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 (Date of earliest event reported): June 11, 2009

GTx, Inc.

(Exact name of Registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization) 000-50549 (Commission File Number) 62-1715807 (I.R.S. Employer Identification No.)

175 Toyota Plaza 7th Floor Memphis, Tennessee 38103

(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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o 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))

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ITEM 8.01 Other Events.

On June 11, 2009, GTx, Inc. issued a press release announcing the 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, 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	Description
00.1	Proce Delegan issued by CTy, Inc. dated June 11, 2000

99.1 Press Release issued by GTx, Inc. dated June 11, 2009

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: June 11, 2009

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

GTx Presents Phase II Ostarine (MK-2866) Cancer Cachexia Clinical Trial Results at Endocrine Society Annual Meeting

Ostarine improved lean body mass and muscle performance in patients with cancer cachexia

WASHINGTON – June 11, 2009 – GTx, Inc. (Nasdaq: GTXI) today announced 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 the study, Ostarine treatment led to statistically significant increase in lean body mass (LBM) and improvement in muscle performance measured by stair climb in patients with cancer cachexia compared to baseline in both the Ostarine 1 mg and 3 mg treatment cohorts. These study results were the subject today of an oral podium presentation at the 2009 Annual Meeting of the Endocrine Society in Washington.

In the study, Ostarine met the primary endpoint of LBM, measured by a dual energy X-ray absorptiometry (DEXA) scan, by demonstrating statistically significant increases in LBM compared to baseline in both the Ostarine 1 mg and 3 mg treatment cohorts. Specifically, the change from baseline in LBM for the placebo, 1 mg and 3 mg treatment groups was 0.1 kg (p=0.874 compared to baseline), 1.5 kg (p=0.001) and 1.3 kg (p=0.045), respectively, at the end of the 16-week trial.

"Approximately half of all cancer patients suffer from the devastating effects of cancer induced muscle loss. Increasing lean body mass may improve patients' quality of life and even their response to cancer treatment," said Adrian Dobs, MD, MHS, an investigator in the Phase II clinical trial of Ostarine and Professor of Medicine and Oncology, The Johns Hopkins University School of Medicine. "These Phase II results demonstrate the potential of a SARM to fill an important unmet need as there are currently no FDA-approved therapies available for cancer cachexia."

GTx and Merck & Co., Inc. are collaborating to develop Ostarine as part of a broader SARMs clinical development program. SARMs are a new class of drugs with the potential to treat musculoskeletal conditions including cancer cachexia and sarcopenia–the loss of skeletal muscle mass resulting in reduced physical strength and ability to perform activities of daily living.

"We are encouraged by results of this Phase II trial in patients with cancer cachexia, where Ostarine showed significant improvements in lean body mass in both treatment cohorts," said Mitchell S. Steiner, MD, CEO of GTx. "We look forward to our continued partnership with Merck on the SARM program, and to evaluating the full potential of our lead product candidate Ostarine in conditions such as cancer cachexia, sarcopenia, and other muscle wasting conditions."

Cancer cachexia is the severe and progressive loss of muscle that occurs in cancer patients and is responsible for at least 20 percent of cancer deaths. An estimated 410,000 patients in the U.S. are diagnosed with cancer cachexia each year. Currently, there are no drugs approved for the treatment of cancer induced muscle loss.

Study Summary

159 cancer patients with non-small cell lung cancer, colorectal cancer, non-Hodgkin's lymphoma, chronic lymphocytic leukemia, or breast cancer were randomized in the placebo-controlled study at 35 sites in the U.S. and Argentina. Participants received placebo, 1 mg or 3 mg Ostarine once daily for 16 weeks. Average weight loss prior to entry among all subjects was 8.8 percent and patients were allowed to receive standard chemotherapy during the trial. The drop-out rate during the trial was 33 percent, lower than the expected 50 percent rate observed in other cancer supportive care clinical trials.

The study also met the secondary endpoint of muscle function (performance) as measured by a 12-step stair climb test measuring speed and calculating power, with each Ostarine treatment arm demonstrating a statistically significant average decrease in time to completion and average percentage increase in power exerted. The change from baseline in stair climb power in the placebo, 1 mg and 3 mg treatment groups was 0.23 watts (p=0.66 compared to baseline), 8.4 watts (p=0.002) and 10.1 watts (p=0.001), respectively. Statistically significant decreases from baseline in stair climb time were also observed. 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 cohorts. The most common side effects reported among all subjects in the trial were fatigue, anemia, nausea, and diarrhea.

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 prevent and treat cancer, fractures and bone loss, muscle loss and other serious medical conditions. GTx has completed a pivotal Phase III clinical trial evaluating toremifene citrate, a selective estrogen receptor modulator, or SERM, at an 80 mg dose for the prevention of bone fractures and treatment of other estrogen deficiency side effects of androgen deprivation therapy in men with prostate cancer. GTx has applied for marketing approval in the United States for toremifene 80 mg and, if approved, plans to commercialize toremifene 80 mg in the U.S. GTx is also developing toremifene citrate at a 20 mg dose in a Phase III clinical trial for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia, or PIN. GTx and Ipsen have 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). In December 2007, GTx and Merck & Co., Inc. formed a collaboration to discover and develop selective androgen receptor modulators, or 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, as well as cancer cachexia (cancer induced muscle loss) and other musculoskeletal wasting conditions. GTx and Merck are evaluating multiple SARM product candidates, including Ostarine™ (designated by Merck as MK-2866) and MK-0773 for a variety of musculoskeletal wasting indications including sarcopenia and cancer cachexia. In the second half of 2009, Merck and GTx expect to complete an ongoing Phase II clinical trial evaluating MK-0773 in sarcopenia. GTx also is conducting a Phase I clinical trial evaluating GTx-758, an oral luteinizing hormone inhibitor, for first line treatment of advanced prostate cancer.

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 be 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 quarterly report on Form 10-Q filed May 11, 2009 contains under the heading, "Risk Factors," a more comprehensive description of these and other risks to which GTx is subject. GTx expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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