# 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): **October 6, 2015**

# 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 October 6, 2015, GTx, Inc. issued a press release announcing the enrollment of the first patient into its Phase 2 clinical trial of enobosarm (GTx-024) to treat women with advanced, androgen receptor positive, triple negative 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 October 6, 2015 |



**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: October 6, 2015 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 October 6, 2015 |

**Exhibit 99.1**

**GTx Announces Enrollment of First Patient in Phase 2 Clinical Trial of Enobosarm in Triple Negative Breast Cancer**

*— Trial evaluating enobosarm in patients with advanced androgen receptor positive triple negative breast cancer —*

*— Data from patient-derived and cell line-derived xenografts of androgen receptor positive TNBC support clinical investigation with enobosarm —*

MEMPHIS, Tenn. — October 6, 2015 — GTx, Inc. (Nasdaq: GTXI) today announced the enrollment of the first patient into its Phase 2 clinical trial of enobosarm (GTx-024) to treat women with advanced, androgen receptor positive (AR+), triple negative breast cancer (TNBC). Enobosarm is the Company's lead product candidate and is also being evaluated in a separate Phase 2 clinical trial to treat estrogen receptor positive (ER+), AR+ breast cancer, which the Company recently announced had also enrolled its first patient.

"Most women with triple negative breast cancer have extremely limited treatment options and poor prognoses," said Robert J. Wills, Ph.D., Executive Chairman of GTx. "Based on our preclinical research and positive data from patient-derived and cell line-derived xenografts of TNBC, we are hopeful that enobosarm, by targeting the androgen receptor, may offer another treatment option to women with this disease."

The open-label, multi-center, multinational Phase 2 clinical trial (NCT02368691) will evaluate the efficacy and safety of orally administered enobosarm in up to 55 women with advanced, AR+ TNBC. Patients will receive 18 mg of enobosarm once daily for up to 12 months. The initial stage will be assessed among the first 21 evaluable patients. If at least 2 of 21 patients achieve clinical benefit at week 16, then the trial will proceed to the second stage of enrollment of up to a total of 41 evaluable patients. Clinical benefit is defined as a complete response, partial response, or stable disease, as measured by Response Evaluation Criteria in Solid Tumors (RECIST) at 16 weeks. The trial, which is being conducted under the leadership of Dr. Hope Rugo from the University of California at San Francisco, will include investigators from more than 40 clinical trial sites in the U.S. and abroad.

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**About enobosarm**
Enobosarm, a selective androgen receptor modulator (SARM), has been evaluated in multiple completed or ongoing clinical trials enrolling over 1,500 subjects 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.

Most recently, 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. Seventeen of the 22 patients were confirmed to be AR+. Six of these 17 patients demonstrated clinical benefit at six months. Seven patients in total (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 serum PSA levels which may 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 Triple Negative 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 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 includes routine characterization of receptor status including the presence or absence of estrogen receptor (ER), progesterone receptor (PR), 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. Although the majority of breast cancers are considered hormone receptor positive, expressing ER and/or PR, 15—20 percent of women diagnosed with breast cancer will have triple negative breast cancer (TNBC), which is characterized by a lack of expression of ER, PR, and HER2. TNBC occurs more frequently in younger patients (< 50 years of age) and generally shows a more aggressive behavior. For those patients with advanced TNBC, standard palliative treatment options are limited to cytotoxic chemotherapy. However, even after initial response to chemotherapy, the duration of the response may be short, and there is a higher likelihood of visceral metastases, rapidly progressing disease, and inferior survival compared to hormone positive breast cancer. Therefore, research is focused on identifying therapeutic targets in TNBC.

Studies have demonstrated that up to 50 percent of TNBC will express the androgen receptor. Both preclinical and patient-derived and cell line-derived

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AR+ TNBC xenografts support the clinical approach of targeting the androgen receptor with 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, 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 GTx's clinical trials for enobosarm (GTx-024) to treat patients with advanced breast cancer. 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 clinical trials being conducted by GTx may not be initiated or completed on schedule, or at all, or may otherwise be suspended or terminated; (ii) that any additional clinical development of GTx's product candidate, enobosarm, beyond the two Phase 2 clinical trials of enobosarm in patients with AR positive advanced breast cancer is contingent on GTx entering into new collaborative arrangements with third parties for such development or otherwise obtaining sufficient additional capital to permit such development, which it may be unable to do; or (iii) that GTx may not be able to obtain required regulatory approvals to commercialize its product candidates in a timely manner or at all. 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 quarter ended June 30, 2015, filed August 10, 2015, 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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