

**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 15, 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 2.02 Results of Operations and Financial Condition.

On May 15, 2018, GTx, Inc. issued its financial press release for the first quarter ended March 31, 2018, a copy of which is furnished as Exhibit 99.1 to this Current Report.

This release is furnished by GTx pursuant to Item 2.02 of Form 8-K and is not to be considered "filed" under the Exchange Act, and shall not be incorporated by reference into any previous or future filing by the Registrant under the Securities Act or the Exchange Act.

ITEM 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit Number	Description
99.1	<a href="#">Press Release issued by GTx, Inc. dated May 15, 2018</a>

**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 15, 2018

GTx, Inc.

By: /s/ Henry P. Doggrell

Name: Henry P. Doggrell

Title: Vice President, Chief Legal Officer and Secretary



## GTx Provides Corporate Update and Reports First Quarter 2018 Financial Results

— Completed patient enrollment in the ASTRID Trial, a Phase 2 double-blinded, placebo-controlled clinical trial of enobosarm in Stress Urinary Incontinence —

— Top-line results from the ASTRID Trial expected early in the fourth quarter of 2018 —

— Podium presentation at the 2018 American Urological Association (AUA) meeting May 18, 2018, will update results from Phase 2 proof-of-concept clinical trial of enobosarm —

MEMPHIS, Tenn. — May 15, 2018 — GTx, Inc. (Nasdaq:GTXI) today reported financial results for the first quarter ended March 31, 2018 and highlighted recent accomplishments and upcoming milestones.

“GTx is off to a strong start in 2018, with data presented at the SUFU Meeting in March supporting enobosarm’s potential to treat stress urinary incontinence (SUI). The data included additional positive results in a subset of women with both SUI and urge incontinence,” said Robert J. Wills, Ph.D., Executive Chairman of GTx. “We look forward to presenting additional data from our open-label, Phase 2 proof-of-concept clinical trial evaluating enobosarm 3 mg in postmenopausal women with SUI at the upcoming AUA meeting in May. In addition, we completed patient enrollment in our placebo-controlled, Phase 2 clinical trial of enobosarm in postmenopausal women with SUI several months ahead of schedule. Enrollment exceeded the 400 patients planned per protocol, and we are eager to report top-line results early in the fourth quarter of 2018.”

### Clinical Highlights and Anticipated Milestones

#### Stress Urinary Incontinence (SUI):

Enobosarm, a Selective Androgen Receptor Modulator (SARM), is being evaluated in Phase 2 clinical development for SUI, the Company’s lead indication. Recent and upcoming important milestones are summarized as follows:

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- At the Society of Urodynamics, Female Pelvic Medicine, & Urogenital Reconstruction (SUFU) Meeting in March, positive results were presented from the Company’s Phase 2 proof-of-concept (POC) clinical trial of enobosarm 3 mg administered orally in post-menopausal women with SUI. Details of the SUFU presentation can be found here and are summarized below:
    - At the end of the 12-week treatment period, all 18 enobosarm-treated women demonstrated clinically meaningful (50 percent or greater) reductions in stress urinary incontinence episodes per day, compared to baseline.
    - The reduction in incontinence episodes was sustained, or durable, well beyond the 12-week treatment period.
    - Additional positive results in a subset of postmenopausal women suggest a dual treatment effect on both SUI and urge incontinence (UI).
    - Magnetic resonance imaging (MRI) results showed a statistically significant increase in several important measurements and support the mechanism of action of enobosarm on the pelvic floor.
    - 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.
  - On May 18, 2018, a podium presentation at the 2018 American Urological Association (AUA) meeting will update results from the Phase 2 POC clinical trial of enobosarm.
  - The Company has an ongoing randomized, double-blinded, placebo-controlled, Phase 2 trial to assess the efficacy and safety of enobosarm administered orally in post-menopausal women with SUI compared to placebo. More information about the ASTRID (Assessing Enobosarm for Stress Urinary Incontinence Disorder) trial can be found here.
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- In April, the Company completed patient enrollment in the ASTRID trial several months ahead of schedule, enrolling 493 women at over 60 clinical trial centers across the United States. Top-line results are expected early in the fourth quarter of 2018.

#### Prostate Cancer:

The Company has a Selective Androgen Receptor Degradar (SARD) preclinical program to evaluate its novel SARD technology in castration-resistant prostate cancer (CRPC). The Company has ongoing mechanistic preclinical studies designed to select the most appropriate compound to potentially advance into a first-in-human clinical trial.

## First Quarter 2018 Financial Results

- As of March 31, 2018, cash and short-term investments were \$32.1 million compared to \$43.9 million at December 31, 2017.
- Research and development expenses for the quarter ended March 31, 2018 were \$11.0 million compared to \$4.2 million for the same period of 2017.
- General and administrative expenses for the quarter ended March 31, 2018 were \$2.7 million compared to \$2.1 million for the same period of 2017.
- The net loss for the quarter ended March 31, 2018 was \$13.6 million compared to a net loss of \$6.3 million for the same period in 2017.
- GTx had approximately 22.5 million shares of common stock outstanding as of March 31, 2018. Additionally, there are warrants outstanding to purchase approximately 5.3 million shares of GTx common stock at an exercise price of \$8.50 per share and approximately 3.3 million shares of GTx common stock at an exercise price of \$9.02.

## 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

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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 (**A**ssessing **E**nobosarm for **S**tress **U**rinary **I**ncontinence **D**isorder), 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. More information about the ASTRID clinical trial can be found [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.

## 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.

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## 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 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.*

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**GTx, Inc.****Investors:**

Argot Partners  
 Kimberly Minarovich or Sam Martin  
 212-600-1902

Or

**Media:**

Red House Consulting  
 Denise Powell, 510-703-9491  
 denise@redhousecomms.com

**GTx, Inc.**  
**Condensed Balance Sheets**  
 (in thousands, except share data)

	March 31, 2018 (unaudited)	December 31, 2017
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 14,958	\$ 15,816
Short-term investments	17,186	28,083
Prepaid expenses and other current assets	2,067	2,178
Total current assets	34,211	46,077
Property and equipment, net	43	51
Intangible assets, net	105	108
Total assets	<u>\$ 34,359</u>	<u>\$ 46,236</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,739	\$ 2,604
Accrued expenses and other current liabilities	7,871	5,371
Total current liabilities	9,610	7,975
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 60,000,000 shares authorized at March 31, 2018 and December 31, 2017; 22,529,690 and 21,541,909 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	23	22
Additional paid-in capital	599,920	599,876
Accumulated deficit	(575,194)	(561,637)
Total stockholders' equity	24,749	38,261
Total liabilities and stockholders' equity	<u>\$ 34,359</u>	<u>\$ 46,236</u>

**GTx, Inc.**  
**Condensed Statements of Operations**  
 (in thousands, except share and per share data)  
 (unaudited)

	Three Months Ended March 31,	
	2018	2017
Expenses:		
Research and development expenses	\$ 11,000	\$ 4,193
General and administrative expenses	2,688	2,087
Total expenses	13,688	6,280
Loss from operations	(13,688)	(6,280)
Other income, net	131	27
Net loss	<u>\$ (13,557)</u>	<u>\$ (6,253)</u>
Net loss per share — basic and diluted	<u>\$ (0.62)</u>	<u>\$ (0.39)</u>
Weighted average shares outstanding — basic and diluted	<u>21,967,805</u>	<u>16,018,342</u>