

**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): **June 2, 2014**

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 June 2, 2014, GTx, Inc. issued a press release announcing positive results from a Phase 2, proof-of-concept, open-label clinical study evaluating enobosarm (GTx-024), a selective androgen receptor modulator (SARM), for the treatment of patients with androgen receptor (AR) positive and estrogen receptor (ER) positive metastatic breast cancer who have previously responded to hormonal therapy. The clinical data is being presented during the Breast Cancer-HER2/ER poster session being held June 2, 2014 during the 50th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, Illinois.

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 June 2, 2014

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: June 2, 2014

GTx, Inc.

By: /s/ Henry P. Doggrell

Name: Henry P. Doggrell

Title: Vice President, Chief Legal Officer and Secretary

3

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by GTx, Inc. dated June 2, 2014

4

GTx Reports Positive Clinical Data from Open Label Phase 2 Study of Enobosarm in Patients with Androgen and Estrogen Receptor Positive Metastatic Breast Cancer

—Study of Targeted Therapy Met Primary Endpoint with 35 Percent of Patients Achieving Clinical Benefit Response—

Memphis, Tenn., June 2, 2014—GTx, Inc. (NASDAQ: GTXI) today announced positive results from a Phase 2, proof-of-concept, open-label clinical study evaluating enobosarm (GTx-024), a selective androgen receptor modulator (SARM), for the treatment of patients with androgen receptor (AR) positive and estrogen receptor (ER) positive metastatic breast cancer who have previously responded to hormonal therapy. The clinical data is being presented today during the Breast Cancer-HER2/ER poster session today at the 50th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago.

“We know from prior studies and our clinical experience that women with hormone receptor positive metastatic breast cancer, which has progressed following treatment with endocrine therapy, often respond to androgen therapy; yet undesirable side effects, such as facial hair growth and deepening of the voice, are not acceptable to most patients. Therefore, alternatives to existing therapies, that are tolerable and effective, are needed,” said Beth A. Overmoyer, M.D., the principal clinical investigator in the enobosarm Phase 2 study and director of the Inflammatory Breast Cancer Program at the Susan F. Smith Center for Women’s Cancers at Dana Farber Cancer Institute, and Assistant Professor of Medicine at Harvard Medical School. “I find these results to be very promising given that, in this patient population, achieving stable disease is considered a success.”

“Based on these encouraging results, we plan to advance the clinical development of enobosarm in patients with AR and ER positive metastatic breast cancer,” said Marc S. Hanover, interim CEO, President and COO of GTx.

Phase 2 Clinical Trial Design and Results

The Phase 2 open-label study is evaluating 22 postmenopausal women with ER positive metastatic breast cancer, who had previously responded to adjuvant hormonal therapy for three years or longer, and women diagnosed with metastatic disease, who had been treated with hormonal therapy for at least six months, prior to disease progression. Study participants were heavily pretreated (72.7 percent received previous chemotherapy and the median number of prior endocrine therapies was 3). The mean time from initial breast cancer diagnosis is 11 years and the mean age of patients is 64 years.

Study participants are receiving enobosarm 9 mg once daily until they display evidence of clinical progression. The primary endpoint is the proportion of subjects with clinical benefit at 6 months in subjects with AR+ metastatic lesions. Clinical benefit is defined as those patients who have either stable disease, a complete response, or a partial response as defined in the modified RECIST (Response Evaluation Criteria In Solid Tumors) 1.1 criteria. Upon completion of the study, clinical benefit response will be correlated with AR status via metastatic tumor biopsy. Serum prostate specific antigen (PSA) is evaluated as a biomarker of androgen receptor activity. The study is being conducted at seven clinical sites in the United States.

Of the 22 patients enrolled in the study, a total of 20 patients had one or more scheduled assessments for determination of clinical benefit. The primary endpoint was assessed in 17 AR+ patients with 6 patients demonstrating clinical benefit at six months, exceeding the pre-defined statistical threshold requiring that at least 3 of 14 patients with an AR+ metastatic lesion demonstrate clinical benefit. Additionally, results showed 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 prostate specific antigen (PSA), which appears to be an indicator of AR activity. The 6 patients achieving clinical benefit (35 percent of the 17 patients with AR+ metastatic lesions) had stable disease. No confirmed complete or partial responses have been observed in the study. Later this month, the final patient in the study will have her six month evaluation and three additional patients continue to demonstrate clinical benefit and remain in the study. Enobosarm was well tolerated. The most common adverse events (AEs) reported were pain, fatigue, nausea, hot flash/night sweats, and arthralgia. The majority of AEs were Grade 1. There were two serious adverse events (SAEs) reported during the study. Only one of the SAEs, bone pain of chest cage, was assessed as possibly related to enobosarm.

A copy of the enobosarm poster is available by contacting the Company.

About Breast Cancer and Receptor Status

Breast cancer is the most commonly diagnosed cancer in women and is the second leading cause of cancer deaths in women in the United States. Each year, over 200,000 new cases of invasive breast cancer will be diagnosed in the U.S., and approximately 39,000 women will die from the disease. Clinical assessment of breast cancer includes routine characterization of a patient’s receptor status, including the presence or absence of ER, progesterone receptor and human epidermal growth factor receptor 2 (HER2) in the tumor tissue. Receptor status is used to assess the potential for developing metastatic disease, as well as guiding treatment decisions.

Hormonal manipulation with selective estrogen receptor modulators or aromatase inhibitors is the standard treatment for patients with tumors that are ER positive. It is expected that a majority (70-95 percent) of patients with ER positive breast cancer will also express AR in their primary tumor samples. High percentages (72-84 percent) of metastatic breast cancer lesions have been found to be AR positive. In preclinical and clinical studies, androgens have been shown to suppress breast cancer growth. In addition, studies have shown that women with metastatic breast cancer who have been previously treated with tamoxifen and who progress have responded to nonselective androgens, including fluoxymesterone, medroxyprogesterone and danazol, with overall response rates ranging from 20 to 60 percent. However, the unwanted virilizing side effects of nonselective androgens, including facial and body hair growth, deepening of the voice box, acne and edema, have limited their widespread clinical use.

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, including prevention and treatment of cancer-related muscle wasting, 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). 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 may not be able to obtain required regulatory approvals to commercialize its product candidates in a timely manner or at all; or (ii) that clinical trials being conducted by GTx may not be completed on schedule, or at all, or may otherwise be suspended or terminated. 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. 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. 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 May 12, 2014 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.

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