

**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 13, 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**  
**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 January 13, 2016, GTx, Inc. issued a press release announcing the initiation of its Phase 2 clinical trial to treat postmenopausal women with stress urinary incontinence.

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 January 13, 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: January 13, 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**

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press Release issued by GTx, Inc. dated January 13, 2016

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## GTx Announces Initiation of Phase 2 Clinical Trial of Enobosarm in Stress Urinary Incontinence

— Trial will evaluate orally administered SARM in postmenopausal women with stress urinary incontinence —

— Objective to determine whether a SARM may increase pelvic floor muscle mass and potentially improve outcomes in women with SUI —

MEMPHIS, Tenn. — January 13, 2016 — GTx, Inc. (Nasdaq: GTXI) today announced the initiation of its Phase 2 clinical trial to treat postmenopausal women with stress urinary incontinence (SUI). The Phase 2 proof-of-concept study of enobosarm (GTx-024) is the first clinical trial to evaluate a selective androgen receptor modulator (SARM) for SUI.

“Given the selective anabolic activity of enobosarm, we are looking forward to evaluating its potential to augment pelvic floor muscle response and potentially improve outcomes for women with stress urinary incontinence,” said Kenneth M. Peters, M.D., Chief of Urology at Beaumont Hospital and the principal investigator in the clinical trial. “I would welcome a safe and effective treatment option, especially since existing non-surgical options are extremely limited and, at times, only marginally effective.”

The trial is a single center, single-arm, open-label proof-of-concept Phase 2 clinical trial evaluating the effects of orally administered enobosarm 3mg in postmenopausal women with SUI. The Company plans to enroll up to 35 patients and evaluate the safety and efficacy of enobosarm. The Company anticipates having top-line results in 2016.

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The primary endpoint of the trial is the change in frequency of daily stress urinary incontinence episodes from baseline to week 12. Secondary efficacy endpoints include accepted measurements of voiding, urethral pressure profile and change in pelvic floor muscles as measured by Magnetic Resonance Imaging (MRI).

The rationale for evaluating enobosarm as a treatment for SUI is supported by preclinical *in vivo* data demonstrating increases in pelvic floor muscle mass following treatment with GTx’s SARM compounds, including enobosarm, as well as human safety and efficacy data from enobosarm clinical trials involving more than 1,500 subjects. Enobosarm has been found to be generally safe and well tolerated. Following results from the proof-of-concept trial, the Company will determine which GTx SARM compound, including enobosarm, may be further developed for this indication.

### About Stress Urinary Incontinence

Stress urinary incontinence (SUI) refers to the unintentional leakage of urine during activities that increase abdominal pressure such as coughing, sneezing or physical exercise. SUI, the most common type of incontinence suffered by women, affects up to 35 percent of adult women. There are a variety of treatments that are used to treat SUI in women, such as behavioral modification and pelvic floor physical therapy, especially as initial treatment options. As the condition worsens however, bulking agents and surgical procedures are often the most widely used treatments.

### About the Enobosarm Clinical Development Program

In addition to this proof-of-concept Phase 2 clinical trial in SUI, the Company is conducting a Phase 2 clinical trial of enobosarm 18mg in women with androgen receptor positive (AR+), triple negative breast cancer, as well as a Phase 2

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clinical trial of enobosarm 9mg or 18mg in women with estrogen receptor positive (ER+), AR+ breast cancer.

Previously, enobosarm 9mg has been tested in 22 postmenopausal women with ER+ metastatic breast cancer in a Phase 2 clinical trial. In total, enobosarm has been evaluated in clinical trials enrolling over 1500 subjects at doses ranging from 0.1 mg to 100 mg. At all evaluated dose levels, enobosarm was observed to be safe and well tolerated.

### 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 planned clinical trial of enobosarm (GTx-024) to treat stress urinary incontinence (SUI) and its ongoing clinical trials for enobosarm 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 or planned to be 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 planned clinical trial to treat SUI and its 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*

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*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 September 30, 2015, filed November 9, 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.*

**GTx Contacts**

Lauren Crosby (Investors)  
GTx, Inc.  
901.271.8622  
lcrosby@gtxinc.com

Denise Powell (Media)  
Red House Consulting  
510.703.9491  
denise@redhousecomms.com

Source: GTx, Inc.

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