

**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): **May 9, 2016**

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 May 9, 2016, GTx, Inc. issued a press release announcing the presentation of preclinical data demonstrating the ability of selective androgen receptor degraders (SARDs) to degrade and inhibit the androgen receptor at the American Urological Association Annual Meeting.

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 May 9, 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: May 9, 2016

GTx, Inc.

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

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EXHIBIT INDEX

| Exhibit No. | Description |
|--------------------|---|
| 99.1 | Press Release issued by GTx, Inc. dated May 9, 2016 |

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GTx Announces Presentation of Preclinical Data Demonstrating the Ability of SARDs to Degrade and Inhibit the Androgen Receptor at the American Urological Association Annual Meeting

— Late breaking poster outlines first data from GTx SARD program; results suggest these molecules are first-in-class androgen receptor antagonists and degraders —

— Novel SARD compounds being developed initially as a potential treatment for men with castration-resistant prostate cancer —

MEMPHIS, Tenn. — May 9, 2016 — GTx, Inc. (Nasdaq: GTXI) today announced the first public presentation of preclinical data from the Company's selective androgen receptor degrader (SARD) program. The results demonstrate that the Company's highly potent SARDs selectively bind to the ligand binding domain (LBD) and interact with the N-terminal domain (NTD) of the androgen receptor (AR) and inhibit and degrade the AR at very low concentrations. These preclinical results suggest that the Company's SARDs may be the first-in-class dual-interacting AR antagonists and degraders.

The preclinical data are being presented at the 2016 American Urological Association (AUA) Annual Meeting taking place May 6-10, 2016, in San Diego, California.

Poster: Novel Dual-Binding Selective Degraders of Full Length and Splice Variant Androgen Receptors for the Treatment of Castration-Resistant Prostate Cancer

Presenter: Ramesh Narayanan, Ph.D., Director, Center for Cancer Drug Discovery and Associate Professor, Department of Medicine, University of Tennessee and Consultant for GTx, Inc.

Date: Saturday, May 7 at 10:30 am until Tuesday, May 10 at 1:00 pm

According to Dr. Narayanan, "One of the limitations of current prostate cancer therapy is that some men with castration-resistant prostate cancer do not respond or eventually develop resistance to the therapy. These preclinical results suggest that novel SARD compounds may degrade and inhibit multiple forms of the androgen receptor, including

AR splice variants, and may therefore potentially treat CRPC in men who are non-responsive to androgen therapy."

The Company's lead SARD compounds are currently being evaluated in preclinical studies in order to select the best SARD compounds for continued development, with a goal of initiating first human clinical trials in 2017.

About SARDs

Selective Androgen Receptor Degradator (SARD) technology is being evaluated as a potentially novel treatment for men with castration-resistant prostate cancer (CRPC), including those who do not respond or are resistant to currently approved therapies. GTx believes that its novel SARD compounds will degrade multiple forms of the androgen receptor, including AR splice variants, such as AR-V7. GTx licensed the SARD technology from the University of Tennessee Research Foundation in 2015 with the goal of expanding its portfolio of product candidates targeting hormonal receptors.

About Prostate Cancer

Prostate cancer that is localized to the prostate can be effectively treated with surgery, radiation, brachytherapy and other modalities in an effort to eradicate all of the disease and cure the patient. In some cases, the tumor advances locally or metastasizes; these are examples of advanced prostate cancer. The goal of treatment for advanced prostate cancer is to control the tumor and keep the patient alive for as long as possible.

In advanced prostate cancer, a number of treatments with hormone blocking therapies or chemotherapy are used to slow the spread of metastases, shrink existing tumors, reduce symptoms and improve quality of life. Although most men with advanced prostate cancer are not cured of their disease, they can live a normal life for many years.

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 ongoing preclinical development of its selective androgen receptor degrader (SARD) technology, and its possible initiation of SARD clinical trials in 2017. 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 the preclinical development studies being conducted by GTx may not be completed on schedule, or at all, or they may indicate that no SARD compound warrants further development; (ii) that any additional preclinical or clinical development of GTx's SARD compounds beyond 2016 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 initiate clinical development of a SARD compound 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 annual report on Form 10-K for the year ended December 31, 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.

Source: GTX, Inc.

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