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 13, 2017**

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 September 13, 2017, GTx, Inc. issued a press release announcing top-line clinical trial results demonstrating that a daily dose of enobosarm 3mg (GTx-024) substantially improved stress urinary incontinence in women, as well as related quality of life measurements.

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 September 13, 2017

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued by GTx, Inc. dated September 13, 2017

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 13, 2017

GTx, Inc.

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

Exhibit 99.1

GTx Announces Positive Results from Enobosarm Phase 2 Proof-of-Concept Clinical Trial in Women with Stress Urinary Incontinence

— Data presented at the International Continence Society Annual Meeting today demonstrated:

** Clinically significant reductions in incontinence episodes per day in all patients completing 12 week treatment*

** Reductions in incontinence episodes were sustained for up to 7 months following completion of enobosarm treatment*

— Placebo-controlled Phase 2 clinical trial designed to further evaluate enobosarm in postmenopausal women with SUI initiated in August 2017 —

MEMPHIS, Tenn. — September 13, 2017 — GTx, Inc. (Nasdaq: GTXI) today announced top-line clinical trial results demonstrating that a daily dose of enobosarm 3 mg (GTx-024) substantially improved stress urinary incontinence (SUI) in women, as well as related quality of life measurements. In this open-label clinical trial, all 17 patients completing 12 weeks of treatment saw a clinically significant reduction (50 percent or greater) in stress leaks per day, compared to baseline. Mean stress leaks decreased by 83 percent from baseline over 12 weeks, and the reductions in daily stress leaks following completion of treatment have been sustained as patients are being followed for up to 7 months post-treatment to assess the durability of treatment effect. No patient has relapsed to her baseline levels. These results were presented at the International Continence Society (ICS) Annual Meeting currently being held in Florence, Italy from September 12-15, 2017.

“All 17 patients completing treatment have shown a significant reduction in the number of leaks per day recorded at their baseline, and the improvements in symptoms were sustained well beyond ceasing enobosarm treatment at 12 weeks,” said Kenneth M. Peters, M.D., Chairman of Urology, Oakland University William Beaumont School of Medicine, and the principal investigator in the trial. “The results in this proof-of-concept study are promising, and we are excited to be participating in a larger, placebo-controlled Phase 2 study.”

The podium presentation entitled “Kegels In A Bottle”: Preliminary Results Of A Selective Androgen Receptor Modulator (GTx-024) For The Treatment Of SUI In Post-Menopausal Women, summarized clinical data from the first 17 patients completing 12 weeks of enobosarm

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treatment, including the duration of response for up to 7 months following completion of enobosarm treatment. In this trial, a total of 19 post-menopausal women were enrolled by three clinical sites to receive enobosarm treatment. In addition to the 17 patients who completed treatment, another will complete treatment in approximately 8 weeks and one patient previously withdrew consent shortly after her initial visit. Data highlights were as follows:

Each of the women treated with enobosarm showed a clinically significant reduction in incontinence episodes per day:

- Mean stress leaks decreased by 83% percent from baseline over 12 weeks
- Stress leaks decreased from a mean of 5.08 leaks/day at baseline, to 0.88 leaks/day at Week 12
- All 17 patients achieved the primary endpoint of reductions in leaks per day, compared to baseline, of at least 50% at Week 12

Reductions in incontinence episodes were sustained well beyond the 12 week treatment period:

- Patients are being followed for up to 7 months post-treatment to assess duration of the drug’s effect, and to date no patient, including 6 patients who have reached 7 months, has returned to her baseline levels of SUI episodes

Women reported improved quality of life measurements in each of the five instruments collected in the study, including the Patient Global Impression of Improvement (PGI-I) and Female Sexual Function Index (FSFI):

- At Week 12, 16 of 17 patients showed improved PGI-I scores and median FSFI scores improved from a baseline score of 15.90 to 28.05 at Week 12

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 were observed, as well as reductions in total cholesterol, LDL, HDL and triglycerides. The presentation can be found on the Company’s website. The abstract is available on the International Continence Society’s website.

Based on the results from its enobosarm Phase 2 proof-of-concept study, the Company has initiated a randomized, placebo-controlled Phase 2 clinical trial to evaluate the change in frequency of daily stress urinary incontinence episodes following 12 weeks of treatment. The

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trial will evaluate the safety and efficacy of enobosarm (1 mg and 3 mg) compared with placebo in postmenopausal women with SUI. Enobosarm has previously been evaluated in clinical trials enrolling in excess of 1,700 patients, in which approximately 1,200 individuals received doses ranging from 0.1 mg to 100 mg, and has been observed to be generally safe and well tolerated.

“Since stress incontinence occurs when muscles that control one’s ability to hold urine get weak or do not work, it stands to reason that increasing pelvic floor muscle mass should reduce involuntary or unintentional leakage of urine,” said Dr. William J. Evans, Adjunct Professor in the geriatrics program at the Duke University Medical Center. “The muscles of the pelvic floor are enriched with androgen receptors and are responsive to the body’s hormonal status which is why we hypothesize that a selective androgen receptor modulator, like enobosarm, could have a beneficial effect on SUI.”

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. More information about the clinical trial can be found 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, a selective androgen receptor modulator (SARM), has been evaluated in 24 completed or ongoing clinical trials enrolling over 1,700 subjects, in which approximately 1,200 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

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demonstrating increases in pelvic floor muscle mass following treatment with GTx's SARM compounds, including enobosarm, and the ongoing 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 trials of, and the therapeutic potential of, enobosarm (GTx-024) to treat 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 clinical trials being conducted by GTx may not be completed on schedule, or at all, or may otherwise be suspended or terminated; (ii) that the development of enobosarm to treat SUI is at an early stage, is subject to the substantial risk of failure inherent in the development of early-stage product candidates, and will require significant additional financial resources in order for such development to continue; (iii) that any additional clinical development of enobosarm to treat SUI is 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; and (iv) that GTx may not be able to obtain required regulatory approvals to commercialize enobosarm in a timely manner or at all. 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, 2017, filed August 14, 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.

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