

**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): **June 12, 2017**

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 June 12, 2017, GTx, Inc. issued a press release announcing release of preliminary clinical data from its ongoing, open-label, Phase 2 clinical trial of enobosarm 3 mg (GTx-024) 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 June 12, 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: June 12, 2017

GTx, Inc.

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

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by GTx, Inc. dated June 12, 2017

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

— Abstract on preliminary results accepted for podium presentation at the International Continence Society Annual Meeting —

— Additional patient data to be included in oral presentation on September 13, 2017, during a session on Female Pelvic Floor Dysfunction —

MEMPHIS, Tenn. — June 12, 2017 — GTx, Inc. (Nasdaq: GTXI) today announced release of preliminary clinical data from its ongoing, open-label, Phase 2 clinical trial of enobosarm 3 mg (GTx-024) in postmenopausal women with stress urinary incontinence (SUI). An abstract entitled “Kegels In A Bottle”: Preliminary Results Of A Selective Androgen Receptor Modulator (GTx-024) For The Treatment Of SUI In Post-Menopausal Women, summarizing clinical data from the first seven patients completing 12 weeks of treatment with enobosarm, is now available on the International Continence Society’s website. This proof-of-concept clinical trial is the first of its kind to evaluate an orally-administered selective androgen receptor modulator (SARM) for SUI.

In this ongoing Phase 2 clinical trial, enobosarm 3 mg is being given to post-menopausal women who have demonstrated SUI symptoms for more than six months, with 3 to 15 reported SUI episodes per day averaged over a three-day period, and a positive bladder stress test. The primary endpoint is the number of SUI episodes per day on the 3-day voiding diary at 12 weeks, compared to base line. The clinical findings from the first seven patients enrolled in the study following their completion of treatment, as outlined in the abstract, are summarized below.

- Each of the women treated with enobosarm showed a clinically significant reduction in incontinence episodes per day:
 - Mean stress leaks decreased by 80.9 percent from baseline over 12 weeks
 - Stress leaks decreased from a mean of 5.7 leaks/day at baseline, to 1.1 leaks/day at Week 12
 - All patients saw at least a 65 percent reduction in number of stress leaks
- Reductions in incontinence episodes were sustained well beyond the stopping of study drug at Week 12:
 - Patients demonstrated continued reduction in incontinence episodes for up to five months

- Women reported improved quality of life in the Patient Global Impression of Improvement (PGI-I) and Female Sexual Function Index (FSFI)
 - At Week 12, all seven patients showed improved PGI-I scores and 5 of 7 patients showed improvement in FSFI
- Reported adverse events are minimal with none above Grade I

“With approximately half the women in the United States experiencing symptoms of SUI, there is a growing need for an effective oral therapy to treat women with stress urinary incontinence,” said Kenneth M. Peters, M.D., Professor and Chairman of Urology, Oakland University William Beaumont School of Medicine. “I am very encouraged by the consistency and strength of these early results, and I look forward to presenting more detailed clinical data from this ongoing clinical trial at the upcoming International Continence Society (ICS) meeting.”

“What caught our attention was the fact that the first seven patients dosed in this study saw impressive positive results. We subsequently added two additional clinical trial sites, and we look forward to presenting data from additional patients from this study at the ICS meeting in September,” said Robert J. Wills, Ph.D., Executive Chairman of GTx. “We believe SUI represents a near-term commercial opportunity in a potentially large population of women whose treatment options are currently limited to non-pharmacologic or invasive treatments.”

About the Phase 2 Proof-of-Concept Clinical Trial

Enrollment in the Phase 2 proof-of-concept clinical trial of 3 mg of enobosarm in women with SUI is ongoing. This is the first clinical trial to evaluate a SARM for SUI. The Company believes that developing an oral therapy to potentially treat the large number of women who face a diminished quality of life from stress urinary incontinence presents a unique commercial opportunity, especially since current therapies may sometimes involve invasive procedures. In the Phase 2 clinical trial, 3 mg of GTx-024 is being given daily for 12 weeks to post-menopausal women. The primary endpoint is the number of stress incontinence episodes per day on the 3-day voiding diary. Secondary endpoints include: pad weights, bladder stress test, and quality of life instruments including the Female Sexual Function Index (FSFI) and Patient Global Impression of improvement (PGI-I). More information about the clinical trial can be found here.

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, of 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 demonstrating increases in pelvic floor muscle mass following treatment with GTx’s SARM compounds, including enobosarm, and data from the Company’s on-going Phase 2 clinical trial continues to validate the use of enobosarm as a potential treatment for SUI.

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 50 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.

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 cancer, including treatments for breast and prostate cancer, 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 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 proof-of-concept study 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 ongoing study; 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 March 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.

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