

**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) **January 8, 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 January 8, 2013, GTx, Inc. issued a press release announcing that the U. S. Food and Drug Administration (FDA) has designated enobosarm (GTx-024) for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer as a Fast Track development program, a copy of which 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 January 8, 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: January 8, 2013

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

GTx Announces FDA's Grant of Fast Track Designation to Enobosarm
For the Prevention and Treatment of Muscle Wasting in patients with Non-Small Cell Lung Cancer

MEMPHIS, TN.— January 8, 2013— GTx, Inc. (Nasdaq: GTXI) today announced that the U.S. Food and Drug Administration (FDA) has designated enobosarm (GTx-024) for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer as a Fast Track development program. Fast Track status is a process designed by FDA to facilitate the development and expedite the review of new drug candidates that are intended to treat serious diseases and have the potential to fill an unmet medical need. With a Fast Track designation, there is an increased possibility for a priority review of a new drug application (NDA) filed for the drug candidate and more opportunity for more frequent interactions with the FDA both prior to and following the filing of a NDA.

GTx is assessing the ability of enobosarm to prevent and treat muscle wasting in non-small cell lung cancer patients in two pivotal Phase III clinical trials, POWER 1 and POWER 2. In each of the placebo-controlled, double-blind clinical trials, approximately 300 patients with Stage III or IV non-small cell lung cancer have been randomized to oral daily doses of placebo or enobosarm 3 mg at the time they began first line standard platinum doublet chemotherapy. The studies are evaluating as co-primary endpoints at three months of treatment the responder rates of enobosarm versus placebo on maintaining or improving total lean body mass (muscle) assessed by dual x-ray absorptiometry and improving physical function measured by the Stair Climb Test. Durability of the drug effect is being evaluated as a secondary endpoint at five months of treatment.

“We are very pleased that FDA has recognized enobosarm as a drug candidate with the potential to address the serious and unmet medical need of preventing and treating muscle wasting in non-small cell lung cancer patients,” said Mitchell Steiner, MD, CEO of GTx. “With approximately 650 patients fully enrolled in our two definitive Phase III clinical studies of enobosarm, we expect to receive top line data from these studies this summer. Assuming the data supports our ability to do so, we will move quickly to meet with FDA to discuss the filing of a new drug application for enobosarm.”

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 November 8, 2012 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.
Marc Hanover, President and Chief Operating Officer
901-523-9700
