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 6, 2011

GTx, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware

(State or Other Jurisdiction of Incorporation)

000-50549	**62-1715807**
(Commission File Number)	(I.R.S. Employer Identification No.)

175 Toyota Plaza
7th Floor
Memphis, Tennessee 38103

(Address of Principal Executive Offices, Including Zip Code)

(901) 523-9700

(Registrant's Telephone Number, Including Area Code)

Not Applicable

(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))

ITEM 8.01 Other Events.

On June 6, 2011, GTx, Inc. issued a press release announcing an agreement with the United States Food and Drug Administration (FDA) on a Phase III clinical development plan designed to evaluate Ostarine™ (GTx-024) for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer. A copy of the press release is attached as Exhibit 99.1 to this Current Report.

ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release issued by GTx, Inc. dated June 6, 2011

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 6, 2011

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

Exhibit 99.1

Source:

GTx, Inc.
McDavid Stilwell, Director, Corporate Communications & Financial Analysis
901-507-2667

GTx Announces Agreement with FDA on Phase III Clinical Development Plan Evaluating Ostarine™ (GTx-024) for the Prevention and Treatment of Muscle Wasting in Patients with Non-Small Cell Lung Cancer

MEMPHIS, Tenn.—(BUSINESS WIRE)— Following the conclusion of a series of meetings with the United States Food and Drug Administration (FDA), GTx, Inc. (Nasdaq: GTXI) announced today the clinical trial design for the two Phase III Ostarine™ registration studies for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer (NSCLC).

In July, GTx will initiate the Ostarine POWER1 and POWER2 (Prevention And Treatment Of Muscle Wasting in CancER) Phase III clinical trials and, assuming enrollment for both studies is completed within one year, expects completion of the two five month studies (last patient last visit) in the fourth quarter of 2012.

“Muscle wasting, which is so common in lung cancer patients, along with the associated weakness and fatigue, can result in diminished quality of life, loss of independence, and decreased ability to tolerate and benefit from cancer treatment,” said Jeffrey Crawford, MD, Chief, Division of Medical Oncology, Duke University Medical Center, and Lead Investigator of the POWER clinical trials. “A medical intervention which helps non-small cell lung cancer patients stay strong would be an important addition to the treatment armamentarium.”

“As a physician specializing in elderly cancer patients, strength is not only an important determinant of a patient’s quality of life, it also predicts outcomes,” said Hyman Muss, MD, Professor of Medicine and Director of Geriatric Oncology at the Lineberger Comprehensive Cancer Center at the University of North Carolina. “Muscle is not only a source of strength, it is also a store of proteins the body needs to help fight cancer and to better tolerate treatment. With three efficacy studies previously showing an increase in muscle and physical function, Ostarine is a promising drug candidate to prevent muscle wasting in cancer.”

In July 2011, GTx expects to initiate the Ostarine Phase III, international clinical trials, POWER1 and POWER2. In each of the placebo controlled, double blind clinical trials, 300 patients with Stage III or IV non-small cell lung cancer initiating first line chemotherapy will be randomized to placebo or Ostarine 3 mg. The studies will evaluate as co-primary endpoints the effect of Ostarine on lean body

mass assessed by dual x-ray absorptiometry (DXA) and on physical function assessed by the Stair Climb Test (each endpoint α=0.05) at three months. Durability of effect will be assessed as a secondary endpoint at five months.

“Since first reporting positive results in the Phase IIb Ostarine clinical trial in 2008, GTx has been excited about the potential for Ostarine to prevent and treat muscle wasting in cancer patients,” said Mitchell S. Steiner, MD, CEO of GTx. “We now have regulatory clarity for the path forward for this important indication.”

About Muscle Wasting, a Common Cancer Related Symptom

Muscle wasting is a common cancer related symptom which can begin early in the course of a patient’s malignancy resulting in decline in physical function and other detrimental clinical consequences. Muscle wasting and muscle weakness are also side effects of many chemotherapy drugs. There are no drugs approved for the prevention and treatment of muscle wasting in patients with cancer.

At diagnosis, approximately 50% of advanced non-small cell lung cancer (NSCLC) patients have severe muscle loss, and approximately 70% of these patients will lose muscle before death. Muscle weakness and functional limitations are highly prevalent, with 88% of NSCLC patients reporting difficulty climbing stairs, lifting and carrying 10 lbs, walking a quarter mile, or stooping, crouching or kneeling. Muscle loss is a predictor of performance status, tolerability to cancer treatment, progression free survival and overall survival. Limitations in physical function predict the ability of a NSCLC patient to tolerate chemotherapy, and patients with functional limitations are less likely to be offered treatment. Functional status is also a predictor of survival.

About Ostarine™

Ostarine™ is an oral selective androgen receptor modulator that GTx is developing for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer.

To date, GTx has evaluated Ostarine™ in eight clinical trials involving approximately 600 subjects including three efficacy studies. A four month Phase IIb Ostarine™ clinical trial enrolled 159 patients with NSCLC, colorectal cancer, breast cancer, non-Hodgkin’s lymphoma, or chronic lymphocytic leukemia. Ostarine treatment compared to placebo resulted in a 1.4 kg increase in lean body mass and increased speed and power in the Stair Climb Test. On June 5, 2011 at the Annual Meeting of the American Society of Clinical Oncology (ASCO), GTx presented a subsequent analysis which defined clinical benefit as a 10% improvement in stair climb power. Among the 61 patients with NSCLC enrolled in the study, 28 had stair climb power assessed at baseline and again at the conclusion of the study at 16 weeks. Seventy-eight percent (78%) of these

patients who were treated with Ostarine™ demonstrated clinical benefit, as compared to 30% of the patients receiving placebo (p=0.02).

Additionally, data GTx presented June 4, 2011 at the ASCO Annual Meeting suggests that Ostarine treatment may offer a potential positive effect on survival in NSCLC patients with severe weight loss. In patients with severe weight loss (>8% at baseline), the 4 month estimated survival was 59% in the placebo group and 83% in patients treated with Ostarine.

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

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 include, but are not limited to, statements relating to GTx's plans to initiate clinical trials for Ostarine™ (GTx-024) and statements related to the therapeutic potential of GTx's product candidates. 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 (i) that GTx will not be able to commercialize its product candidates if clinical trials do not demonstrate safety and efficacy in humans; (ii) that GTx may not be able to obtain required regulatory approvals to commercialize its product candidates in a timely manner or at all; (iii) that clinical trials planned to be conducted by GTx may not be initiated or completed on schedule, or at all, or may otherwise be suspended or terminated; (iv) that 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 candidate 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 with the Securities and Exchange Commission on May 9, 2011, 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.