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): **October 13, 2015**

GTx, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**000-50549**	**62-1715807**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

175 Toyota Plaza 7th Floor Memphis, Tennessee	**38103**
(Address of Principal Executive Offices)	(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 October 13, 2015, GTx, Inc. issued a press release announcing that the U.S. Food and Drug Administration has accepted the Company's investigational new drug application for a Phase 2 clinical trial of enobosarm 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*.

Exhibit No.	**Description**
99.1	Press Release issued by GTx, Inc. dated October 13, 2015

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: October 13, 2015 GTx, Inc.

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued by GTx, Inc. dated October 13, 2015

Exhibit 99.1

GTx Receives FDA Clearance to Initiate Clinical Trial in Stress Urinary Incontinence

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

— Preclinical data demonstrates a SARM can increase pelvic floor muscle mass and potentially improve outcomes in women with SUI —

MEMPHIS, Tenn. — October 13, 2015 — GTx, Inc. (Nasdaq:GTXI) today announced that the U.S. Food and Drug Administration (FDA) has accepted the Company's investigational new drug (IND) application for a Phase 2 clinical trial to treat postmenopausal women with stress urinary incontinence (SUI). The IND enables GTx to initiate a Phase 2 proof-of-concept trial of enobosarm that will be the first clinical trial to evaluate a selective androgen receptor modulator (SARM) for SUI. The Company plans to initiate the trial by the first quarter of 2016 and anticipates top-line data later in 2016.

The rationale for evaluating enobosarm (GTx-024) as a treatment for SUI in the proof-of-concept trial 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.

"SUI represents a unique opportunity for GTx, given the androgen receptor rich environment of the pelvic floor muscles which are potentially sensitive to relatively low doses of enobosarm," said Robert J. Wills, Ph.D., Executive Chairman of GTx. "With current treatment options limited to pelvic floor physical therapy, injectable bulking agents, implants or surgery, we hope to offer an orally administered treatment option where none currently exists."

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 SARMS

Selective androgen receptor modulators (SARMS) are a class of drugs that has been shown to stimulate the growth of skeletal muscle, similar to traditional anabolic steroids, but without the undesirable side effects. SARMS, such as enobosarm, are orally bioavailable and tissue-selective, whereas testosterone and other anabolic steroids have limited oral bioavailability and are only available in transdermal and intramuscular formulations potentially leading to skin reactions and fluctuations in serum concentrations of testosterone. GTx is developing a family of SARM compounds to treat unmet medical needs.

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 for enobosarm (GTx-024) to treat patients with stress urinary incontinence (SUI). 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 clinical trial that is planned to be conducted by GTx to treat SUI or it's Phase 2 clinical trials to treat advanced breast cancer 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 Phase 2 clinical trial in women with SUI and its ongoing Phase 2 clinical studies to treat advanced breast cancer are 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 enobosarm or other 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 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 June 30, 2015, filed August 10, 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.

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