

**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 12, 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 March 12, 2018, GTx, Inc. issued its financial press release for the fourth quarter and year ended December 31, 2017, 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**  
99.1

**Description**  
[Press Release issued by GTx, Inc. dated March 12, 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 12, 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 Fourth Quarter and Full Year 2017 Financial Results

— *Enobosarm for Stress Urinary Incontinence (SUI) continues to show sustained durability of response in Phase 2 proof of concept clinical trial* —

— *Top-line results from the ASTRID trial, a Phase 2 placebo-controlled clinical trial of enobosarm for the treatment of SUI, are expected in the second half of 2018* —

**MEMPHIS, Tenn.—March 12, 2018**— GTx, Inc. (Nasdaq:GTXI) today reported financial results for the fourth quarter and year ended December 31, 2017 and highlighted recent accomplishments and upcoming milestones.

“2017 was a transformational year for GTx, marked by positive results from our Phase 2 proof-of-concept clinical trial in post-menopausal women with stress urinary incontinence and the initiation of the ASTRID trial, a Phase 2 placebo-controlled clinical trial of enobosarm for the treatment of SUI,” said Robert J. Wills, Ph.D., Executive Chairman of GTx. “We believe that there is a significant opportunity for an effective oral therapy to treat SUI and look forward to results from the ASTRID trial in the second half of 2018.”

### Clinical Highlights and Anticipated Milestones

#### Stress Urinary Incontinence (SUI) Phase 2 Proof-of-Concept Trial:

Last week at the Society of Urodynamics, Female Pelvic Medicine, & Urogenital Reconstruction (SUFU) Meeting and at the International Continence Society (ICS) annual meeting in 2017, 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. The results, including additional positive results presented at SUFU in a subset of women with both urge and stress incontinence, are summarized as follows:

*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; 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.

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

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, also known as mixed incontinence.

- Mean urge leaks decreased by 68 percent from baseline;
- Urge leaks decreased from a mean of 1.41 leaks/day at baseline, to 0.45 leaks/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.

*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; and
- At week 12, mean outer urethral muscle diameter increased 0.7 mm (p=0.0003) from a baseline measurement of 15.4 mm.

There were no serious adverse events reported during the trial 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.

#### SUI Phase 2 Placebo-Controlled ASTRID Clinical Trial:

Based on the positive results from the Phase 2 POC trial, the Company initiated a randomized, double-blinded, placebo-controlled, Phase 2 trial to assess the efficacy and safety of enobosarm administered orally in approximately 400 post-menopausal women with SUI compared to placebo. More information about

the ASTRID (Assessing Enobosarm for Stress Urinary Incontinence Disorder) trial, which is ongoing, can be found here. Top-line results from the Phase 2 placebo-controlled clinical trial are expected in the second half of 2018.

### **Prostate Cancer:**

The Company has a Selective Androgen Receptor Degradator (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.

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### **Fourth Quarter and Year-End 2017 Financial Results**

- As of December 31, 2017, cash and short-term investments were \$43.9 million compared to \$21.9 million at December 31, 2016.
- Research and development expenses for the quarter ended December 31, 2017 were \$6.9 million compared to \$4.6 million for the same period of 2016. Research and development expenses for the year ended December 31, 2017 were \$21.5 million compared to \$17.2 million for the year ended December 31, 2016.
- General and administrative expenses for the quarter ended December 31, 2017 were \$2.5 million compared to \$2.3 million for the same period of 2016. General and administrative expenses for the year ended December 31, 2017 were \$9.2 million compared to \$8.7 million for the year ended December 31, 2016.
- The net loss for the quarter ended December 31, 2017 was \$9.3 million compared to a net loss of \$6.9 million for the same period in 2016.
- The net loss for the year ended December 31, 2017 was \$30.4 million compared to a net loss of \$17.7 million for the year ended December 31, 2016. The net loss for the year ended December 31, 2016 included a non-cash gain of \$8.2 million related to the change in the fair value of the Company's warrant liability. During the first quarter of 2016, the Company modified its outstanding warrants with no further adjustment to the fair value of these warrants being required.
- GTx had approximately 21.5 million shares of common stock outstanding as of December 31, 2017. Additionally, there are warrants outstanding to purchase approximately 6.4 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 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. For more information, please visit <http://www.gtxinc.com>.

### *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 the enrollment and conduct of GTx's ongoing Phase 2 placebo-controlled clinical trial of enobosarm (GTx-024) in post-menopausal women with stress urinary incontinence (SUI), as well as GTx's plans for its ongoing preclinical research and potential future development of GTx's licensed selective androgen receptor degrader (SARD) technology, and the timing thereof; and the potential therapeutic applications for, and potential benefits of SARM (including enobosarm) and SARD technology. 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 GTx's evaluation of its licensed SARD technology is at a very early stage and it is possible that GTx may determine not to move forward with any meaningful development of the program; (ii) that if GTx*

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*determines to move forward with additional development of enobosarm for the treatment of SUI or if GTx does determine to move forward with development of its SARD program, GTx will require additional funding, which it may be unable to raise, in which case, GTx may fail to realize the anticipated benefits from its SARM and/or SARD technology; (iii) that GTx may not be successful in developing a clinical SARD product candidate to advance into clinical studies or the clinical product candidate may fail such clinical studies; (iv) that the Phase 2 placebo-controlled clinical trial of enobosarm to treat SUI being conducted by GTx may not be completed on schedule, or at all, or may otherwise be suspended or terminated; (v) related to the difficulty and uncertainty of pharmaceutical product development, including the time and expense required to conduct preclinical and clinical trials and analyze data, and the uncertainty of preclinical and clinical success; and (vi) related to issues arising during the uncertain and time-consuming regulatory process, including the risk that GTx may not receive any approvals to advance the clinical development of one or more potential clinical SARM or SARD candidates. 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 ending December 31, 2017, which is being filed subsequent to this release, 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.*

### **Investors:**

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

or

### **Media:**

Red House Consulting  
Denise Powell, 510-703-9491  
[denise@redhousecomms.com](mailto:denise@redhousecomms.com)

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

	December 31,	
	2017 (unaudited)	2016
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 15,816	\$ 8,910
Short-term investments	28,083	12,959
Prepaid expenses and other current assets	2,178	2,429
Total current assets	46,077	24,298
Property and equipment, net	51	81
Intangible assets, net	108	123
Total assets	<u>\$ 46,236</u>	<u>\$ 24,502</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,604	\$ 1,220
Accrued expenses and other current liabilities	5,371	3,391
Total current liabilities	7,975	4,611
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 60,000,000 shares authorized at December 31, 2017 and December 31, 2016; 21,541,909 and 15,919,572 shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively	22	16
Additional paid-in capital	599,876	551,073
Accumulated deficit	(561,637)	(531,198)
Total stockholders' equity	38,261	19,891
Total liabilities and stockholders' equity	<u>\$ 46,236</u>	<u>\$ 24,502</u>

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

	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
<b>Expenses:</b>				
Research and development expenses	\$ 6,912	\$ 4,585	\$ 21,467	\$ 17,228
General and administrative expenses	2,487	2,279	9,188	8,705
Total expenses	9,399	6,864	30,655	25,933
Loss from operations	(9,399)	(6,864)	(30,655)	(25,933)
Other income, net	122	—	216	46
Gain on change in fair value of warrant liability	—	—	—	8,163
Net loss	<u>\$ (9,277)</u>	<u>\$ (6,864)</u>	<u>\$ (30,439)</u>	<u>\$ (17,724)</u>
Net loss per share — basic and diluted:	<u>\$ (0.43)</u>	<u>\$ (0.44)</u>	<u>\$ (1.75)</u>	<u>\$ (1.22)</u>
Weighted average shares outstanding — basic and diluted:	<u>21,541,909</u>	<u>15,713,210</u>	<u>17,441,280</u>	<u>14,559,541</u>