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): **March 5, 2018**

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):

- o Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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 o

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. o

Item 8.01 Other Events.

On March 5, 2018, GTx, Inc. issued a press release announcing additional results from a Phase 2 proof-of-concept clinical trial of 3 mg enobosarm administered orally in postmenopausal women with stress urinary incontinence, including magnetic resonance imaging results from patients' pelvic floor muscle.

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 March 5, 2018

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued by GTx, Inc. dated March 5, 2018

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: March 5, 2018

GTx, Inc.

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

Exhibit 99.1

GTx Announced New Data Demonstrating Enobosarm's Potential to Treat Stress Urinary Incontinence at SUFU 2018

— MRI results show increases in pelvic floor muscle and urethral muscle diameter supporting enobosarm's mechanism of action —

— Additional positive results in subset of postmenopausal women suggest dual treatment effect on urge incontinence and stress urinary incontinence —

— Top-line results for a Phase 2 placebo-controlled clinical trial expected in the second half of 2018 —

MEMPHIS, Tenn. — March 5, 2018 — GTx, Inc. (Nasdaq: GTXI) today announced additional results from a Phase 2 proof-of-concept clinical trial of 3 mg enobosarm administered orally in postmenopausal women with stress urinary incontinence (SUI), including magnetic resonance imaging (MRI) results from patients' pelvic floor muscle. New data in a subset of women also suggests a positive treatment effect of enobosarm for urge incontinence (UI) suggesting a possible treatment effect for women with mixed incontinence. Results from a pre-specified analysis of MRI data demonstrate a statistically significant increase in pelvic floor muscle thickness and urethral muscle diameter after enobosarm treatment. Treatment with enobosarm also reduced mean UI episodes by approximately 68 percent in patients who experienced UI as well as SUI, based on a post hoc analysis of a subset of women with both UI and SUI. These results were outlined during a podium presentation which took place at the Society of Urodynamics, Female Pelvic Medicine, & Urogenital Reconstruction (SUFU) 2018 Meeting on Saturday, March 3, 2018. The presentation included clinical data from all 18 patients completing 12 weeks of enobosarm treatment, which, as previously reported, demonstrated an 81 percent reduction in the number of mean stress leaks per day (the primary endpoint of the clinical trial), as well as additional data demonstrating duration of response following completion of treatment, including nine patients who have now reached seven months post-treatment.

"Enobosarm's overall treatment effect was consistent with previously announced results, and importantly, these new results demonstrate that enobosarm may address a broader treatment need since many women suffer from symptoms of both stress and urge incontinence, also known as mixed incontinence," said Kenneth M. Peters, M.D., Chairman of Urology, Oakland University William Beaumont School of Medicine, and the principal investigator in the trial. "In addition, with the MRI results, we are seeing anatomical changes supporting enobosarm's mechanism of action on pelvic floor muscle."

Magnetic Resonance Imaging (MRI) Summary of Results

Magnetic resonance imaging (MRI) was used to quantitatively measure muscle in the pelvic floor of 17 women at 12 weeks compared to their baseline. The results showed a statistically significant increase in several important measurements and support the mechanism of action of enobosarm on the pelvic floor.

- At week 12, mean levator ani muscle thickness increased 1.15 mm (p=0.006) from a baseline measurement of 4.79 mm.
- At week 12, mean inner urethral muscle diameter increased 0.7 mm (p=0.002) from a baseline measurement of 10.7 mm.
- At week 12, mean outer urethral muscle diameter increased 0.7 mm (p=0.0003) from a baseline measurement of 15.4 mm.

Urge Incontinence Summary of Results

While all of the women in the trial had predominant SUI, some also experienced urge incontinence (UI). Eleven of the 18 women completing 12 weeks of treatment were determined to have both SUI and UI at baseline, and these 11 women with mixed incontinence demonstrated a mean reduction in their UI episodes of approximately 68 percent.

- Urge leaks decreased from a mean of 1.41 leaks per day at baseline, to 0.45 leaks per day;
- 9 of 11 women demonstrated a reduction in their number of UI leaks, compared to baseline, with 8 of 11 demonstrating a clinically meaningful reduction in their UI episodes per day of at least 50 percent; and
- Median Medical, Epidemiologic and Social Aspects of Aging (MESA) scores for UI decreased from 56 percent to 22 percent.

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 per day at baseline to 1.00 leak per day;
- All 18 patients demonstrated clinically meaningful reductions in stress urinary incontinence episodes per day, compared to baseline, of at least 50 percent; and
- Median Medical, Epidemiologic and Social Aspects of Aging (MESA) scores for SUI decreased from 79.5 percent to 44.5 percent.

The reduction in incontinence episodes 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 nine patients who have reached seven months, has returned to her baseline level of SUI episodes.

Women reported improved quality of life measurements in various instruments collected in the study, including the Patient Global Impression of Improvement (PGI-I), Urogenital Distress Inventory (UDI-6) and Incontinence Impact Questionnaire (IIQ-7). Improvements in Female Sexual Function Index (FSFI) were also noted. At Week 12:

- 17 of 18 patients showed improved PGI-I scores;
- Median UDI-6 scores decreased from 45.83 at baseline to 31.25;
- Median IIQ-7 scores decreased from 50.00 at baseline to 11.90; and
- Median FSFI scores improved from a baseline score of 15.85 to 28.00.

Safety and Tolerability Summary

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.

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. In the trial, a total of 19 postmenopausal women were enrolled at three clinical trial sites to receive enobosarm treatment. A total of 18 patients completed treatment with one patient having previously withdrawn her consent shortly after her initial clinical visit. More information about the clinical trial can be found on clinicaltrials.gov. The presentation, entitled “Oral Enobosarm Shows Promising Activity in Post-Menopausal Women with Stress Urinary Incontinence: Results of A Phase 2 Study”, can be found on the Company’s website.

About the Phase 2 ASTRID Clinical Trial

In addition to the Phase 2 proof-of-concept clinical trial that was presented at SUFU, GTx also has a larger, ongoing, placebo-controlled Phase 2 clinical trial in postmenopausal women with SUI. The study, called ASTRID (**A**ssessing Enobosarm for **Str**ess Urinary **I**ncontinence **D**isorder), is currently recruiting women at over 60 clinical trial centers across the United States. Top-line results are expected in the second half of 2018. 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 1,700 subjects, of which approximately 1,200 subjects were treated with enobosarm at doses ranging from 0.1 mg to 100 mg, excluding the ASTRID clinical trial. 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 data from the Company’s ongoing Phase 2 proof-of-concept clinical trial continues to validate the use of enobosarm as a potential treatment for SUI.

About Stress and Urge 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 however, bulking agents and surgical procedures are often the most widely used treatments. Urge incontinence refers to the involuntary loss of urine that usually occurs when a person has a strong, sudden need to urinate. Stress and urge incontinence often coexist. Approximately half of the women with mixed incontinence (stress and urge) will be relieved of urge incontinence following a procedure for stress incontinence.

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 quarterly report on Form 10-Q for the quarter ended September 30, 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.

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