# 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) January 29, 2014

### GTx, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware000-50549(State or Other Jurisdiction<br/>of Incorporation)(Commission File<br/>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):

- 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 January 29, 2014, GTx, Inc. (the "Company") issued a press release announcing that preliminary findings from the Company's Phase 2 clinical trial evaluating GTx-758 (Capesaris®), an oral estrogen receptor alpha agonist, in men with metastatic castrate resistant prostate cancer will be presented on Thursday, January 30, 2014, during the 2014 American Society of Clinical Oncology Genitourinary Cancer Symposium being held in San Francisco, California.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report.

ITEM 9.01 <u>Financial Statements and Exhibits.</u>
(d) *Exhibits.* 

Exhibit

Number 99.1 Description Press Release issued by GTx, Inc. dated January 29, 2014

### **SIGNATURE**

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Date: January 29, 2014

GTx, Inc.

By: Name: /s/ Henry P. Doggrell

Henry P. Doggrell

Title: Vice President, Chief Legal Officer and Secretary

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### Preliminary findings from the Phase 2 clinical trial of GTx-758 in men with castration resistant prostate cancer to be presented at ASCO Genitourinary Cancer Symposium

#### Enrollment of the 125mg cohort is completed and 250mg cohort is currently enrolling

January 29, 2014—GTx, Inc. (NASDAQ: GTXI) announced today that Dr. Evan Yu, Associate Professor of Medicine and Oncology at the University of Washington School of Medicine and Clinical Trials Director, Genitourinary Oncology Clinical Trials Core, Seattle Cancer Care Alliance, will present preliminary findings from the Company's Phase 2 clinical trial evaluating GTx-758 (Capesaris®), an oral estrogen receptor alpha agonist, in men with metastatic castrate resistant prostate cancer (CRPC) at the 2014 American Society of Clinical Oncology (ASCO) Genitourinary (GU) Cancer Symposium in San Francisco, CA on Thursday, January 30, 2014.

In men undergoing androgen deprivation therapy (ADT), residual levels of serum free testosterone, the biologically active and unbound form of the hormone, remain elevated in a significant subset of men. Medical literature suggests that maximal suppression of serum free testosterone may benefit men with advanced prostate cancer.

The Phase 2 clinical trial (G200712, NCT01615120) is sequentially testing for safety and effectiveness of 125mg oral daily dose and 250mg oral daily dose of GTx-758 as secondary hormonal therapy in men with CRPC. The goal of the Phase 2 trial is to show that lower doses of GTx-758 are well tolerated and effective in reducing free testosterone and, in greater than 50 percent of subjects, achieving a 50 percent reduction of serum prostate specific antigen (PSA) by Day 90. The 125mg arm has completed enrollment of 38 patients with metastatic CRPC, and, following a planned safety review by an independent data safety monitoring board, the trial is now enrolling an additional 38 patients in the 250mg oral daily dose arm. The first 10 patients to receive the 250mg dose will be men with metastatic CRPC, and thereafter, enrollment will be open to men with either metastatic or non-metastatic CRPC, assuming there continues to be no safety concerns with the drug candidate. The mechanism of drug action, induction of sex hormone binding globulin (SHBG) and reduction of free testosterone, was confirmed by the cohort of patients receiving 125mg of GTx-758 treatment. Of the 36 patients with available lab values, 83 percent had levels of sex hormone binding globulin (SHBG) more than double from baseline and free testosterone was reduced in 92 percent of these patients, with 81 percent of patients having at least a 50 percent reduction in free testosterone. Of the 22 patients who had completed 90 days on the trial at the time Dr. Yu assembled data for his presentation, 91 percent had experienced decreases in PSA levels, with 36 percent exhibiting a decrease greater than 30 percent.

Estrogen deficiency side effects associated with ADT, including hot flashes and bone loss, may negatively affect quality of life and mortality. Treatment with an estrogen receptor alpha agonist, like GTx-758, should ameliorate these estrogen deficiency side effects. Preliminary data shows that a majority of subjects who were experiencing hot flashes prior to taking GTx-758 have reported improvement in (38 percent) and/or stabilization of (43 percent) their hot flashes and bone turnover biomarkers have

decreased in a majority of the patients. As for safety, GTx-758 continues to be well tolerated, with no reported venous thromboembolic events or deaths.

Poster Sessions Golden Gate Hall Thursday, January 30, 2014 11:30AM - 1:00PM 5:15PM - 6:45PM Presenter: Evan Yu

Abstract #60

The effect of low dose GTx-758 on free testosterone levels in men with metastatic castration resistant prostate cancer (mCRPC) Yu EY, Getzenberg RH, Smith J, Hancock M, Tutrone R, Flaig T, Westenfelder K, Szucs M, Dalton JT, Steiner MS

### Abstract #144

Optimal testosterone suppression on medical ADT should strive to suppress free testosterone levels, to levels similar to orchiectomy—what is that value? Yu EY, Getzenberg RH, Smith J, Hancock M, Smith MR, Malkowicz SB, Sieber P, Dalton JT, Steiner MS

Copies of the posters are available by contacting the Company.

### **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 trial of GTx-758 (Capesaris®). 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; (ii) that clinical trials being conducted by GTx may not be completed on schedule, or at all, or may otherwise be suspended or terminated; or (iii) 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. 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 November 12, 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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