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): **December 8, 2016**

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):

o Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 December 8, 2016, GTx, Inc. issued a press release announcing positive data from its ongoing open-label Phase 2 clinical trial of enobosarm in 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*.

Exhibit No.	**Description**
99.1	Press Release issued by GTx, Inc. dated December 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: December 8, 2016 GTx, Inc.

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

EXHIBIT INDEX

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

GTx Reports Results from Ongoing Enobosarm Phase 2 Clinical Trial in ER+/AR+ Breast Cancer

- Primary efficacy endpoint met in the enobosarm 9 mg cohort -

- To date, of 22 evaluable patients, 2 had a partial response and 7 had stable disease at 24 weeks -

- Current mean duration of response is 31 weeks, with 7 of 9 responders still receiving enobosarm -

MEMPHIS, Tenn. — December 8, 2016 — GTx, Inc. (Nasdaq: GTXI) announced today positive initial data from its ongoing open-label enobosarm Phase 2 clinical trial in women with advanced, estrogen receptor positive (ER+), androgen receptor positive (AR+) breast cancer. The pre-specified threshold for success of the trial was met early in the 9 mg cohort with 9 patients achieving a clinical benefit response at 24 weeks among the first 22 evaluable patients in that cohort, as reported by the Company on November 28, 2016. Clinical Benefit Response (CBR) is defined as a complete response (CR), partial response (PR) or stable disease (SD), as measured by Response Evaluation Criteria in Solid Tumors (RECIST) at 24 weeks of treatment.

For the 9 patients achieving CBR in the 9 mg cohort, the results are as follows:

- 2 patients demonstrated a PR with a mean reduction in tumor size of 44.4% from baseline;
- 7 patients exhibited SD; and of these patients:
  - 3 patients had measurable disease with an average reduction in tumor size from baseline of approximately 13%. One of these 3 patients, whose tumor size was reduced by 25% from baseline at 24 weeks, had demonstrated a PR ($\geq$ 30% reduction) at 12 weeks.
  - 4 patients with SD had bone-only disease, which made them unevaluable for PR.
- The mean duration of response at the time of the Company's November 28, 2016 announcement for the 9 responders was 31 weeks, with 7 of the 9 patients still on study drug.
- Based on a current CBR of 41%, the Company estimates the 95% confidence interval for the CBR rate in the 9 mg cohort to be 22% to 62% at study completion.

In addition to the CBR, the trial is evaluating the Best Overall Response (BOR) rate of the patients, defined as a CBR at any time point during treatment with enobosarm. Of the 22 evaluable patients:

- 7 patients who did not show CBR at 24 weeks had stable disease earlier at 12 weeks, corresponding to an approximately 73% (16/22) BOR;
- 3 patients discontinued early due to reasons other than progression, and therefore did not have post treatment scans; and
- When the analysis is performed with those patients who had post treatment follow-up scans, the CBR is 47% (9/19), with a BOR of 84% (16/19).

The baseline demographics for the 22 evaluable patients are consistent with advanced breast cancer patients who typically undergo multiple treatments. The majority of the 22 patients in the 9 mg dose

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cohort were heavily pretreated prior to study entry. On average, these patients had 4 prior hormonal therapies for the treatment of their breast cancer and 91% also received prior chemotherapy. Eight of the 22 evaluable patients (36%) had bone-only disease, while the remaining patients had measurable disease per RECIST.

Enobosarm 9 mg appears to be safe and generally well tolerated. The majority of adverse events are grade 1 and 2. The most common adverse events (occurring in $\geq$10% of patients) reported include nausea (31%), fatigue (18%), and arthralgias (13%). Elevations in transaminases (ALT and AST) during enobosarm treatment were mild with the majority being grade 1 or 2. The independent Safety Monitoring Committee met on December 1, 2016, and recommended that the clinical trial continue as planned.

The trial will continue as planned with a daily dose of either enobosarm 9 mg or 18 mg until 44 evaluable patients in each cohort have been enrolled to better characterize the CBR, evaluate secondary endpoints and describe the safety profile of the dose levels. The Company plans to report top-line clinical results following completion of the clinical trial, which is anticipated to occur in mid-2017.

"From my perspective as a clinician, the results with enobosarm in treating advanced breast cancer are encouraging. The goal for treating advanced breast cancer patients who have exhausted other hormonal therapies for metastatic disease and whose only treatment alternative is chemotherapy, is to achieve stabilization of their disease," said Dr. Beth Overmoyer, from the Dana Farber Cancer Institute and the Harvard Medical School, who is the lead investigator for the clinical trial. "Stabilization of disease and delaying subsequent chemotherapy treatment while maintaining quality of life benefits a large population of patients with hormone-receptor positive metastatic breast cancer."

"We are pleased that the study has demonstrated an acceptable clinical benefit rate sooner than initially anticipated in the 9 mg cohort, which we believe warrants further development of the drug candidate for the treatment of advanced metastatic breast cancer," said Robert J. Wills, Ph.D., Executive Chairman of GTx.

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 dose 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 CBR at week 24, then the trial will proceed to the second stage of enrollment for that cohort to assess CBR in a total of 44 evaluable patients per arm. As reported in September and November, 2016, respectively, patients in both the 9 mg and 18 mg cohorts demonstrated sufficient CBR among the first 18 evaluable patients in each such cohort to advance to the second and final stage of the clinical trial.

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 1,000 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

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who have previously responded to endocrine therapy. 17 of the 22 patients were confirmed to be AR+, and 6 of those 17 patients demonstrated CBR at six months. In total, 7 patients (one patient with indeterminate AR status) achieved CBR 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 CBR as best response . 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 trial of enobosarm for the treatment of ER+/AR+ 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 ER+/AR+ 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 trial of enobosarm to treat ER+/AR+ breast cancer being conducted by GTx may not be completed on

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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 September 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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