# 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) June 28, 2013

# GTx, Inc.

(Exact Name of Registrant as Specified in Charter)

**Delaware** (State or Other Jurisdiction of Incorporation) 000-50549 (Commission File Number) 62-1715807 (IRS 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 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 June 28, 2013, GTx, Inc. (the "Company") issued a press release announcing that the Company showcased two scientific poster presentations on enobosarm, a selective androgen receptor modulator (SARM), for the prevention and treatment of muscle wasting in cancer patients during the 2013 MASCC/ISOO International Symposium on Supportive Care in Cancer being held at the InterContinental Convention Centre in Berlin, Germany, June 27-29, 2013.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report.

### ITEM 9.01 <u>Financial Statements and Exhibits</u>.

(d) Exhibits.

Exhibit Number Description

99.1 Press Release issued by GTx, Inc. dated June 28, 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: June 28, 2013 GTx, Inc.

By: /s/ Henry P. Doggrell

Name: Henry P. Doggrell

Title: Vice President, Chief Legal Officer and Secretary

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## GTx Presents on Enobosarm for the Prevention and Treatment of Muscle Wasting in Cancer Patients at the 2013 MASCC/ISOO International Symposium on Supportive Care in Cancer

MEMPHIS, Tenn.—(BUSINESS WIRE)—June 28, 2013—GTx, Inc. (Nasdaq: GTXI) announced today that the Company showcased two scientific poster presentations on enobosarm, a selective androgen receptor modulator (SARM), for the prevention and treatment of muscle wasting in cancer patients during the 2013 MASCC/ISOO International Symposium on Supportive Care in Cancer being held at the InterContinental Convention Centre in Berlin, Germany, June 27-29, 2013.

Poster presentations that took place at 9:30 Central European time this morning at MASCC/ISOO include the following:

# Randomized Trials in NSCLC Investigating the Selective Androgen Receptor Modulator (SARM) Enobosarm to Prevent and Treat Muscle Wasting: Feasibility and Characteristics of Patients at Baseline

This poster outlined the baseline characteristics of the patients in the POWER trials as well as the design of the trials.

Enobosarm is currently being evaluated in two Phase 3 clinical trials, POWER 1 and POWER 2, for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer (NSCLC). In each of these placebo-controlled, double-blind clinical trials, approximately 325 patients with stage III or IV NSCLC have been randomized to receive oral daily doses of enobosarm 3 mg or placebo at the time they began 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 three months of treatment on total lean body mass (LBM) assessed by dual-energy X-ray absorptiometry (DXA) and physical function measured by the stair climb test (power).

#### Baseline characteristics included:

- Median weight-loss at baseline was 5%.
- LBM and stair climb power were lower than typically observed in healthy individuals indicating significant functional decline before starting chemotherapy for NSCLC.
- Majority of patients presented with stage IV NSCLC.
- Most patients were ECOG 1.

The Company plans to release topline data from the two pivotal Phase 3 clinical trials for enobosarm 3 mg for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer in 3Q 2013.

## Improved Physical Function is Associated with Increased Lean Body Mass (LBM): Findings From a Phase 2 Trial of the Selective Androgen Receptor Modulator (SARM) Enobosarm.

This poster summarized the associations between changes in lean body mass and physical function in a Phase 2 enobosarm trial.

Enobosarm has been evaluated in a randomized, double-blind, placebo-controlled Phase 2 clinical trial to assess its effects on muscle wasting and physical function in patients with cancer. The Phase 2 trial enrolled 159 patients with NSCLC, colorectal cancer (CRC), non-Hodgkin lymphoma (NHL), chronic lymphocytic leukemia (CLL) or breast cancer, who had not yet begun chemotherapy or were between chemotherapy cycles. The trial was designed to assess the effects of enobosarm on total LBM (muscle), with secondary objectives including assessments of the effects of enobosarm on total body weight, physical function, and quality of life. Total LBM assessed by DXA and physical function measured by the stair climb test (power) were assessed at baseline and Day 113/end of study.

Key findings included:

- Patients with >0.25 kg gain in LBM were more likely to have a substantially meaningful response in physical function (62% versus 34%, p=0.017; Fisher's Exact Test). These patients also had improvement in percentage change in stair climb power, median +12% versus +0.8% (p=0.017; Wilcoxon Rank Sum Test).
- This finding validates the value of these endpoints in the ongoing Phase 3 trials with enobosarm directed at preventing and treating muscle wasting in patients with cancer.

#### **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 May 6, 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.

Source: GTx, Inc.

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