

**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): **April 9, 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 April 9, 2018, GTx, Inc. issued a press release announcing that it has completed patient enrollment several months ahead of schedule in its placebo-controlled, Phase 2 clinical trial of enobosarm in 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 April 9, 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: April 9, 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 Early Completion of Patient Enrollment in the ASTRID Trial, a Phase 2 Clinical Trial of Enobosarm in Stress Urinary Incontinence

— Top-line results from placebo-controlled clinical trial expected early in the fourth quarter of 2018 —

MEMPHIS, Tenn. — April 9, 2018 — GTx, Inc. (Nasdaq: GTXI) today announced that it has completed patient enrollment several months ahead of schedule in its placebo-controlled, Phase 2 clinical trial of enobosarm in postmenopausal women with stress urinary incontinence (SUI). The ASTRID (Assessing Enobosarm for **S**tress **U**rinary **I**ncontinence **D**isorder) trial enrolled 493 women at over 60 clinical trial centers across the United States. Top-line results are expected early in the fourth quarter this year.

“Due to overwhelming interest from women wanting to participate in the clinical trial, and the extraordinary teamwork by the clinical trial centers, enrollment in the ASTRID trial was completed in approximately eight months, with enrollment exceeding the 400 patients planned per protocol,” said Robert J. Wills, Ph.D., Executive Chairman of GTx. “The ASTRID trial has the same enrollment inclusion/exclusion criteria as the company’s enobosarm proof-of-concept clinical trial in SUI that provided the compelling data previously announced.”

About the Phase 2 ASTRID Clinical Trial

The ASTRID (Assessing Enobosarm for **S**tress **U**rinary **I**ncontinence **D**isorder) trial is an ongoing, placebo-controlled Phase 2 clinical trial in postmenopausal women with SUI. Top-line results from ASTRID are expected early in the fourth quarter of 2018. The rationale for evaluating enobosarm as a treatment for SUI is supported by a Phase 2 proof-of-concept clinical trial, the results of which were outlined at the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) meeting in March 2018, and preclinical *in vivo* data demonstrating increases in pelvic floor muscle mass following treatment with GTx’s SARM compounds, including enobosarm. More information about the ASTRID clinical trial can be found [here](#).

About Enobosarm and SUI

Enobosarm, a selective androgen receptor modulator (SARM), has been evaluated in 25 completed or ongoing clinical trials. These clinical trials have enrolled over 2,100 subjects, of 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.

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 in the United States. 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, bulking agents and surgical procedures are often the most widely used treatments.

About GTx

GTx, Inc., headquartered in Memphis, Tenn., is a biopharmaceutical company dedicated to the discovery, development and commercialization of medicines to treat serious and/or significant unmet medical conditions, including SUI and prostate cancer.

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 enobosarm (GTx-024) for the treatment of 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 Phase 2 placebo-controlled clinical trial being conducted by GTx for the treatment of SUI may not be completed on schedule; (ii) that additional clinical development of enobosarm for the treatment of SUI will be required beyond the two ongoing Phase 2 studies; and (iii) any future development of enobosarm as a treatment for SUI is contingent on obtaining sufficient additional capital to permit such development, which it may be unable to do. 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, 2017, 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.

GTx, Inc.

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