

**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 18, 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**  
**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))

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 May 18, 2018, GTx, Inc. issued a press release announcing the release of additional data supporting the durability of the response to a 12-week treatment with enobosarm 3 mg in an open-label, Phase 2 proof-of-concept clinical trial evaluating 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 May 18, 2018

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release issued by GTX, Inc. dated May 18, 2018</a>

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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: May 18, 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 Updates Phase 2 Enobosarm Clinical Trial Results in Stress Urinary Incontinence at 2018 AUA Annual Meeting

— Updated patient durability results from proof-of-concept trial presented; reductions in incontinence episodes continue to be sustained for up to 7 months following completion of enobosarm treatment —

— Top-line results from ASTRID, an ongoing Phase 2 placebo-controlled clinical trial, are expected early in the fourth quarter of 2018 —

MEMPHIS, Tenn. - May 18, 2018— GTx, Inc. (Nasdaq: GTXI) today released additional data supporting the durability of the response to a 12-week treatment with enobosarm 3 mg in an open-label, Phase 2 proof-of-concept clinical trial evaluating enobosarm in postmenopausal women with stress urinary incontinence (SUI). The presentation, entitled Oral Enobosarm Shows Promising Activity in Post-Menopausal Women with Stress Urinary Incontinence: Results of a Phase 2 Study, took place at the 2018 American Urological Association annual meeting being held in San Francisco, CA, from May 18 to 21, 2018.

“The overall treatment effect of enobosarm in this proof-of-concept trial demonstrates the potential of enobosarm to effectively treat SUI, the most common type of incontinence suffered by women,” said Kenneth M. Peters, M.D., Chairman of Urology, Oakland University William Beaumont School of Medicine, and the principal investigator in the trial. “We now look forward to completing the ASTRID trial, which was designed with the same primary endpoint as the proof-of-concept trial, to determine whether clinically meaningful improvements in SUI are similarly achieved in this almost 500-person double-blinded, placebo-controlled clinical trial.”

### Stress Urinary Incontinence Summary of Results

Consistent with previous findings, at the end of the 12-week treatment period, all of the 18 enobosarm-treated women showed a clinically meaningful reduction in stress urinary incontinence episodes per day (the primary endpoint of the trial).

- Mean stress leaks decreased by 81 percent from baseline;
- Stress leaks decreased from a mean of 5.17 leaks/day at baseline to 1.00 leak/day;
- All 18 patients demonstrated clinically meaningful reductions in stress urinary incontinence episodes per day, compared to baseline, of at least 50 percent;
- Median Medical, Epidemiologic and Social Aspects of Aging (MESA) scores for SUI decreased from 79.5 percent to 44.5 percent; and
- There were no serious adverse events reported and reported adverse events were minimal and included headaches, nausea, fatigue, hot flashes, insomnia, muscle weakness and acne. Mild transient elevations in liver enzymes that were within normal limits were observed, except for one patient with levels greater than 1.5 times the upper limit of normal which returned to normal following her 12-week treatment period. Reductions in total cholesterol, LDL-C, HDL-C and triglycerides were also observed.

Dr. Peters provided an update on the reduction in incontinence episodes (a secondary endpoint of the trial), which was sustained, or durable, well beyond the 12-week treatment period.

- Patients are being followed for up to seven months post-treatment to assess enobosarm’s duration of effect, and to date no patient, including the 17 patients who have reached seven months, has returned to her baseline level of SUI episodes.

The Company has previously reported positive results from the proof-of-concept clinical trial that demonstrates a reduction in urinary incontinence episodes in a subset of women who had both SUI and urge incontinence (UI) at baseline. In addition, a previous presentation of the results also highlighted statistically significant magnetic resonance imaging results showing

increases in several important measurements that support the mechanism of action of enobosarm on the pelvic floor. A more detailed summary of these results can be found [here](#).

### About the Phase 2 Proof-of-Concept Clinical Trial

The single-arm, open-label Phase 2 clinical trial is evaluating enobosarm in postmenopausal women with SUI, and is the first clinical trial to evaluate an orally-administered selective androgen receptor modulator (SARM) for SUI. This clinical trial is closed to enrollment; more information about the clinical trial can be found [here](#).

### About the Phase 2 ASTRID Clinical Trial

In addition to the Phase 2 proof-of-concept clinical trial being presented at AUA, GTx also has a larger, ongoing, placebo-controlled Phase 2 clinical trial evaluating enobosarm in postmenopausal women with SUI. The study, called ASTRID (Assessing Enobosarm for Stress Urinary Incontinence Disorder), completed enrollment (n=493) recently and is being conducted at over 60 clinical trial centers across the United States. Top-line results are expected early in the fourth quarter of this year. To learn more about the ASTRID clinical trial, [click here](#).

### About Enobosarm and SUI

Enobosarm (GTx-024), a selective androgen receptor modulator (SARM), has been evaluated in 25 completed or ongoing clinical trials enrolling over 2,100 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.

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## **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 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 stress urinary incontinence 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 its selective androgen receptor modulator (SARM) 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 the Phase 2 placebo-controlled clinical study being conducted by GTx for the treatment of stress urinary incontinence (SUI) may not be completed on schedule; (ii) that additional clinical development of GTx's SARM compound for the treatment of SUI will be required beyond the ongoing study; and (iii) any future development of SARMs in 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*

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*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 March 31, 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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