

**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) **March 14, 2013**

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
(Address of principal executive offices)

38103
(Zip Code)

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

(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)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- 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 March 14, 2013, GTx, Inc. issued a press release announcing that the journal, *The Lancet Oncology*, has published online ahead of its April print edition (www.thelancet.com/journals/lanonc/onlinefirst) the results from GTx's randomized, double-blind, placebo-controlled Phase 2 clinical trial of enobosarm to assess its effects on muscle wasting and physical function in patients with cancer. A copy of the press release is furnished as Exhibit 99.1 to this Current Report.

ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits

**Exhibit
Number**
99.1

Description
Press Release issued by GTx, Inc. dated March 14, 2013

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: March 14, 2013

By: /s/ Henry P. Doggrell
Name: Henry P. Doggrell
Title: Vice President, Chief Legal Officer
and Secretary

ENOBOSARM PHASE 2 TRIAL FOR MUSCLE WASTING AND PHYSICAL FUNCTION IN PATIENTS WITH CANCER PUBLISHED IN THE LANCET ONCOLOGY

Trial demonstrated significant increases in lean body mass (muscle) and physical function in cancer patients treated with enobosarm

MEMPHIS, TN.— March 14, 2013— GTx, Inc. (Nasdaq: GTXI) today announced that the journal, *The Lancet Oncology*, has published online ahead of its April print edition (www.thelancet.com/journals/lanonc/onlinefirst) the results from GTx's randomized, double-blind, placebo-controlled Phase 2 clinical trial of enobosarm to assess its effects on muscle wasting and physical function in patients with cancer. Enobosarm (GTx-024) is a selective androgen receptor modulator (SARM), a new class of non-steroidal, tissue-specific anabolic agents that has the potential to increase muscle mass and improve physical function without the unwanted side effects on the prostate, skin or hair that are commonly associated with testosterone or non-selective, synthetic anabolic steroids. The lead author was Dr. Adrian S. Dobs, Professor of Medicine at the Division of Endocrinology and Metabolism, Johns Hopkins University School of Medicine in Baltimore, Maryland.

Cancer-induced muscle wasting begins early in the disease process, resulting in decreased physical function and other detrimental consequences, such as fatigue and weight loss, which can contribute to disability, reduced quality of life and shorter overall survival, compared with patients without muscle loss. There are no drugs approved for the prevention and treatment of muscle wasting in patients with cancer. The Phase 2 trial, which enrolled patients with non-small cell lung cancer (NSCLC), colorectal cancer (CRC), non-Hodgkin lymphoma (NHL), chronic lymphocytic leukemia (CLL) or breast cancer, demonstrated significant increases in lean body mass (primary endpoint) and physical function (one of the secondary endpoints) in patients treated with enobosarm 1 mg or 3 mg oral daily doses. Patients receiving placebo during the same period did not show significant increases in total lean body mass or in physical function.

The lead author, Dr. Adrian Dobs, an investigator in the Phase 2 trial, stated, "Muscle wasting is a common and devastating cancer-related symptom for which there are no effective therapies today. This is the first well controlled clinical trial to show that a selective anabolic agent, enobosarm, has the ability to not only increase muscle mass, but also improve physical function in a clinically relevant stair climb activity across a broad number of cancer types. After seeing the results of this Phase 2 clinical trial, I am looking forward to the results from the two Phase 3 clinical studies, POWER 1 and POWER 2, to confirm enobosarm's ability to prevent and treat muscle wasting in patients with advanced non-small cell lung cancer."

About the Phase 2 Trial

The Phase 2 multicenter, randomized clinical trial evaluated the safety and efficacy of either 1 mg or 3 mg doses of enobosarm, compared to placebo, in 159 patients who had been diagnosed with NSCLC, CRC, NHL, CLL or breast cancer and who had not yet begun chemotherapy or were between chemotherapy cycles. Eligible patients had a body mass index (BMI) of 35 kg/m² or less and were men older than 45 years or postmenopausal women. Additional inclusion criteria included at least 2% weight loss in the 6 months before randomization and a life expectancy of more than 6 months. Participants were randomized to receive enobosarm 1 mg or 3 mg or matching placebo orally daily for up to 113 days. The primary objective of the trial was to assess the effects of enobosarm on total lean body mass (muscle). Secondary objectives included assessments of the effects of enobosarm on total body weight, physical function, and quality of life. Baseline demographic (age, sex, race and BMI) and clinical characteristics (cancer type and cancer stage) were much the same across treatment groups. Lean body mass and body fat mass were assessed by dual-energy x-ray absorptiometry (DXA) at baseline and Day 113/end of study. Also, physical function was assessed by a stair climb test at baseline and Day 113/end of study. Efficacy analyses were done in the approximately 100 patients who had both a baseline and an on-treatment assessment within the protocol-specified

window for baseline and Day 113/end of study assessments (the "efficacy evaluable population"). All statistical analyses were performed in the efficacy evaluable population except those related to safety and survival, which were performed in the intent to treat (ITT) population (159 subjects randomized in the trial). Results from the trial included the following:

- Cancer patients receiving enobosarm (either 1 mg or 3 mg per day) showed a statistically significant increase from baseline to Day 113/end of trial in total lean body mass and a significant improvement from baseline in the time and power to climb 12 stairs
- Cancer patients receiving placebo during the same period did not show significant increases in total lean body mass and no improvement from baseline in their mean time or power to climb 12 stairs
- In each of the cancers types (NSCLC, CRC and other cancers), an increase in median lean body mass and stair climb power (physical function) was observed for both enobosarm 1 mg and 3 mg, with a greater increase in lean body mass being observed in the CRC patients and the greatest increases in stair climb power being observed in the NSCLC patients
- Although the trial was not powered to assess survival, in a post-hoc analysis, the survival hazard ratio for patients assigned enobosarm 1 mg versus placebo was 0.80 and for those assigned enobosarm 3 mg versus placebo was 0.70, representing a 20% and 30% improvement in survival, respectively
- Enobosarm was generally well tolerated, with the occurrence of serious adverse events and overall pattern of adverse events being much the same among placebo and treatment groups

About The POWER Trials

The 3 mg dose of enobosarm is now being studied in two Phase 3 clinical trials to prevent and treat muscle wasting in patients with NSCLC. In each of these placebo-controlled, double-blind clinical trials, approximately 325 patients with stage III or IV NSCLC have been randomized to oral daily doses of placebo or enobosarm 3 mg at the time they begin first-line standard platinum doublet chemotherapy. The POWER trials are designed to assess the response rates of enobosarm versus placebo for the co-primary endpoints at 3 months of treatment on maintenance or improvement of total lean body mass (muscle) assessed by DXA and improvement in physical function measured by the stair climb test (power). Durability of enobosarm treatment will be assessed at five months. Secondary endpoints include an assessment of whether enobosarm-treated patients have an improved quality of life and reduced healthcare resource utilization compared to placebo. Overall survival is being assessed as an additional safety endpoint. GTx announced early this year that the U.S. Food and Drug Administration has designated enobosarm for the prevention and treatment of muscle wasting in patients with NSCLC as a *Fast Track* development program. The Company plans to report top line data from the POWER trials in the third quarter of this year.

About GTx

GTx, Inc., headquartered in Memphis, Tenn., is a biopharmaceutical company dedicated to the discovery, development, and commercialization of small molecules for the treatment of cancer, cancer supportive care, and other serious medical conditions.

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, and include, but are not limited to, statements relating to GTx's clinical trials for enobosarm (also known as Ostarine® or GTx-024). 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 being conducted by GTx may not be completed on schedule, or at all, or may otherwise be suspended or terminated; or (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 annual report on Form 10-K filed with the Securities and Exchange Commission on March 5, 2013 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.

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