2016 and interim periods thereafter.

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Results of Operations

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 31,		
		2014	2013	2012
		(in thousands)		
Enobosarm Prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer	**SARM**	$ 12,025	$ 18,541	$ 24,320
Enobosarm Treatment of women with AR positive advanced breast cancer	**SARM**	4,384	1,980	-
GTx-758 Secondary hormonal therapy in men with metastatic and nonmetastatic CRPC	**Selective ER alpha agonist**	4,201	5,492	7,458
Other research and development		260	6,305	7,109
Total research and development expenses		$ 20,870	$ 32,318	$ 38,887

Research and development expenses decreased 35% to $20.9 million for the year ended December 31, 2014 from $32.3 million for the year ended December 31, 2013. Research and development expenses for enobosarm for the prevention and treatment of muscle wasting in patients with advanced NSCLC decreased by $6.5 million in 2014 as the last patients completed the POWER 1 and POWER 2 Phase 3 clinical trials in May 2013. This decrease was partially offset by increased activities in 2014 related to satisfying the prerequisites necessary for our then-planned MAA submission for enobosarm 3 mg, including conducting seven Phase 1 clinical trials. Research and development expenses for enobosarm for the treatment of women with AR positive advanced breast cancer increased by $2.4 million in 2014 as we initiated in the second quarter of 2013 a Phase 2 proof-of-concept clinical trial evaluating a 9 mg daily dose of enobosarm for the treatment of AR positive and ER positive metastatic breast cancer in women who have previously responded to hormonal therapy for the treatment of their metastatic breast cancer, and, to a lesser extent, expenses related to activities necessary to initiate our planned Phase 2 clinical trials in AR positive advanced breast cancer. Research and development expenses related to GTx-758 decreased by $1.3 million for the year ended December 31, 2014 compared to the prior year related to the ongoing Phase 2 clinical trial to evaluate GTx-758 as secondary hormonal therapy in men with metastatic CRPC due to the timing of patient activities and related management expenses as this trial was initiated in the third quarter of 2012 and is nearing completion of enrollment as of December 31, 2014. Additionally, all product candidates and "Other research and development" shown above were impacted by the

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workforce reduction implemented in October 2013, which served to decrease personnel related costs for the year ended December 31, 2014 as compared to prior year.

Research and development expenses decreased 17% for the year ended December 31, 2013 from $38.9 million for the year ended December 31, 2012. The $5.8 million decrease in enobosarm 3 mg research and development expenses was due primarily to a decrease in expenses as the last patients completed the POWER 1 and POWER 2 Phase 3 clinical trials for enobosarm for the prevention and treatment of muscle wasting in patients with advanced NSCLC in May 2013. Research and development expenses for enobosarm for the treatment of AR positive advanced breast cancer increased by $2.0 million as we initiated in the second quarter of 2013 a Phase 2 clinical trial evaluating enobosarm 9 mg for the treatment of AR positive and ER positive metastatic breast cancer in women who have previously responded to hormonal therapy for the treatment of their metastatic breast cancer. Additionally, research and development expenses related to GTx-758 decreased by $2.0 million from the year ended December 31, 2012. During year ended December 31, 2013, we were conducting our ongoing Phase 2 clinical trial evaluating GTx-758 as secondary hormonal therapy in men with metastatic and non-metastatic CRPC, which was initiated in the third quarter of 2012. In the first quarter of 2012, we discontinued our three Phase 2 clinical trials of GTx-758 to treat men with advanced prostate cancer.

"Other research and development" expenses include the cost of personnel, supplies and facilities associated with preclinical and discovery research and development activities and decreased in both periods as we ceased conducting in-house drug discovery activities in October 2013.

General and Administrative Expenses

General and administrative expenses decreased 16% to $9.5 million for the year ended December 31, 2014 from $11.3 million for the year ended December 31, 2013. This decrease was primarily due a reduction in personnel costs as a result of the workforce reduction implemented in October 2013, a decrease in the accrual for product returns due to the closure of the return period for a portion of the previously sold inventory of FARESTON®, and decreased legal fees. These decreases were partially offset by increases related to cash retention bonuses and stock option and RSU grants made to employees as part of our efforts to retain essential employees needed for us to continue our business operations following the October 2013 workforce reduction, as well as severance and stock option modifications related to the resignation of our CEO during the second quarter of 2014.

General and administrative expenses increased 4% to $11.3 million for the year ended December 31, 2013 from $10.8 million for the year ended December 31, 2012. This increase was primarily due to increased legal expenses related to intellectual property activities and the preparation of new equity incentive plans.

Other (Expense) Income, Net

Other expense, net for the year ended December 31, 2014 was $259,000 compared to other income, net of $1.5 million for the year ended December 31, 2013. The year ended December 31, 2014 included an allocation of the total expenses related to the private placement of common stock and warrants completed in November 2014 as the warrants issued were accounted for as a liability. The remaining expenses were reflected as a reduction of equity. For the year ended December 31, 2013, we recorded a gain of $1.4 million from the sale of research and development property and equipment sold subsequent to the workforce reduction that occurred in October 2013.

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Loss on Change in Fair Value of Warrant Liability

We recognized a warrant liability due to certain provisions of the warrants issued as part of the November 2014 private placement of common stock and warrants. The warrants are required to be accounted for as a liability at fair value and the fair value must be revalued at each balance sheet date until the earlier of the exercise of the warrants or, assuming stockholder approval is obtained for the authorization of additional common stock, the expiration of the provision on December 31, 2016 that could require cash settlement upon certain change of control transactions. The resulting non-cash gain or loss on the fair value revaluation at each balance sheet date is recorded as non-operating income in our statement of operations.

These warrants were revalued at fair value as of December 31, 2014 and the increase in fair value of $8.8 million was recorded as a non-cash loss on the change in fair value of warrant liability in the Company's statement of operations.

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®.

The components of FARESTON® operating income for the years ended December 31, 2012 were as follows:

		December 31, 2012
		(in thousands)
Product sales, net	$	5,284
Cost of product sales		(784)
Operating expenses		(655)
FARESTON® operating income	$	3,845

Liquidity and Capital Resources

We have financed our operations to date primarily through public offerings and private placements of our securities, 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, 2014, we had an accumulated deficit of $494.8 million, which resulted primarily from:

our research and development activities associated with:

the preclinical and clinical development of our SARM compounds, including enobosarm;

the preclinical and clinical development of GTx-758 for the treatment of advanced prostate cancer;

the development of our discontinued toremifene 80 mg product candidate to reduce fractures and treat other estrogen deficiency side effects of androgen deprivation therapy in men with prostate cancer, including two Phase 2 clinical trials, a Phase 3 clinical trial, and the preparation and submission of a NDA to the FDA;

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- the development of our discontinued toremifene 20 mg product candidate for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia, including a Phase 2b clinical trial and a Phase 3 clinical trial; and

- the preclinical development of other product candidates; and

- general and administrative expenses.

We expect to incur significant operating losses for the foreseeable future as we continue our clinical development activities and potentially seek regulatory approval of our product candidates. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital. We do not expect to obtain FDA or EMA approval, or any other regulatory approvals, to market any of our product candidates, including enobosarm, for the foreseeable future, and it is possible that none of our product candidates will ever receive regulatory approvals.

At December 31, 2014, we had cash, cash equivalents and short-term investments of $49.3 million, compared to $14.7 million at December 31, 2013 and $56.1 million at December 31, 2012. On November 14, 2014, we completed a private placement of units consisting of an aggregate of 64.3 million shares of our common stock and warrants to purchase an aggregate of 64.3 million shares of our common stock for net proceeds of approximately $42.8 million. The purchasers in the private placement included certain existing GTx stockholders and certain members of the GTx management team and board of directors. The warrants we issued in the November 2014 private placement, which have a per share exercise price of $0.85, will be subject to net cash settlement if at the time of any exercise, there are then an insufficient number of authorized and reserved shares of our common stock to effect a share settlement of the warrants. We do not currently have a sufficient number of authorized and unreserved shares of common stock necessary to settle exercises of the warrants in full in shares of common stock. In connection with the November 2014 private placement we agreed to seek stockholder approval, at a special or annual meeting to be held no later than May 27, 2015, of an amendment to our Certificate of Incorporation to increase our authorized common stock to an amount necessary to effect the share settlement of all of the warrants we issued in the November 2014 private placement. Assuming such approval is obtained, warrant exercises would no longer be subject to net cash settlement. If we are unable to obtain such stockholder approval, our obligation to cash settle warrant exercises could be substantial and we are further obligated under the definitive purchase agreement we entered into with the investors in the November 2014 private placement to maintain adequate funds in order to satisfy any such cash settlement obligations, which may require us to raise additional capital and in any event could adversely impact our liquidity in future periods. The warrants will generally become exercisable on the date such stockholder approval is obtained (but in no event later than June 1, 2015) and would continue to be exercisable for four years thereafter.

On March 6, 2014, we completed a private placement of units consisting of 12.0 million shares of common stock and warrants to purchase 10.2 million shares of our common stock for net proceeds of approximately $21.1 million. The warrants, which had a one year term, expired unexercised on March 6, 2015.

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®.

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The following table shows a summary of our cash flows for the periods indicated:

	Years Ending December 31,		
	2014	2013	2012
	(in thousands)		
Net cash used in operating activities	$ (28,759)	$ (43,971)	$ (37,109)
Net cash (used in) provided by investing activities	(31,220)	9,237	21,405
Net cash provided by financing activities	63,330	1,219	3
Net increase (decrease) in cash and cash equivalents	$ 3,351	$ (33,515)	$ (15,701)

Net cash used in operating activities in all periods resulted primarily from funding our operations.

Net cash used in investing activities for the year ended December 31, 2014 primarily resulted from purchase of short-term investments of $41.9 million, partially offset by proceeds from the maturities of short-term investments of $10.7 million. Net cash provided by investing activities for the year ended December 31, 2013 resulted from the maturities of short-term investments of $9.3 million and proceeds from the sale of property and equipment of $1.4 million, partially offset by the purchase of short-term investments of $1.4 million and the purchase of information technology equipment and research and development equipment of approximately $32,000. Net cash used in 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 provided by financing activities for the year ended December 2014 reflected aggregate net proceeds of $63.9 million from the issuance of common stock and warrants related to the March and November 2014 private placements, partially offset by $617,000 of employee withholding tax payments related to vested RSUs. Net cash provided by financing activities for the year ended December 31, 2013 and 2012 reflected proceeds from the exercise of employee stock options of $1.2 million and $85,000, respectively. Proceeds in all years presented were reduced by payments on our capital lease and financed equipment obligations.

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 through the end of 2016. 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. While we estimate that our current cash, cash equivalents and short-term investments are sufficient to fund our operations through 2016 (during which time we expect, at a minimum, to obtain results from patients enrolled to stage one of each of our planned open-label Phase 2 clinical trials of enobosarm in patients with AR positive advanced breast cancer, using a Simon's two-stage clinical trial design), we will need to obtain substantial additional funding to commence and complete stage two of both of our planned open-label Phase 2 clinical trials of enobosarm in patients with AR positive advanced breast cancer and to otherwise seek regulatory approval for enobosarm in patients with AR positive advanced breast cancer. In addition, if we decide to undertake any further development of GTx-758 and/or enobosarm beyond our ongoing and currently-planned clinical trials, we would need to obtain additional funding for such development, either through financing or by entering into collaborative arrangements or partnerships with third parties for such further development.

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Our estimate of the period of time or events 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 I, 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 activities, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures associated with the future development of our product candidates, if any. Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical development programs, including our ongoing and any future clinical trials of enobosarm and GTx-758;
- the terms and timing of any potential collaborative, licensing and other strategic arrangements that we may establish;
- the amount and timing of any licensing fees, milestone payments and royalty payments from potential 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 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.

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 potential collaboration, partnering or other strategic arrangements, as well as through public or private equity offerings or debt financings, or a combination of the foregoing. In October 2013, following our announcement that the POWER trials failed to achieve the results required by the FDA for us to submit a NDA for enobosarm, we announced and implemented a workforce reduction of approximately 60%. 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 use to meet our cash requirements, and they may negatively affect our business and growth prospects.

To the extent that we raise additional funds through potential collaboration, partnering or other strategic 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, any of which could result in the stockholders of GTx having little or no continuing interest in our enobosarm and/or GTx-758 programs as stockholders or otherwise. To the extent we raise additional funds by issuing equity securities, our stockholders may experience significant dilution, particularly given our currently depressed stock price, and debt financing, if available, may involve restrictive covenants. For example, we completed a private placement of common stock and warrants in March 2014, which was substantially dilutive, and

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completed a subsequent private placement in November 2014 that represented even greater dilution, and our stockholders may experience additional, perhaps substantial, dilution should we again raise additional funds by issuing equity securities. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Our ability to raise additional funds and the terms upon which we are able to raise such funds have been severely harmed by the failure of the two enobosarm Phase 3 clinical trials to meet both of the co-primary endpoints agreed upon with the FDA, and may in the future be adversely impacted by the uncertainty regarding the prospects of our planned development of enobosarm for the treatment of patients with AR positive advanced breast cancer and our ability to advance the development of enobosarm and GTx-758, if at all. Our ability to raise additional funds and the terms upon which we are able to raise such funds may also be adversely affected by the uncertainties regarding our financial condition, the sufficiency of our capital resources, our ability to maintain the listing of our common stock on the NASDAQ Global Market or another market tier of the NASDAQ Stock Market and recent and potential future management turnover. 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 enobosarm and GTx-758 programs, or conduct additional workforce or other expense reductions, any of which could have a material adverse effect on our business and our prospects.

NASDAQ Listing Compliance

On October 2, 2014, we received a letter from NASDAQ notifying us that for the previous 30 consecutive business days, the closing bid price for our common stock was below the minimum $1.00 per share requirement for continued listing on The NASDAQ Global Market, or the Bid Price Requirement. The notification had no immediate effect on the listing of our common stock.

In accordance with NASDAQ listing rules, we were afforded 180 calendar days, or until March 31, 2015, to regain compliance with the Bid Price Requirement. In anticipation of not meeting the Bid Price Requirement by March 31, 2015, we applied to transfer the listing of our common stock to The NASDAQ Capital Market on March 13, 2015. If our transfer application is approved and we are able meet certain initial listing criteria for listing on The NASDAQ Capital Market on April 1, 2015, we expect to be afforded an additional 180 calendar day compliance period to regain compliance with the Bid Price Requirement (as applied to listing on The NASDAQ Capital Market); however, we cannot assure you that we will in fact be afforded an additional 180 calendar day compliance period, in part since NASDAQ retains discretion to not afford us an additional compliance period irrespective of our meeting these initial listing criteria, in which case, our common stock will be subject to delisting. If our transfer application is approved and we are afforded an additional 180 calendar day compliance period on April 1, 2015, we would have until September 28, 2015 in order to regain compliance with the Bid Price Requirement. In this regard, we have provided written notice to NASDAQ of our intention to cure the Bid Price Requirement deficiency during this second 180 calendar day compliance period by effecting a reverse stock split, if necessary. If our transfer application is approved and we are afforded an additional 180 day compliance period but we do not regain compliance by September 28, 2015, then NASDAQ will provide written notice that our common stock will be subject to delisting from The NASDAQ Capital Market. To regain compliance, our common stock must close at or above the $1.00 minimum bid price for at least 10 consecutive days or more at the discretion of NASDAQ. If we are not afforded an additional 180 day compliance period our common stock would be subject to immediate delisting. In either of those events, we may appeal the decision to a NASDAQ Listing Qualifications Panel, but there can be no assurance that any such appeal would be successful. In addition, we may be unable to meet other applicable NASDAQ listing requirements, including maintaining minimum levels of stockholders' equity or market values of our common stock in which

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case, our common stock could be delisted notwithstanding our ability to demonstrate compliance with the Bid Price Requirement. If our common stock is delisted, this would, among other things, substantially impair our ability to raise additional funds and could result in a loss of institutional investor interest and fewer development opportunities for us.

Contractual Obligations

At December 31, 2014, we had contractual obligations as follows:

	Payment Due by Period (in thousands)				
Contractual Obligations[1]	**Total**	**Less than 1 year**	**1-3 years**	**4-5 years**	**More than 5 years**
Operating lease obligations[2]	$ 184	$ 184	$ -	$ -	$ -

(1) This table does not include any royalty obligations under our license agreement with UTRF 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.

(2) Our long-term commitment under the operating lease consists of payments relating to a sublease for office space at 175 Toyota Plaza, Memphis, Tennessee. The sublease for the premises at 175 Toyota Plaza expires on April 30, 2015.

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, 2014.

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 initiating or conducting clinical trials for enobosarm and GTx-758 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 immaterial change 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, 2014. Actual results may differ materially. We have elected not to hedge our exposure to foreign currency fluctuations.

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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 principal executive officer and principal 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 principal executive officer and principal 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 principal executive officer and principal 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, 2014 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 (2013 framework). Based on this evaluation, we concluded that, as of December 31, 2014, 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.

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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 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

On March 13, 2015, we submitted a transfer application to The NASDAQ Stock Market LLC ("NASDAQ") to transfer the listing of our common stock from The NASDAQ Global Market to The NASDAQ Capital Market. If our transfer application is approved by NASDAQ, our common stock will continue to trade under the symbol "GTXI" on The NASDAQ Capital Market. The NASDAQ Capital Market is a continuous trading market that operates in substantially the same manner as The NASDAQ Global Market and listed companies must meet certain financial requirements and comply with NASDAQ's corporate governance requirements.

As previously reported, on October 2, 2014, we received a letter from NASDAQ notifying us that for the previous 30 consecutive business days, the closing bid price for our common stock was below the minimum $1.00 per share requirement for continued listing on The NASDAQ Global Market, or the Bid Price Requirement. In accordance with NASDAQ listing rules, we were afforded 180 calendar days, or until March 31, 2015, to regain compliance with the Bid Price Requirement. In anticipation of not meeting the Bid Price Requirement by March 31, 2015, we applied to transfer the listing of our common stock to The NASDAQ Capital Market on March 13, 2015. If our transfer application is approved and we are able meet certain initial listing criteria for listing on The NASDAQ Capital Market on April 1, 2015, we expect to be afforded an additional 180 calendar day compliance period to regain compliance with the Bid Price Requirement (as applied to listing on The NASDAQ Capital Market); we cannot assure you that we will in fact be afforded an additional 180 calendar day compliance period, in part since NASDAQ retains discretion to not afford us an additional compliance period irrespective of our meeting these initial listing criteria, in which case, our common stock will be subject to delisting. If our transfer application is approved and we are afforded an additional 180 calendar day compliance period on April 1, 2015, we would have until September 28, 2015 in order to regain compliance with the Bid Price Requirement. In this regard, we have provided written notice to NASDAQ of our intention to cure the Bid Price Requirement deficiency during this second 180 calendar day compliance period by effecting a reverse stock split, if necessary. If our transfer application is approved and we are afforded an additional 180 day compliance period but we do not regain compliance by September 28, 2015, then NASDAQ will provide written notice that our common stock will be subject to delisting from The NASDAQ Capital Market. To regain compliance, our common stock must close at or above the $1.00 minimum bid price for at least 10 consecutive days or more at the discretion of NASDAQ. If we are not afforded an additional 180 day compliance period our common stock would be subject to immediate delisting. In either of those events, we may appeal the decision to a NASDAQ Listing Qualifications Panel. In the event of an appeal, our common stock would remain listed on the NASDAQ Capital Market pending a written decision by the Panel following a hearing. In the event that the NASDAQ Listing Qualifications Panel determines not to continue our listing and we are delisted from The NASDAQ Capital Market, our common stock may be delisted and trade on the OTC Bulletin Board or other small trading markets, such as the pink sheets.

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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 2015 Annual Meeting of Stockholders with the U.S. Securities and Exchange Commission pursuant to Regulation 14A (the "2015 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 2015 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 2015 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 2015 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 the 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., Chief Legal Officer, 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 2015 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 2015 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 2015 Proxy Statement under the section entitled "Compensation Committee Report."

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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 2015 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 2015 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 2015 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 2015 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 2015 Proxy Statement under the section entitled "Proposal No. 5 Ratification of Appointment of Independent Registered Public Accounting Firm."

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PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Index to Financial Statements

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

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

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

Exhibit Number	Exhibit Description	Incorporation By Reference			
		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	Certificate of Amendment of Restated Certificate of Incorporation of GTx, Inc.	8-K	000-50549	3.3	05/09/2014
3.4	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, 3.3 and 3.4	-	-	-	-
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 J. R. Hyde, III dated August 7, 2003	S-1	333-109700	4.4	10/15/2003
4.4	Consent, Waiver and Amendment among Registrant, J. R. Hyde, III and Pittco Associates, L.P. dated December 3, 2007	S-3	333-148321	4.6	12/26/2007

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Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
4.5	Waiver and Amendment Agreement among Registrant, J.R. Hyde, III and Pittco Associates, L.P. dated March 6, 2014	10-K	000-50549	4.5	03/12/2014
4.6	Amended and Restated Registration Rights Agreement among Registrant, J.R. Hyde, III and The Pyramid Peak Foundation, dated August 4, 2014	10-Q	000-50549	4.6	08/05/2014
4.7	Form of Common Stock Warrant, issued by Registrant pursuant to the Securities Purchase Agreement, dated March 3, 2014, among the Registrant, J.R. Hyde III and The Pyramid Peak Foundation	10-K	000-50549	4.7	03/12/2014
4.8	Consent, Waiver and Amendment Agreement between Registrant and J.R. Hyde, III and Pittco Associates, L.P., dated August 4, 2014	10-Q	000-50549	4.8	08/05/2014
4.9+	Form of Common Stock Warrant, issued by Registrant pursuant to the Purchase Agreement, dated November 9, 2014, between Registrant and the purchasers identified in Exhibit A therein	-	-	-	-
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*	Form of Indemnification Agreement	S-1	333-109700	10.12	12/22/2003
10.4*	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
10.5*	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

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Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.6*	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
10.7*	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
10.8*	GTx, Inc. 2004 Equity Incentive Plan and Form of Stock Option Agreement	S-1	333-109700	10.5	01/15/2004
10.9*	GTx, Inc. 2004 Equity Incentive Plan, as amended effective April 30, 2008	8-K	000-50549	10.6	05/06/2008
10.10*	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
10.11*	GTx, Inc. 2004 Non-Employee Directors' Stock Option Plan and Form of Stock Option Agreement	S-1	333-109700	10.6	01/15/2004
10.12*	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
10.13*	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
10.14*	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
10.15*	GTx, Inc. 2013 Equity Incentive Plan	S-8	333-188377	99.1	05/06/2013
10.16*	Form of Stock Option Grant Notice and Option Agreement under the GTx, Inc. 2013 Equity Incentive Plan (Standard Form)	10-Q	000-50549	10.2	07/22/2013
10.17*	Form of Retention Stock Option Grant Notice and Option Agreement under the GTx, Inc. 2013 Equity Incentive Plan	10-Q	000-50549	10.3	11/12/2013
10.18*	Form of Retention Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the GTx, Inc. 2013 Equity Incentive Plan	10-Q	000-50549	10.4	11/12/2013

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Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.19*	GTx, Inc. 2013 Non-Employee Director Equity Incentive Plan	S-8	333-188377	99.2	05/06/2013
10.20*	Form of Stock Option Grant Notice and Option Agreement under the GTx, Inc. 2013 Non-Employee Director Equity Incentive Plan	10-Q	000-50549	10.4	07/22/2013
10.21*	Amended and Restated Employment Agreement dated February 14, 2013, between Registrant and Mitchell S. Steiner, M.D.	10-K	000-50549	10.19	03/05/2013
10.22*	Severance Agreement, made effective as of April 3, 2014, between Mitchell S. Steiner, M.D. and the Registrant	10-Q	000-50549	10.2	05/12/2014
10.23*	Amended and Restated Employment Agreement dated February 14, 2013, between Registrant and Marc S. Hanover	10-K	000-50549	10.20	03/05/2013
10.24*	Amendment to Amended and Restated Employment Agreement, effective as of April 3, 2014, between Registrant and Marc S. Hanover	10-Q	000-50549	10.3	05/12/2014
10.25*+	Amended and Restated Employment Agreement dated February 12, 2015, between Registrant and Marc S. Hanover	-	-	-	-
10.26*	Amended and Restated Employment Agreement dated February 14, 2013, between Registrant and Henry P. Doggrell	10-K	000-50549	10.22	03/05/2013
10.27*	Amended and Restated Employment Agreement dated February 14, 2013 between Registrant and James T. Dalton	10-K	000-50549	10.23	03/05/2013
10.28*	Consulting Agreement, made effective as of September 1, 2014, between the Registrant and James T. Dalton	10-Q	000-50549	10.3	08/05/2014
10.29*+	Employment Agreement dated October 1, 2013 between Registrant and Jason T. Shackelford	-	-	-	-
10.30*	Form of Retention Benefits Letter Agreement for Mitchell S. Steiner and Marc S. Hanover	10-Q	000-50549	10.1	11/12/2013

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Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.31*	Form of Retention Benefits Letter Agreement for James T. Dalton, Jason T. Shackelford and Henry P. Doggrell	10-Q	000-50549	10.2	11/12/2013
10.33*	Amended and Restated GTx, Inc. Executive Bonus Compensation Plan, effective November 4, 2008	10-K	000-50549	10.53	03/03/2009
10.34*+	2014 Compensation Information for Registrant's Executive Officers	-	-	-	-
10.35*+	2015 Compensation Information for Registrant's Executive Officers	-	-	-	-
10.36*	Directors' Deferred Compensation Plan, as amended effective November 4, 2008	10-K	000-50549	10.49	03/03/2009
10.37*	Directors' Deferred Compensation Plan, as amended and restated effective February 14, 2013	10-K	000-50549	10.28	03/05/2013
10.38*	Non-Employee Director Compensation Policy of GTx, Inc., effective February 14, 2013	10-K	000-50549	10.30	03/05/2013
10.39*+	Non-Employee Director Compensation Policy of GTx, Inc., effective February 12, 2015	-	-	-	-
10.40	Lease Agreement, dated March 7, 2001, between The University of Tennessee and TriStar Enterprises, Inc.	S-1	333-109700	10.13	10/15/2003
10.41	Sublease Agreement dated October 1, 2000, as amended, between Registrant and TriStar Enterprises, Inc.	S-1	333-109700	10.14	10/15/2003
10.42	Sublease Agreement dated April 1, 2005, as amended, between Registrant and TriStar Enterprises, Inc.	10-Q	000-50549	10.27	07/27/2005
10.43	Sublease Agreement dated October 1, 2009 between Registrant and University of Tennessee Research Foundation	10-K	000-50549	10.55	03/15/2010
10.44	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

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Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.45	Second Memorandum of Understanding Concerning the Lease Agreement between Registrant and The University of Tennessee Research Foundation as Amended July 20, 2009	10-Q	000-50549	10.5	07/22/2013
10.46	Third Memorandum of Understanding, made effective as of October 1, 2013, Concerning the Lease Agreement between Registrant and The University of Tennessee Research Foundation as Amended July 20, 2009	10-Q	000-50549	10.5	11/12/2013
10.47	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
10.48	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
10.49	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
10.50	Securities Purchase Agreement, dated March 3, 2014, by and among Registrant, J.R. Hyde III and The Pyramid Peak Foundation	10-K	000-50549	10.46	03/12/2014
10.51	Purchase Agreement, dated November 9, 2014, between Registrant and the purchasers identified in Exhibit A therein	8-K	000-50549	10.1	11/10/2014
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 Principal Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a)	-	-	-	-

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Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
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)(1)	-	-	-	-
32.2+	Certification of Principal 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)(1)	-	-	-	-
101.INS+	XBRL Instance Document	-	-	-	-
101.SCH+	XBRL Taxonomy Extension Schema Document	-	-	-	-
101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document	-	-	-	-
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document	-	-	-	-
101.LAB+	XBRL Taxonomy Extension Labels Linkbase Document	-	-	-	-
101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document	-	-	-	-

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

*

Indicates a management contract or compensation plan or arrangement.

+

Filed herewith

(1)

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.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GTx, Inc.

By /s/ Marc S. Hanover

Marc S. Hanover
Chief Executive Officer
(Principal Executive Officer)

Date: March 16, 2015

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENT, that each person whose signature appears below constitutes and appoints Marc S. Hanover and Jason T. Shackelford, 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.

/s/ Marc S. Hanover Marc S. Hanover	Chief Executive Officer (Principal Executive Officer)	March 16, 2015
/s/ Jason T. Shackelford Jason T. Shackelford	Senior Director, Accounting and Corporate Controller and Principal Financial and Accounting Officer (Principal Financial and Accounting Officer)	March 16, 2015
/s/ Robert J. Wills Robert J. Wills, B.S., M.S., Ph.D	Executive Chairman of the Board of Directors	March 16, 2015
/s/ Michael G. Carter Michael G. Carter, M. D.	Director	March 16, 2015

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/s/ J. Kenneth Glass	Director	March 16, 2015
J. Kenneth Glass		
/s/ J. R. Hyde, III	Director	March 16, 2015
J. R. Hyde, III		
/s/ Kenneth S. Robinson	Director	March 16, 2015
Kenneth S. Robinson, M.D.		

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GTx, Inc.

INDEX TO FINANCIAL STATEMENTS

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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, 2014 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 (2013 framework). Based on this evaluation, we concluded that, as of December 31, 2014, 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 who also audited the Company's financial statements included in this Annual Report on Form 10-K. Ernst & Young LLP's report on the Company's internal control over financial reporting is included in the Annual Report on the 10-K.

/s/ Marc S. Hanover

Marc S. Hanover
Chief Executive Officer
Principal Executive Officer

/s/ Jason T. Shackelford

Jason T. Shackelford
Senior Director, Accounting and
Corporate Controller
Principal Financial and Accounting Officer

Memphis, Tennessee
March 16, 2015

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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, 2014, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), (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, 2014, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of GTx, Inc. as of December 31, 2014 and 2013, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2014 and our report dated March 16, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Memphis, Tennessee
March 16, 2015

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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, 2014 and 2013, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2014. 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, 2014 and 2013, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, 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, 2014, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 16, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Memphis, Tennessee
March 16, 2015

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

	December 31, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,880	$ 14,529
Short-term investments	31,415	200
Prepaid expenses and other current assets	856	442
Total current assets	50,151	15,171
Property and equipment, net	29	112
Intangible and other assets, net	471	322
Total assets	$ 50,651	$ 15,605
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 512	$ 808
Warrant liability	30,430	-
Accrued expenses and other current liabilities	1,850	3,759
Total current liabilities	32,792	4,567
Other long-term liabilities	30	354
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value: 200,000,000 and 120,000,000 shares authorized at December 31, 2014 and December 31, 2013, respectively; 140,325,643 and 63,185,389 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively	140	63
Additional paid-in capital	512,460	465,981
Accumulated deficit	(494,771)	(455,360)
Total stockholders' equity	17,829	10,684
Total liabilities and stockholders' equity	$ 50,651	$ 15,605

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

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

	Years Ended December 31,		
	2014	**2013**	**2012**
Expenses:			
Research and development expenses	$ 20,870	$ 32,318	$ 38,887
General and administrative expenses	9,478	11,281	10,845
Total expenses	30,348	43,599	49,732
Loss from operations	(30,348)	(43,599)	(49,732)
Other income (expense), net	(259)	1,488	(19)
Loss on change in fair value of warrant liability	(8,804)	-	-
Loss from operations before income taxes	(39,411)	(42,111)	(49,751)
Income tax benefit	-	-	8,821
Net loss from continuing operations	(39,411)	(42,111)	(40,930)
Income from discontinued operations before income taxes	-	-	22,676
Income tax expense	-	-	(8,821)
Net income from discontinued operations	-	-	13,855
Net loss	$ (39,411)	$ (42,111)	$ (27,075)
Net (loss) income per share basic and diluted:			
Net loss from continuing operations	$ (0.48)	$ (0.67)	$ (0.65)
Net income from discontinued operations	-	-	0.22
Net loss per share	$ (0.48)	$ (0.67)	$ (0.43)
Weighted average shares outstanding:			
Basic and diluted	81,807,706	63,057,142	62,809,219

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

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GTx, Inc.
STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years Ended December 31, 2014, 2013 and 2012
(in thousands, except share data)

	Stockholders' Equity				
	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balances at January 1, 2012	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
Issuance of common stock under deferred compensation arrangements	45,667	-	-	-	-
Exercise of employee stock options	321,298	-	1,226	-	1,226
Directors' deferred compensation	-	-	135	-	135
Share-based compensation	-	-	3,733	-	3,733
Net loss	-	-	-	(42,111)	(42,111)
Balances at December 31, 2013	63,185,389	63	465,981	(455,360)	10,684
Issuance of common stock and warrants in March 2014 private placement, net of offering costs	11,976,048	12	21,123	-	21,135
Issuance of common stock and warrants in November 2014 private placement, net of offering costs	64,311,112	64	21,420	-	21,484
Vesting of restricted stock units, net of shares withheld for tax payments	853,094	1	(617)	-	(616)
Directors' deferred compensation	-	-	125	-	125
Share-based compensation	-	-	4,428	-	4,428
Net loss	-	-	-	(39,411)	(39,411)
Balances at December 31, 2014	140,325,643	$ 140	$ 512,460	$ (494,771)	$ 17,829

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

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

	Years Ended December 31,		
	2014	**2013**	**2012**
Cash flows from operating activities:			
Net loss	$ (39,411)	$ (42,111)	$ (27,075)
Adjustments to reconcile net loss to net cash used in operating activities:			
Loss on change in fair value of warrant liability	8,804	-	-
Private placement expenses recorded as other income (expense), net	297		
Gain on sale of FARESTON®	-	-	(18,831)
Share-based compensation	4,428	3,733	2,648
Directors' deferred compensation	125	135	169
Depreciation and amortization	102	384	750
Gain on sale of property and equipment	-	(1,366)	-
Changes in assets and liabilities:			
Prepaid expenses and other assets	(577)	399	1,857
Accounts payable	(296)	(899)	488
Accrued expenses and other liabilities	(2,231)	(4,246)	2,885
Net cash used in operating activities	(28,759)	(43,971)	(37,109)
Cash flows from investing activities:			
Purchase of property and equipment	(5)	(32)	(142)
Proceeds from the sale of property and equipment	-	1,424	-
Purchase of short-term investments, held to maturity	(41,905)	(1,425)	(11,980)
Proceeds from maturities of short-term investments, held to maturity	10,690	9,270	14,630
Proceeds from the sale of FARESTON®, net of cash expenses	-	-	18,897
Net cash (used in) provided by investing activities	(31,220)	9,237	21,405
Cash flows from financing activities:			
Net proceeds from the issuance of common stock and warrants	63,949	-	-
Tax payments related to shares withheld for vested restricted stock units	(617)	-	-
Proceeds from exercise of employee stock options	-	1,226	85
Payments on capital lease and financed equipment obligations	(2)	(7)	(82)
Net cash provided by financing activities	63,330	1,219	3
Net increase (decrease) in cash and cash equivalents	3,351	(33,515)	(15,701)
Cash and cash equivalents, beginning of period	14,529	48,044	63,745
Cash and cash equivalents, end of period	$ 17,880	$ 14,529	$ 48,044

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

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

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, including treatments for breast and prostate cancer, and other serious medical conditions.

The Company is developing selective androgen receptor modulators ("SARMs"), including its lead product candidate, enobosarm (GTx-024). SARMs are a new class of drugs that the Company believes have the potential to be used as a novel hormonal therapy for the treatment of advanced breast cancer, as well as the potential to prevent and treat muscle wasting in patients with cancer and other musculoskeletal wasting or muscle loss conditions. The Company announced during the second quarter of 2014 positive results from an ongoing Phase 2 proof-of-concept, open-label clinical trial evaluating a 9 mg oral daily dose of enobosarm for the treatment of patients with estrogen receptor ("ER") positive and androgen receptor ("AR") positive metastatic breast cancer who have previously responded to hormonal therapy. The Company's current strategy is focused on further development of enobosarm in two breast cancer indications targeting the androgen receptor. Subject to the receipt of necessary regulatory approvals, the Company plans to initiate a Phase 2 proof-of-concept clinical trial of enobosarm in the second quarter of 2015 that is designed to evaluate the efficacy and safety of enobosarm in patients with advanced AR positive triple-negative breast cancer. Subject to the receipt of necessary regulatory approvals, the Company also plans to initiate a second Phase 2 clinical trial in the third quarter of 2015 evaluating enobosarm in patients with ER positive and AR positive advanced breast cancer.

The Company announced in August 2013 that its POWER 1 (platinum plus taxane chemotherapy) and POWER 2 (platinum plus non-taxane chemotherapy) Phase 3 clinical trials evaluating enobosarm 3 mg daily for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer ("NSCLC") failed to meet the statistical criterion for the co-primary endpoints of lean body mass and physical function that were assessed using responder analyses as pre-specified for the United States Food and Drug Administration ("FDA"). Based upon input from representatives from the FDA and from member countries to the European Medicines Agency ("EMA"), the Company believes that the data from the POWER trials is not sufficient to support the filing and approval of a new drug application in the United States or a marketing authorization application in the European Union for enobosarm 3 mg for the prevention and treatment of muscle wasting in patients with advanced NSCLC. The Company's strategy does not currently include further development of enobosarm for this indication in the United States or in the European Union unless such development is part of a third-party collaborative arrangement or strategic partnership.

Additionally, the Company is developing GTx-758 (Capesaris®), an oral nonsteroidal selective estrogen receptor alpha agonist, for secondary hormonal therapy in men with castration resistant prostate cancer, and, potentially, as a secondary hormonal treatment for advanced prostate cancer used in combination with androgen deprivation therapy. The Company is presently conducting a Phase 2 clinical trial evaluating GTx-758 as a secondary hormonal therapy in men with metastatic and high risk non-metastatic castration resistant prostate cancer.

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

2. Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("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.

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, 2014 and 2013, 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.

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

Warrant Liability

On November 14, 2014, the Company issued warrants to purchase 64,311,112 shares of its common stock. The Company classifies the warrants as a liability on its balance sheet since the warrants contain certain terms that could require the Company (or its successor) to purchase the warrants for cash in an amount equal to the value (as calculated utilizing a contractually-agreed Black-Scholes option pricing formula) of the unexercised portion of the warrants in connection with certain change of control transactions occurring on or prior to December 31, 2016, with such cash payment capped at an amount equal to $0.125 per unexercised share underlying each warrant. In addition, each warrant is subject to net cash settlement if, at the time of any exercise, there are then an insufficient number of authorized and reserved shares of common stock to effect a share settlement of the warrant. As of December 31,

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2014, the Company did not have a sufficient number of authorized and reserved shares of common stock to effect the share settlement of all of these warrants; however, these warrants were not exercisable at December 31, 2014.

As a result of the foregoing provisions, the Company is required to account for these warrants as a liability at fair value and the estimated warrant liability is required to be revalued at each balance sheet date until the earlier of the exercise of the warrants or, assuming stockholder approval is obtained for the authorization of additional common stock, the expiration of the provision on December 31, 2016 that could require cash settlement upon certain change of control transactions. Upon the exercise of the warrants or, assuming stockholder approval is obtained for the authorization of additional common stock, the expiration of the provision on December 31, 2016 that could require cash settlement upon certain change of control transactions, the fair value of the warrants will be reclassified from a liability to stockholders' equity on the Company's balance sheets and no further adjustment to the fair value would be made in subsequent periods. See Note 6, *Stockholders' Equity*, for further information regarding these warrants and the Company's valuation of the warrant liability.

Fair Value of Financial Instruments and Warrant Liability

The carrying amounts of the Company's financial instruments (which include cash, cash equivalents, short-term investments, and accounts payable) and its warrant liability approximate their fair values. The fair value of the warrant liability is estimated using the Black-Scholes-Merton pricing valuation model. See Note 6, *Stockholders' Equity*, for additional disclosure on the valuation methodology and significant assumptions. The Company's financial assets and liabilities are classified within a three-level fair value hierarchy that prioritizes the inputs used to measure fair value, which is defined as follows:

Level 1 Quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date

Level 2 Inputs other than quoted prices in active markets that are observable for the asset or liability, either directly or indirectly

Level 3 Inputs that are unobservable for the asset or liability

Asset and liabilities measured at fair value on a recurring basis as of December 31, 2014 included only the Company's warrant liability of $30,430, which was classified within Level 3 of the hierarchy. As of December 31, 2013, the Company had no assets or liabilities measured at fair value on a recurring basis within Level 3 of the hierarchy. A loss of $8,804 related to the change in the fair value of the warrant liability was recognized during the year ended December 31, 2014 as a non-cash loss in the Company's statement of operations.

As the Company has the positive intent and ability to hold its 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.

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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.

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 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, 2014 and December 31, 2013, net of the valuation allowance, the net deferred tax assets were reduced to zero. See Note 9, *Income Taxes*, for further discussion.

The Company has recognized the tax effect of discontinued operations in the statement of operations for the year ended December 31, 2012 in accordance with the intra-period accounting rules. An offsetting tax benefit was recorded in continuing operations for the year ended December 31, 2012 in relation to the tax expense that was recognized for discontinued operations.

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

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

Other Income (Expense), Net

Other income (expense), 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. Other income (expense), net for the year ended December 31, 2014 also included expenses related to the private placement of common stock and warrants completed in November 2014 as the warrants issued were accounted for as a liability. Other income (expense), net for the year ended December 31, 2013 also included a gain of $1,366 from the sale of research and development property and equipment sold subsequent to the workforce reduction that occurred in October 2013. See Note 4, *Property and Equipment, Net*, for further discussion.

Basic and Diluted Net Loss Per Share

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

Weighted average potential shares of common stock of 24,628,775, 6,773,394, and 5,574,915 were excluded from the calculation of diluted net loss per share for the years ended December 31, 2014, 2013 and 2012, respectively, as inclusion of the potential shares would have had an anti-dilutive effect on the net loss per share for the periods. The increase in the weighted average potential shares of common stock excluded from the calculation of diluted net loss per share increased from the prior year due to the issuance of warrants under the two financing transactions that occurred during the year ended December 31, 2014. See Note 6, *Stockholders' Equity,* for further discussion. At December 31, 2014, the Company had outstanding 140,325,643 shares of common stock.

Comprehensive Loss

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

Discontinued Operations

Effective September 30, 2012, the Company entered into an asset purchase agreement (the "FARESTON® Purchase Agreement") with Strakan International S.á r.l., an affiliate of ProStrakan Group plc ("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® for a total cash purchase price of $21,671. 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 7, *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. As a result, revenue of $5,284, cost of goods sold of $784, and operating expenses of $655 related to FARESTON® were excluded from the respective captions in the statement

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of operations and were included in discontinued operations for the years ended December 31, 2012. Under the FARESTON® Purchase Agreement, the Company remains liable for future product returns relating to sales of FARESTON® made by the Company prior to September 30, 2012. For the year ended December 31, 2014, the Company recorded a benefit of $576 as general and administrative expenses in the statement of operations for adjustments to the Company's accrual for product returns related to the closure of the return period for a portion of the previously sold inventory.

FARESTON® Revenue Recognition

Revenue from product sales of FARESTON®, which is included in income from discontinued operations before income taxes for the year ended December 31, 2012, 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, 2014 and December 31, 2013, the Company's accrual for product returns, was $141 and $918, respectively. Of these amounts, $30 and $332 have been included in "Other long-term liabilities" in the Company's balance sheet at December 31, 2014 and December 31, 2013, respectively, and represents the portion of the Company's product returns accrual estimated to be payable after one year.

Restructuring

In October 2013, the Company implemented a reduction in its workforce following the announced results from its two Phase 3 clinical trials evaluating enobosarm 3 mg for the prevention and treatment of muscle wasting in patients with advanced NSCLC. The reduction in force was effective immediately and represented approximately 60% of the Company's total workforce.

As a result of the workforce reduction, the Company incurred severance related cash expenses of $1,306, of which $351 was included in general and administrative expenses and $955 was included in research and development expenses for the year ended December 31, 2013. All of these expenses were paid as of December 31, 2013. Additionally, the Company recognized a net benefit of approximately $370 resulting from the reversal of share-based compensation expense related to the modification of certain stock option provisions for the severed employees. Of this amount, $81 was included as a benefit to general and administrative expenses and $289 was included as a benefit to research and development expenses for the year ended December 31, 2013.

As a result of the October 2013 reduction in its workforce, the Company is no longer conducting in-house drug discovery activities. During the fourth quarter of 2013, the Company cancelled its sublease for the laboratory facilities and office space utilized for drug discovery. Additionally, the Company sold its related property and equipment for a gain of $1,366, which was included in other income (expense), net for the year ended December 31, 2013.

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Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board issued Accounting Standard Update 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The new guidance is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern within one year of the date the financial statements are issued and to provide related footnote disclosure. This new guidance is effective for the first annual period ending after December 15, 2016 and interim periods thereafter.

Subsequent Events

The Company has evaluated all events or transactions that occurred after December 31, 2014 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 and RSUs under the Company's stock option and equity incentive plans and deferred compensation arrangements for the Company's non-employee directors.

The Company has granted and continues to grant to employees and non-employees 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 generally vest over three years from the grant date for director and non-employee options and over periods of up to five years from the grant date for employee options. Under the terms of the Company's stock option and equity incentive plans, 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 post-termination exercise periods are generally longer. As described below, however, certain of the Company's outstanding options were modified in 2013 to provide an extended post-termination exercise period. The Company issues new shares of common stock upon the exercise of options. The Company estimates the fair value of stock option awards as of the date of the grant by applying the Black-Scholes-Merton 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 stock 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.

As part of the October 2013 workforce reduction, the Company modified stock options of the terminated employees to accelerate the vesting of certain outstanding non-vested stock options and to extend the post-termination exercise period of their vested stock options. The terminated employees' stock options were modified to accelerate the vesting of all outstanding and unvested stock options as if an employee had remained in continuous service as an employee of the Company through January 1, 2014. Further, the Company extended the post-termination exercise period of each terminated

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employee's outstanding and vested options until the earliest to occur of June 1, 2014 or the expiration of the original term of the particular option.

As part of the Company's efforts to retain the essential employees continuing with the Company following the October 2013 workforce reduction, the Company modified certain stock options held by continuing employees in the fourth quarter of 2013 to accelerate the vesting of certain outstanding non-vested stock options and to extend the post-termination exercise period of vested stock options. For these continuing employees, each of their outstanding stock options was modified to provide that if the employee's service continued through the end of business on May 31, 2014, then: (i) an additional number of shares subject to such option would immediately vest as if the employee's service had continued through January 1, 2015 and (ii) the period during which the vested portion of such options will generally expire would be extended from 90 days to six months after the employee's termination of service, subject in each case to the earlier expiration of the original term of the applicable stock option award.

Additionally, in the fourth quarter of 2013, the Company granted RSUs to certain of the continuing employees, which RSUs vested in full June 1, 2014. The Company estimated the fair value of RSUs using the closing price of its stock on the grant date. The fair value of the RSUs was amortized on a straight-line basis over the requisite service period of the awards. At December 31, 2013, the Company had 1,225,000 unvested RSUs outstanding with a weighted average grant date fair value per share of $1.87. All of the Company's outstanding RSUs vested during the second quarter of 2014 and no RSUs were outstanding as of December 31, 2014. The number of RSUs vested includes 371,906 shares that were withheld on behalf of the Company's employees to satisfy the statutory tax withholding requirements.

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, 2014:

	Years Ended December 31,		
	2014	**2013**	**2012**
Research and development expenses	$ 2,512	$ 1,875	$ 1,046
General and administrative expenses	2,041	1,993	1,771
Total share-based compensation	$ 4,553	$ 3,868	$ 2,817

Share-based compensation expense recorded in the statement of operations as general and administrative expense for the years ended December 31, 2014, 2013 and 2012 included share-based compensation expense related to deferred compensation arrangements for the Company's non-employee directors of $125, $135 and $169, respectively. See Note 10, *Directors' Deferred Compensation Plan*, for further discussion of deferred compensation arrangements for the Company's non-employee directors.

In the second quarter of 2014, in connection with the severance agreement entered into with the Company's then Chief Executive Officer in connection with his resignation, all of the executive's outstanding unvested stock options were vested and became immediately exercisable on April 13, 2014. The Company extended the post-termination exercise period of all of these stock options until the earlier to occur of (i) April 13, 2019 or (ii) the expiration of the term of a particular stock option

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grant. The Company recorded a one-time, noncash net compensation expense of $215 relating to these stock option modifications.

As a result of the October 2013 modifications of certain stock options held by terminated employees, the Company recognized a net benefit of approximately $370 resulting from the reversal of previously recognized share-based compensation expense that was in excess of the modified fair value of the options. Of this amount, $81 was included as a benefit to general and administrative expenses and $289 was included as a benefit to research and development expenses for the year ended December 31, 2013. The modifications of certain stock options held by the Company's continuing employees during the year ended December 31, 2013 did not have a material impact on share-based compensation expense recognized during the period.

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.

For the years ended December 31, 2014, 2013 and 2012, the weighted average grant date fair value per share of stock options granted was $1.04, $2.13 and $2.14, respectively. The weighted average for key assumptions used in determining the grant date fair value of options granted in 2014, 2013 and 2012, and a summary of the methodology applied to develop each assumption is as follows:

	Years Ended December 31,		
	2014	**2013**	**2012**
Expected price volatility	86.5%	82.9%	69.6%
Risk-free interest rate	2.3%	1.27%	1.22%
Weighted average expected life in years	6.9 years	5.9 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.

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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, 2014:

	Number of Shares	Weighted Average Exercise Price Per Share
Options outstanding at January 1, 2012	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 granted	2,784,200	3.12
Options forfeited or expired	(1,400,419)	5.86
Options exercised	(321,298)	3.81
Options outstanding at December 31, 2013	6,445,342	6.58
Options granted	3,094,500	1.34
Options forfeited or expired	(1,435,408)	8.50
Options exercised	-	-
Options outstanding at December 31, 2014	8,104,434	4.24
Options vested and expected to vest at December 31, 2014	7,795,136	4.34

The following table summarizes information about stock options outstanding at December 31, 2014:

	Options Outstanding			Options Exercisable	
Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$0.61 - $1.56	3,038,000	9.41	$ 1.34	100	$ 1.51
$1.88 - $4.20	3,697,200	6.55	3.11	3,037,803	2.97
$4.44 - $20.40	1,369,234	3.05	13.72	1,314,702	14.09
	8,104,434	7.03	4.24	4,352,605	6.33

At December 31, 2014, the aggregate intrinsic value of all outstanding options was $5 with a weighted average remaining contractual term of 7.03 years. Of the Company's outstanding options, 4,352,605 options were exercisable and had a weighted average remaining contractual term of 5.28 years and no aggregate intrinsic value. Additionally, the Company's vested and expected to vest options had a weighted average remaining contractual term of 6.94 years and an aggregate intrinsic value of $4.

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There were no options exercised during the year ended December 31, 2014. The total intrinsic value of options exercised during the years ended December 31, 2013 and 2012 was $688 and $36, respectively. At December 31, 2014, the total compensation cost related to non-vested options not yet recognized was $4,030, with a weighted average expense recognition period of 3.94 years. Shares available for future issuance under the Company's stock option and equity incentive plans were 4,979,673 at December 31, 2014. On January 1, 2015, shares available for future issuance under the 2013 equity incentive plan and 2013 non-employee director equity incentive plan increased by an aggregate of 6,113,026 shares in accordance with the automatic increase provisions of such plans.

4. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
	2014	**2013**
Computer equipment and software	$ 2,128	$ 2,130
Furniture and fixtures	1,032	1,032
Leasehold improvements	355	355
Office and laboratory equipment	261	261
	3,776	3,778
Less: accumulated depreciation	(3,747)	(3,666)
	$ 29	$ 112

Depreciation and amortization expense for the years ended December 31, 2014, 2013 and 2012 was $88, $369 and $730, respectively. Of these amounts, $1, $169 and $290, respectively, were included in research and development expenses in the statements of operations.

Subsequent to the reduction in workforce implemented in October 2013 and the Company's determination to cease drug discovery activities, the Company sold its related property and equipment and recognized a gain of $1,366 during the year ended December 31, 2013. The carrying value associated with the property and equipment that was sold was $58 and related to laboratory equipment.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2014	**2013**
Clinical trials	$ 929	$ 1,127
Net deferred income tax liabilities	319	156
General and administrative	267	497
Employee compensation	160	1,354
Product returns	112	586
Research and development	63	39
	$ 1,850	$ 3,759

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6. Stockholders' Equity

Authorized Capital

The Company's certificate of incorporation authorizes the Company to issue 200,000,000 shares of common stock, $0.001 par value per share, and 5,000,000 shares of preferred stock, $0.001 par value per share.

Common Stock and Associated Warrant Liability

On November 14, 2014, the Company completed a private placement of units consisting of an aggregate of 64,311,112 shares of common stock and warrants to purchase an aggregate of 64,311,112 shares of its common stock for net proceeds of $42,814, after deducting offering expenses. The purchasers in the private placement included certain existing GTx stockholders and certain members of the GTx management team and board of directors. The net proceeds from the private placement were allocated to the common stock and warrants based upon the fair value method. Similarly, the offering expenses were allocated between the common stock and the warrants with the portion allocated to common stock offset against the proceeds allocated to stockholders' equity, whereas the portion allocated to the warrants was expensed immediately. The warrants have a per share exercise price of $0.85 and will be exercisable at any time and from time to time from and after the earlier of (i) the date the Company obtains stockholder approval of an amendment to its Restated Certificate of Incorporation to increase its authorized common stock to an amount necessary to effect the share settlement of all of the warrants, which approval the Company has contractually-agreed to seek no later than May 27, 2015, or (ii) the trading day immediately prior to the occurrence of a "fundamental transaction" (as defined in the warrants), but in no event later than June 1, 2015, and will continue to be exercisable for four years thereafter. The Company does not currently have a sufficient number of authorized and unreserved shares of common stock necessary to settle exercises of all of the warrants in full in shares of common stock; accordingly, the warrants will be subject to net cash settlement if, at the time of any exercise, there are then an insufficient number of authorized and reserved shares of common stock to effect a share settlement of the warrants. Assuming stockholder approval of an amendment to the Company's Restated Certificate of Incorporation to increase its authorized common stock to an amount necessary to effect the share settlement of all of the warrants is obtained, warrant exercises would no longer be subject to net cash settlement. The warrants also contain certain terms that could require the Company (or its successor) to purchase the warrants for cash in an amount equal to the value (as calculated utilizing a contractually-agreed Black-Scholes-Merton pricing valuation model) of the unexercised portion of the warrants in connection with certain change of control transactions occurring on or prior to December 31, 2016, with the cash payment capped at an amount equal to $0.125 per unexercised share underlying each warrant. Due to these provisions, the Company is required to account for these warrants as a liability at fair value using the Black-Scholes-Merton pricing valuation model and the estimated warrant liability is required to be revalued at each balance sheet date until the earlier of the exercise of the warrants or, assuming stockholder approval is obtained for the authorization of additional common stock, the expiration of the provision on December 31, 2016 that could require cash settlement upon certain change of control transactions. The Company's warrant liability is influenced by several factors including the price of the Company's common stock as of the balance sheet date.

At issuance, the fair value of the warrant liability was estimated to be $21,626. These warrants were revalued at fair value as of December 31, 2014 and the resulting increase in fair value of $8,804

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was recorded as a non-cash loss on the change in fair value of warrant liability in the Company's statement of operations. The fair value of the warrants at December 31, 2014 of $30,430 was estimated using the Black-Scholes-Merton pricing valuation model with the following assumptions: expected volatility of 91%, risk-free interest rate of 1.5%, expected life of approximately 4.5 years and no dividends. Significant changes to the Company's market price for its common stock will impact the implied and/or historical volatility used to fair value the warrants. Any significant increases in the Company's stock price will likely create an increase to the fair value of the warrant liability. Similarly, any significant decreases in the Company's stock price will likely create a decrease to the fair value of the warrant liability.

On March 6, 2014, the Company completed a private placement of units consisting of an aggregate of 11,976,048 shares of common stock and warrants to purchase an aggregate of 10,179,642 shares of its common stock for net proceeds of $21,135, after deducting offering expenses. The net proceeds from the private placement were allocated to the common stock and warrants based upon their relative fair values. The warrants, which had a one year term that expired on March 6, 2015, carried a per share exercise price of $1.67. The Company assessed whether the warrants require accounting as derivatives. The Company determined that the warrants were indexed to the Company's own stock. As such, the Company has concluded the warrants met the scope exception for determining whether the instruments require accounting as derivatives and are classified in stockholders' equity. The fair value of the warrants on the date of grant was estimated at $4,478 using the Black-Scholes-Merton pricing valuation model with the following assumptions: expected volatility of 67%, risk free interest rate of 0.12%, expected life of one year and no dividends. All of these warrants expired unexercised on March 6, 2015.

7. 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

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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.

8. 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 that the Company entered into with UTRF in July 2007, the Company paid a one-time up-front fee of $290.

The Company's remaining intangible asset, net at December 31, 2014 and 2013 was $152 and $166, respectively, related to the SARM License Agreement.

9. 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,	
	2014	**2013**
Deferred income tax assets:		
Net federal and state operating loss carryforwards	$ 139,126	$ 127,819
Research and development credits	12,754	11,934
Share-based compensation	6,800	8,670
Depreciation and amortization	89	170
Other	69	425
Total deferred tax assets	158,838	149,018
Deferred income tax liabilities:		
Other	329	157
Total deferred tax liabilities	329	157
Net deferred tax assets	158,509	148,861
Valuation allowance	(158,509)	(148,861)
	$ -	$ -

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 $9,648, $17,318 and $8,836 in 2014, 2013, and 2012, respectively.

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At December 31, 2014, the Company had net federal operating loss carryforwards of approximately $358,702, which expire from 2018 to 2034 if not utilized. The Company had state operating loss carryforwards of approximately $337,735, which expire from 2015 to 2034 if not utilized. The Company also had research and development credits at December 31, 2014 of approximately $12,754, which expire from 2020 to 2034 if not utilized.

Both of the net federal and state operating loss carryforwards include approximately $2,301 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, 2014, 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 Section 382 of 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 completed a study of its net operating losses through December 31, 2014 to determine whether such amounts are likely to be limited by Section 382. As a result of this study, the Company does not currently believe any Section 382 limitation exists through December 31, 2014. However, any future ownership changes under Section 382 may limit the Company's ability to fully utilize these tax benefits. 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. An in-depth study may result in an increase or decrease to the Company's research and development credits and until such study is conducted of the Company's 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.

10. Directors' Deferred Compensation Plan

Non-employee directors may defer all or a portion of their fees under the Company's Directors' Deferred Compensation Plan until termination of their status as directors. Deferrals can be made into a cash account, a stock account, or a combination of both. Stock accounts will be paid out in the form of Company common stock, except that any fractional shares will be paid out in cash valued at the then current market price of the Company's common stock. Cash accounts and stock accounts under the

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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, 2014, 2013 and 2012, the Company incurred non-employee director fee expense of $247, $259 and $237, respectively, of which $125, $135 and $169 was deferred into stock accounts and will be paid in common stock following separation from service as a director. At December 31, 2014, 237,100 shares of the Company's common stock had been credited to individual director stock accounts under the Directors' Deferred Compensation Plan, and no amounts had been credited to individual director cash accounts under the Directors' Deferred Compensation Plan.

11. 401(k) Plan

The Company sponsors a 401(k) retirement savings plan that is available to all eligible employees. The plan is intended to qualify under Section 401(k) of the Internal Revenue Code of 1986, as amended. The plan provides that each participant may contribute up to a statutory limit of their pre-tax compensation which was $17.5 for employees under age 50 and $23 for employees 50 and older in calendar year 2014. 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 $200, $338 and $363 in 2014, 2013 and 2012, respectively.

12. Commitments and Contingencies

Operating Lease Commitments

The Company previously leased laboratory facilities and office space pursuant to a sublease, which had been accounted for as an operating lease. Subsequent to the reduction in force implemented in October 2013, this lease was cancelled effective December 31, 2013. The Company subleases 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 the operating leases was approximately $513, $674 and $963 for the years ended December 31, 2014, 2013 and 2012, respectively. As of December 31, 2014, future annual minimum payments under operating lease arrangements were $184 for the year ended December 31, 2015.

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13. Quarterly Financial Data (Unaudited)

The following is a summary of the quarterly results of operations for the years ended December 31, 2014 and 2013:

	2014 Quarters Ended			
	March 31	June 30	September 30	December 31
Expenses:				
Research and development expenses	$ 6,360	$ 7,894	$ 3,362	$ 3,254
General and administrative expenses	2,629	3,052	1,594	2,203
Total expenses	8,989	10,946	4,956	5,457
Loss from operations	(8,989)	(10,946)	(4,956)	(5,457)
Other income (expense), net	2	2	21	(284)
Loss on change in fair value of warrant liability (a)	-	-	-	(8,804)
Net loss	$ (8,987)	$ (10,944)	$ (4,935)	$ (14,545)
Net loss per share basic and diluted	$ (0.14)	$ (0.15)	$ (0.06)	$ (0.13)
Weighted average shares outstanding:				
Basic and diluted	66,512,069	75,433,302	76,014,531	108,869,121

(a) The loss on change in fair value of warrant liability is related to the private placement of warrants completed in November 2014. See Note 6, *Stockholders' Equity*, for further information.

	2013 Quarters Ended			
	March 31	June 30	September 30	December 31
Expenses:				
Research and development expenses	$ 9,614	$ 10,139	$ 6,477	$ 6,088
General and administrative expenses	3,023	2,684	2,483	3,091
Total expenses	12,637	12,823	8,960	9,179
Loss from operations	(12,637)	(12,823)	(8,960)	(9,179)
Other income, net	55	21	23	1,389
Net loss	$ (12,582)	$ (12,802)	$ (8,937)	$ (7,790)

Net loss per share	basic and diluted	$ (0.20)	$ (0.20)	$ (0.14)	$ (0.12)
Weighted average shares outstanding:					
Basic and diluted		62,864,140	62,994,771	63,179,394	63,185,389