

**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): **September 8, 2016**

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 September 8, 2016, GTx, Inc. issued a press release announcing the achievement of the Stage 1 milestone for the 9 mg cohort of its Phase 2 clinical trial of enobosarm (GTx-024) to treat women with advanced, estrogen receptor positive, androgen receptor positive breast 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.*

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by GTx, Inc. dated September 8, 2016

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: September 8, 2016

GTx, Inc.

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

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EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued by GTx, Inc. dated September 8, 2016

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GTx Achieves Stage 1 Milestone in Phase 2 Clinical Trial of Enobosarm in ER+/AR+ Breast Cancer

- Demonstration of Clinical Benefit in a pre-defined number of evaluable patients in Stage 1 of study triggers enrollment for the second and final Stage of study; Stage 1 data expected in Q4 2016 -

- Enobosarm may offer a novel hormonal treatment prior to chemotherapy for women who are ER+/AR+, representing the largest population of breast cancer patients -

MEMPHIS, Tenn. — September 8, 2016 — GTx, Inc. (Nasdaq: GTXI) today announced the achievement of the Stage 1 milestone for the 9 mg cohort of its Phase 2 clinical trial of enobosarm (GTx-024) to treat women with advanced, estrogen receptor positive (ER+), androgen receptor positive (AR+) breast cancer. A pre-defined number of patients demonstrated clinical benefit per protocol to allow the clinical trial to advance to the second and final stage of the trial (Stage 2). GTx also expects to provide an update on Stage 1 of the second dosing cohort (18 mg) in the clinical trial once there are sufficient evaluable patients to assess clinical benefit in this cohort. The Company anticipates reporting Stage 1 data from the clinical trial in the fourth quarter of 2016.

“The demonstration of clinical benefit among a pre-defined number of evaluable patients in Stage 1 of the 9 mg cohort of our ER+/AR+ breast cancer study represents an important milestone for GTx since we have met the protocol specified success criteria to continue with enrollment in Stage 2 of this cohort,” said Robert J. Wills, Ph.D., Executive Chairman of GTx. “We believe enobosarm may provide a new hormonal approach for the treatment of estrogen receptor positive breast cancer and may delay the need for chemotherapy in these women.”

About the Phase 2 Clinical Trial in ER+/AR+ Breast Cancer

The open-label, multi-center, multinational Phase 2 clinical trial (NCT02463032) will assess the efficacy and safety of orally administered enobosarm in up to 88 evaluable patients with metastatic or locally advanced, ER+/AR+ breast cancer. Patients will receive orally-administered enobosarm (9 mg or 18 mg) daily for up to 24 months. The two cohorts in the trial will be treated independently for the

purpose of assessing efficacy. The first stage of evaluation will be assessed among the first 18 evaluable patients for each cohort. If at least 3 of 18 patients achieve clinical benefit at week 24, then the trial will proceed to the second stage of enrollment for that cohort to assess clinical benefit in a total of 44 evaluable patients per arm. Clinical benefit is defined as a complete response, partial response, or stable disease, as measured by Response Evaluation Criteria in Solid Tumors (RECIST) at 24 weeks. The lead investigator for the trial is Dr. Beth Overmoyer from the Dana Farber Cancer Institute and the Harvard Medical School.

About enobosarm

Enobosarm, a selective androgen receptor modulator (SARM), has been evaluated in 24 completed or ongoing clinical trials enrolling over 1,500 subjects, of which approximately 1000 subjects were treated with enobosarm at doses ranging from 0.1 mg to 100 mg. At all evaluated dose levels, enobosarm was observed to be generally safe and well tolerated.

Previously, enobosarm 9 mg has been tested in a Phase 2, proof of concept clinical trial of 22 postmenopausal women with ER+ metastatic breast cancer who have previously responded to endocrine therapy. 17 of the 22 patients were confirmed to be AR+, and 6 of those 17 patients demonstrated clinical benefit at six months. In total, 7 patients (one patient with indeterminate AR status) achieved clinical benefit at six months. The results also demonstrated that, after a median duration on study of 81 days, 41 percent of all patients (9/22) achieved clinical benefit as best response and also had increased PSA which appears to be an indicator of AR activity. Enobosarm was well tolerated. The most common adverse events reported were pain, fatigue, nausea, hot flash/night sweats, and arthralgia.

About ER+/AR+ Breast Cancer

Breast cancer is the most commonly diagnosed cancer in women, and one in eight women will develop invasive breast cancer in their lifetime. In 2012, 1.7 million women world-wide were diagnosed with breast cancer, and there were 6.3 million women alive who had been diagnosed with breast cancer in the previous five years. Clinical assessment of breast cancer provides for routine characterization of receptor status, including the presence or absence of estrogen receptor (ER), progesterone receptor, and human epidermal growth factor receptor 2 (HER2) in the tumor tissue. Receptor status is used to assess metastatic potential as well as to guide treatment decisions. The majority of breast cancers are considered hormone receptor positive (expressing ER or progesterone receptor). Approximately 70 percent of women in the U.S. with breast cancer have ER+ tumors, and 75 to 90 percent of these cancers are also AR+.

Estrogen promotes the growth of breast cancers that are hormone receptor positive. Therefore, treatment is directed at blocking the effects of estrogen on the breast cancer either through blocking the estrogen receptor or minimizing the production of estrogen. This endocrine therapy is the cornerstone of treatment for the majority of women with hormone receptor positive advanced breast cancer and is the preferred initial treatment over alternative approaches such as chemotherapy, due to its efficacy and favorable safety profile. Patients who respond to one endocrine therapy are likely to respond to subsequent hormonal therapies. Therefore, the standard of care for women with hormone receptor positive breast cancer typically involves the sequencing of endocrine agents until intolerance or development of resistance occurs, or metastatic progression necessitates a transition to chemotherapy.

Enobosarm may offer an alternate hormonal approach for the treatment of endocrine sensitive advanced breast cancer prior to the introduction of chemotherapy.

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, including treatments for breast and prostate cancer, 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 the enrollment and conduct of GTx's ongoing Phase 2 clinical trials of enobosarm for the treatment of advanced breast cancer and the timing thereof, including the potential therapeutic applications for, and potential benefits of its SARM (including enobosarm) technology. 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 if GTx determines to move forward with additional development of enobosarm for the treatment of advanced breast cancer, GTx will require additional funding, which it may be unable to raise, in which case, GTx may fail to realize the anticipated benefits from its SARM technology; (ii) that the clinical trials of enobosarm to treat advanced breast cancer being conducted by GTx may not be completed on schedule, or at all, or may otherwise be suspended or terminated; (iii) related to the difficulty and uncertainty of pharmaceutical product development, including the time and expense required to conduct clinical trials and analyze data, and the uncertainty of clinical success; and (iv) related to issues arising during the uncertain and time-consuming regulatory process,

including the risk that GTx may not receive any approvals to advance the clinical development of one or more potential clinical SARM candidates. In addition, GTx will continue to need additional funding and may be unable to raise capital when needed, which would force GTx to delay, reduce or eliminate its product candidate development programs and potentially cease operations. 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. 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 for the period ending June 30, 2016, 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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