UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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) August 19, 2013

GTx, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**000-50549**	**62-1715807**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

175 Toyota Plaza	
7th Floor	
Memphis, Tennessee	**38103**
(Address of Principal Executive Offices)	**(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 communication 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 August 19, 2013, GTx, Inc. (the "Company") issued a press release announcing the Company's topline results from its pivotal Phase 3 clinical trials evaluating enobosarm 3 mg for cancer wasting in non-small cell lung cancer patients.

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	Description
99.1	Press Release issued by GTx, Inc. dated August 19, 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.

Date: August 19, 2013

GTx, Inc.

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

Exhibit 99.1

GTx Reports Results for Enobosarm POWER Trials for the Prevention and Treatment of Muscle Wasting in Patients with Non-Small Cell Lung Cancer

Lean body mass (LBM) and stair climb power (SCP) responder analyses were mixed and the trials did not meet the pre-specified criteria

Enobosarm demonstrated significant quantitative advantage in LBM compared to placebo in both trials

Findings from both trials consistent with published data on the relationship between LBM and survival

Company plans to meet with US and European regulatory authorities to discuss path forward

MEMPHIS, TN.— August 19, 2013— GTx, Inc. (Nasdaq: GTXI) today announced results of its two Phase 3 enobosarm clinical trials, the POWER trials, in patients with non-small cell lung cancer (NSCLC) receiving chemotherapy. The Company announced that the clinical trials failed to meet the overall criteria for the co-primary responder endpoints of lean body mass and physical function as agreed upon with the United States Food and Drug Administration (FDA); the responder endpoints showed mixed results (for POWER1 and POWER2, p values at Day 84 for LBM were 0.036 and 0.113, respectively; p values at Day 84 for SCP were 0.315 and 0.289, respectively).

Initial exploratory quantitative (continuous variable) analysis demonstrated that enobosarm had a consistent effect on LBM relative to placebo in both studies at all assessment times (p values were 0.0003 and 0.0227 at Day 84 for POWER1 and POWER2, respectively). Corresponding analyses for SCP were inconsistent between trials (p values were 0.0336 and 0.7923, respectively). Missing data were well balanced between the arms in both trials for both endpoints.

Across both clinical trials, enobosarm was generally well tolerated, with the occurrence of serious adverse events and overall incidence of adverse events similar across placebo and treatment groups. In POWER1, the four most common adverse events reported (in decreasing order of incidence) were nausea, alopecia, anemia and vomiting. In POWER2, the four most common adverse events reported were anemia, nausea, neutropenia and vomiting. In the safety analysis of survival, there was no evidence of a difference between patients treated with enobosarm and placebo in either clinical trial.

“While we are disappointed that both studies did not meet the pre-specified responder analyses, we are encouraged by the unambiguous effect of enobosarm on muscle and we are confident that it will translate to clinical benefit and potentially increase survival in patients with non-small cell lung cancer,” said Mitchell Steiner, M.D., CEO of GTx. “We look forward to sharing our clinical data from these and previous trials with FDA and European authorities to discuss the path forward. I would like to personally thank all the employees at GTx for their tremendous effort in conducting two high quality Phase 3 clinical studies and the principal investigators and their staff at over 80 clinical sites in 8 countries for their help recruiting and managing these studies. Most of all, I want to thank the patients with non-small cell lung cancer who participated in the POWER1 and POWER2 clinical trials in order to make it possible for future patients to potentially have access to important therapies.”

Published observational data suggest that LBM is related to survival outcome. This observational finding has been replicated based on exploratory analysis of current survival data from the POWER studies using landmark analysis and time-dependent covariate Cox regression modeling that includes LBM response and arm as covariates. The effect size and direction were similar in both trials.

GTx plans to initiate discussions with both the FDA and European regulatory authorities to determine the path forward.

“Muscle wasting in patients with non-small cell lung cancer is devastating and unfortunately it affects hundreds of thousands of patients worldwide,” said Jeffrey Crawford, M.D., Chief, Division of Medical Oncology at Duke University School of Medicine, and principal investigator for the POWER1 and POWER2 trials. “While some of the pre-specified primary endpoints were not met, I am encouraged by the substantial and consistent effect of enobosarm on muscle in these patients with lung cancer receiving chemotherapy.”

“Data from the POWER trials provide compelling evidence that enobosarm maintains or increases muscle, said Carla Prado, Ph.D., Assistant Professor, Nutrition, Food and Exercise Sciences at Florida State University. “Loss of muscle, independent of weight loss, is a common and often occult feature of cancer, and is acknowledged as a remarkable and powerful prognostic indicator of shorter survival.”

About The POWER Trials

A 3 mg dose of enobosarm was 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 were randomized to oral daily doses of placebo or enobosarm 3 mg at the time they began first-line standard platinum doublet chemotherapy. The POWER trials were 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 Dual-energy X-ray Absorptiometry (DXA) and improvement in physical function measured by the stair climb test (power). Durability of enobosarm treatment was assessed at five months. Secondary endpoints included an assessment of whether enobosarm-treated patients had 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 FDA has designated enobosarm for the prevention and treatment of muscle wasting in patients with NSCLC as a *Fast Track* development program.

About Cancer-Induced Muscle Wasting

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 currently no drugs approved for the prevention and treatment of muscle wasting in patients with cancer.

About Non-Small Cell Lung Cancer

The American Cancer Society estimates about 228,190 new cases of lung cancer will be diagnosed in the United States in 2013, and approximately 85 to 90 percent of these are non-small cell lung cancer. Approximately 159,480 Americans are expected to die from lung cancer this year.

Conference Call Details

The GTx management team will host a conference call and webcast to discuss this announcement. The event will be held today at 9:00 a.m. Eastern Time (ET). The live event will be available from the GTx website at http://www.gtxinc.com under the Investors section, or by calling (866) 700-5192 (domestic) or (617) 213-8833 (international). The access code is 35408233. A replay of the discussion will be available beginning at approximately 11:00 a.m. ET today from the GTx website or by calling (888) 286-8010 (domestic) or (617) 801-6888 (international), using access code 18733881. The telephone and website replays will be available until 11:59 p.m. ET on September 2, 2013.

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 quarterly report on Form 10-Q filed with the Securities and Exchange Commission on July 22, 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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