

**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): **September 21, 2018**

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On September 21, 2018, GTx, Inc. issued a press release announcing that the ASTRID Trial, a Phase 2 double-blind, placebo-controlled clinical trial of orally-administered enobosarm (3 mg or 1 mg) in post-menopausal women with stress urinary incontinence, did not achieve statistical significance on the primary endpoint of the proportion of patients with a greater than 50% reduction in incontinence episodes per day compared to placebo.

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 September 21, 2018

EXHIBIT INDEX

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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: September 21, 2018

GTx, Inc.

By: /s/ Henry P. Doggrell

Name: Henry P. Doggrell

Title: Vice President, Chief Legal Officer and Secretary

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GTx Announces Top-Line Results from Placebo-Controlled ASTRID Trial of Enobosarm in Women with Stress Urinary Incontinence

MEMPHIS, Tenn.—(BUSINESS WIRE)—Sept. 21, 2018— GTx, Inc. (Nasdaq: GTXI) today announced that the ASTRID Trial, a Phase 2 double-blind, placebo-controlled clinical trial of orally-administered enobosarm (3 mg or 1 mg) in post-menopausal women with stress urinary incontinence (SUI), did not achieve statistical significance on the primary endpoint of the proportion of patients with a greater than 50% reduction in incontinence episodes per day compared to placebo. The percentage of patients with a greater than 50% reduction after 12 weeks of enobosarm treatment was 58.9% for 3mg, 57.7% for 1mg and 52.7% for placebo. Enobosarm was generally safe and well tolerated. Reported adverse events were minimal and similar across all treatment groups.

“We are very disappointed that the ASTRID Trial did not achieve its primary endpoint,” said Robert J. Wills, Ph.D., Executive Chairman of GTx. “We plan to conduct a full review of all the data. We want to thank the patients, physicians, study coordinators and the entire GTx team for their support of this novel study. We have an ongoing preclinical program assessing the potential of SARDs, our novel selective androgen receptor degrader technology, to treat castration-resistant prostate cancer. We are currently on target to have development candidates by year end, which we potentially plan to take into IND-enabling studies.”

About the ASTRID Trial

The ASTRID (Assessing Enobosarm for Stress Urinary Incontinence Disorder) Trial is a double-blind, placebo-controlled, parallel design, Phase 2 study to assess clinical activity and safety of enobosarm (GTx-024) in postmenopausal women with Stress Urinary Incontinence (SUI). The trial enrolled 493 women and was conducted at over 60 clinical trial centers across the United States. To learn more about the ASTRID clinical trial, [click here](#).

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 Enobosarm and SUI

Enobosarm (GTx-024), a selective androgen receptor modulator (SARM), has been evaluated in 27 completed or ongoing clinical trials enrolling over 2,200 subjects, in which approximately 1,500 subjects were treated with enobosarm at doses ranging from 0.1 mg to 100 mg. At all

evaluated dose levels, enobosarm was observed to be generally safe and well tolerated. 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, and the proof-of-concept Phase 2 clinical trial of enobosarm 3 mg for the treatment of postmenopausal women with SUI.

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 muscle-related diseases 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 clinical development of its selective androgen receptor degrader (SARD) compounds. 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 additional clinical development of GTx’s SARD compounds for the treatment of castration-resistant prostate cancer (CRPC) will be required beyond the ongoing study; and (ii) any future development of SARDs in CRPC is contingent on obtaining sufficient additional capital to permit such development, which it may be unable to do. 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 period ended June 30, 2018, 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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