

**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) **April 15, 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 April 15, 2013, GTx, Inc. issued a press release announcing that a per protocol safety review of unblinded safety data on Friday April 12, 2013, by an independent Data Safety Monitoring Board (DSMB), resulted in a determination that GTx continue as planned its two pivotal Phase III clinical trials of enobosarm (GTx-024) for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung 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 April 15, 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: April 15, 2013

By: /s/ Henry P. Doggrell

Name: Henry P. Doggrell

Title: Vice President, Chief Legal Officer
and Secretary

GTx's Phase III Clinical Studies of Enobosarm (GTx-024) To Continue as Planned Following Planned Safety Review

MEMPHIS, TN.— April 15, 2013—GTx, Inc. (Nasdaq: GTXI) today announced that a per protocol safety review of unblinded safety data on Friday April 12, 2013, by an independent Data Safety Monitoring Board (DSMB), resulted in a determination that GTx continue as planned its two pivotal Phase III clinical trials of enobosarm (GTx-024) for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer. The DSMB has met regularly every six months to review safety data from the two pivotal Phase III clinical trials and will not meet again until the data is locked and unblinded for a final assessment of safety data from the two studies.

“We are pleased that the DSMB has recommended that GTx continue as planned with our clinical studies of enobosarm under the existing protocols,” said Mitchell S. Steiner, MD, Chief Executive Officer of GTx. “The extensive safety database GTx is compiling from the numerous clinical studies of enobosarm will be a critical component of GTx’s application for marketing approval, which we hope to submit following receipt of topline data from our Phase III clinical trials in the 3rd quarter of 2013.”

GTx has completed enrollment of approximately 650 subjects with advanced non-small cell lung cancer in two pivotal Phase III clinical trials, POWER 1 and POWER 2. These international Phase III studies are being conducted in clinical sites in the United States, Europe, Russia and South America. In each of the placebo-controlled, double-blind clinical trials, approximately 325 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 begin first line standard chemotherapy. The studies are evaluating as co-primary endpoints at three months of treatment the response rates of enobosarm versus placebo on maintaining or improving total lean body mass (muscle) assessed by dual x-ray absorptiometry and improving physical function assessed by the Stair Climb Test. Durability of the drug effect is being evaluated as a secondary endpoint at five months of treatment. Topline data from the studies should be released during the third quarter of 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 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.

Source:
GTx, Inc.
Marc Hanover, President and Chief Operating Officer
901-523-9700
