

**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) **April 30, 2013**

**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**  
**7<sup>th</sup> 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 April 30, 2013, GTx, Inc. issued a press release announcing that it is initiating a proof of concept, Phase 2, open-label clinical study to evaluate GTx-024 (enobosarm), a selective androgen receptor modulator, for the potential treatment of metastatic 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 Number	Description
99.1	Press Release issued by GTx, Inc. dated April 30, 2013

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**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 30, 2013

GTx, Inc.

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

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**GTx INITIATING PHASE 2, OPEN-LABEL STUDY  
OF ENOBOSARM TO TREAT ER POSITIVE METASTATIC BREAST CANCER**

**MEMPHIS, TN** — April 30, 2013 — GTx, Inc. (Nasdaq: GTXI), announced today that it is initiating a proof of concept, Phase 2, open-label clinical study to evaluate enobosarm (GTx-024), a selective androgen receptor modulator (SARM), for the potential treatment of metastatic breast cancer.

“We know from prior studies that women with hormone receptor positive metastatic breast cancer which has progressed following treatment with tamoxifen often respond to androgen (male hormone) therapy; yet the side effects, such as facial hair growth and deepening of the voice, are not acceptable to most patients” said Beth A. Ovmoyer, M.D., a clinical investigator in this enobosarm Phase 2 study and the Director, Inflammatory Breast Cancer Program, Dana Farber Cancer Institute and Assistant Professor of Medicine at the Harvard Medical School. “Hopefully, treatment with enobosarm will result in efficacy similar to androgen therapy without the masculinizing side effects.”

“We believe enobosarm has the potential to selectively treat metastatic breast cancer while minimizing the unwanted side effects associated with steroidal androgens,” said Mitchell S. Steiner, MD, Chief Executive Officer of GTx. “Enobosarm would be the first new targeted hormonal therapy introduced for the treatment of breast cancer in many years.”

The proof of concept, Phase 2, open-label study will randomize twenty (20) postmenopausal women with estrogen receptor (ER) positive metastatic breast cancer who have previously responded to hormone therapy at approximately six clinical sites in the United States. The women will receive 9 mg of enobosarm once a day until they evidence clinical progression or have completed 336 days of treatment. The primary endpoint is clinical benefit, which will be assessed at 6 months, and is defined as either those women receiving treatment who have demonstrated a complete response (disappearance of all targeted lesions), a partial response (at least a 30% decrease in the sum of the diameters of the targeted lesions) or stable disease (no disease progression from baseline). The response from treatment will be correlated with androgen receptor (AR) status of tumor samples from the women. The study will recruit women 18 or older with ER positive metastatic breast cancer who have previously responded to adjuvant hormonal therapy for 3 years or longer and women diagnosed with metastatic disease who have been treated with hormonal therapy for at least 6 months and now have progressive disease.

### **About Breast Cancer And Receptor Status**

Breast cancer is the most commonly diagnosed cancer in women, and 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

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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 given to patients with tumors that are ER positive. It is expected that a majority (70-95%) of women with ER positive breast cancer will also express AR in their primary tumor samples. High percentages (72-84%) of metastatic breast cancer lesions have also been found to be AR positive. In preclinical and clinical studies, androgens have been shown to suppress breast cancer growth. In addition, prior studies have shown that women with metastatic breast cancer who have been previously treated with tamoxifen and progress have responded to nonselective androgens like fluoxymesterone, medroxyprogesterone and danazol, with overall response rates ranging from 20 to 60%. Although these nonselective androgens have been used to treat breast cancer, the unwanted virilizing side effects, including facial and body hair, enlargement of 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, 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 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.*

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Source:

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Marc Hanover, President and Chief Operating Officer  
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