# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### FORM 8-K

# CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report October 14, 2008 (Date of earliest event reported October 13, 2008)

## GTx, Inc.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

005-79588

(Commission File Number)

**62-1715807** (I.R.S. Employer Identification No.)

3 N. Dunlap Street Van Vleet Building Memphis, Tennessee 38163 (901) 523-9700

(Address, including zip code, of Registrant's principal executive offices Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

### ITEM 8.01 Other Events.

On October 13, 2008, GTx, Inc. issued a press release announcing the results of its Phase II cancer cachexia clinical trial, a copy of which is furnished as Exhibit 99.1 to this Current Report.

### ITEM 9.01 Financial Statements and Exhibits.

(c) Exhibits

Exhibit Number 99.1

Description
Press Release issued by GTx, Inc. dated October 13, 2008

#### **SIGNATURE**

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

GTx, Inc.

Date: October 14, 2008

By: /s/ Henry P. Doggrell
Name: Henry P. Doggrell
Title: Vice President, General Counsel/Secretary



Contact: McDavid Stilwell Director, Corporate Communications & Financial Analysis GTx, Inc. 901-523-9700

### GTx Announces Investigational Ostarine™ (MK-2866) Met the Primary Endpoint in the Phase II Cancer Cachexia Clinical Trial

MEMPHIS, Tenn. — October 13, 2008 — GTx, Inc. (NASDAQ: GTXI) today announced topline results of a Phase II clinical trial evaluating Ostarine™ (MK-2866), an investigational selective androgen receptor modulator (SARM), in patients with cancer induced muscle loss, also known as cancer cachexia. In this analysis, the study met its primary endpoint of absolute change in total lean body mass (muscle) compared to placebo and the secondary endpoint of muscle function (performance) after 16 weeks of treatment. GTx and Merck & Co., Inc. are collaborating to develop Ostarine and other SARMs, which are a new class of drugs with the potential to treat sarcopenia, which is the loss of skeletal muscle mass resulting in reduced physical strength and ability to perform activities of daily living, cancer cachexia, and other musculoskeletal conditions.

GTx plans to present complete study results at an upcoming scientific meeting in 2009.

"Cachexia continues to represent one of the most devastating features of cancer," said an investigator in the Phase II clinical trial, Adrian Dobs, MD, MHS, Professor of Medicine and Oncology and Vice Chair of the Department of Medicine, Division of Endocrinology and Metabolism, The Johns Hopkins University School of Medicine. "This study provided encouraging evidence for using Ostarine to treat patients with cancer cachexia by increasing lean body mass and improving functional performance."

The clinical trial enrolled 159 cancer patients (average age of 66 years) with non-small cell lung cancer, colorectal cancer, non-Hodgkin lymphoma, chronic lymphocytic leukemia, or breast cancer at 35 sites in the US and Argentina. Participants were randomized to receive placebo, 1 mg or 3 mg oral capsule of Ostarine once daily for 16 weeks. Average reported weight loss prior to entry among all subjects was 8.8 percent. Subjects were allowed to have standard chemotherapy during the trial. The drop out rate during the trial was 33 percent, lower than the expected 50 percent rate which has been observed in other cancer supportive care clinical trials.

The primary endpoint of the study was lean body mass measured by dual energy X-ray absorptiometry (DEXA) scan. A prespecified analysis was comparison of treatment arms with placebo using the exact Wilcoxon rank sum test stratified by cancer type in patients with DEXA scans performed at baseline and at the end of the study. Topline results show that Ostarine treatment resulted in a statistically significant increase in lean body mass compared to placebo.

Ostarine treatment resulted in clinically meaningful increases (greater than 1 kg) in lean body mass compared to baseline in both the Ostarine 1 mg and 3 mg treatment arms.

Topline results also show that Ostarine treatment improved muscle function (performance) in a 12 step stair climb test measuring speed and calculating power, a secondary endpoint of the study. No improvement in speed or power was observed for the placebo group. There were no improvements in the endpoints of grip strength and gait speed.

The incidence of serious adverse events, deaths and tumor progression were similar among placebo and the treatment arms. The most common side effects reported among all subjects in the trial were fatigue, anemia, nausea, and diarrhea. Changes in alanine amino transferase (ALT), a marker of liver function, greater than twice the upper limit of normal were observed in two patients in the placebo, Ostarine 1 mg and Ostarine 3 mg cohorts. No subjects discontinued treatment as a result of ALT changes.

"We are excited that Ostarine met the primary endpoint of the Phase II cancer cachexia clinical trial," said Mitchell S. Steiner, MD, CEO of GTx. "Even with the background of a heterogeneous cancer population, cancer induced inflammation, and chemotherapy, the changes compared to placebo in lean body mass and stair climb performance observed in this study are similar in magnitude to the changes observed in the earlier Ostarine Phase II proof of concept sarcopenia clinical trial. We are looking forward to continuing our work with Merck on the future development of Ostarine and other SARMs."

"We are committed to moving forward with our program on SARMs and look forward to continuing our work with GTx," said Alan B. Ezekowitz, MBChB, D.Phil., senior vice president and franchise head, Bone, Respiratory, Immunology, and Endocrine, Merck Research Laboratories.

#### About cancer cachexia

Cancer induced muscle loss occurs in about 50 percent of cancer patients and may lead to loss of protein stores, severe weakness and fatigue, immobility, loss of independence, and an inability to tolerate and respond to cancer treatments. Cancer induced muscle wasting is responsible for at least 20 percent of cancer deaths. There are no drugs currently approved for the treatment of cancer wasting.

#### **About GTx**

GTx, Inc., headquartered in Memphis, Tenn., is a biopharmaceutical company dedicated to the discovery, development, and commercialization of small molecules that selectively target hormone pathways to treat cancer, osteoporosis and bone loss, muscle wasting and other serious medical conditions. GTx is developing toremifene citrate, a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: first, a completed pivotal Phase III clinical trial evaluating toremifene 80 mg for the treatment of estrogen deficiency side effects of androgen deprivation therapy for advanced prostate cancer, and second, an ongoing pivotal Phase III clinical trial evaluating toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia, or PIN.

In 2006, GTx and Ipsen Group entered into a development and collaboration agreement for toremifene citrate in all indications except breast cancer for Europe and the Commonwealth of Independent States (CIS). GTx will file for marketing approval and, if approved, plans to commercialize toremifene 80 mg in the United States.

In December 2007, GTx and Merck & Co., Inc. formed a collaboration to discover and develop selective androgen receptor modulators (SARMs), a new class of drugs with the potential to treat sarcopenia, which is the loss of skeletal muscle mass resulting in reduced physical strength and ability to perform activities of daily living, cancer cachexia (muscle wasting), as well as other musculoskeletal conditions. Merck and GTx are conducting several Phase I and Phase II clinical trials evaluating multiple SARM product candidates including Ostarine™ (also designated as MK-2866) for sarcopenia. Merck and GTx are evaluating additional muscle loss indications for potential SARM clinical development.

GTx also is developing its preclinical compounds, GTx-758, an oral LH inhibitor for advanced prostate cancer, and GTx-878, an estrogen receptor beta agonist for the treatment of benign prostatic hyperplasia and chronic prostatitis.

Forward-Looking Information is Subject to Risk and Uncertainty

This press release contains forward-looking statements based upon GTx's current expectations. Forward-looking statements involve risks and uncertainties. GTx's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, the risks that (i) GTx and its collaboration partners will not be able to commercialize their product candidates if clinical trials do not demonstrate safety and efficacy in humans; (ii) GTx may not able to obtain required regulatory approvals to commercialize product candidates; (iii) clinical trials being conducted by GTx and its collaboration partners may not be completed on schedule, or at all, or may otherwise be suspended or terminated; and (iv) GTx could utilize its available cash resources sooner than it currently expects and may be unable to raise capital when needed, which would force GTx to delay, reduce or eliminate its product development programs or commercialization efforts. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this press release. GTx's annual report on Form 10-K filed March 11, 2008, and its most recent Form 10-Q filed August 5, 2008, contain under the heading, "Risk Factors," a more comprehensive description of these and other risks to which GTx is subject. GTx expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.