

**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) **November 14, 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 2.02 Results of Operations and Financial Condition.

On November 14, 2017, GTx, Inc. issued its financial press release for the third quarter ended September 30, 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	Description
99.1	Press Release issued by GTx, Inc. dated November 14, 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: November 14, 2017

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 Third Quarter 2017 Financial Results

— Positive results achieved in all patients after 12-week treatment in the enobosarm Phase 2 proof-of-concept clinical trial in women with stress urinary incontinence (SUI) —

— Enobosarm Phase 2 proof-of-concept clinical trial for SUI continues to show sustained durability of response —

— Initiated ASTRID study, a Phase 2 placebo-controlled clinical trial of orally-administered enobosarm for the treatment of SUI —

— Closed private placement with \$45.6 million in net proceeds —

MEMPHIS, Tenn.—November 14, 2017— GTx, Inc. (Nasdaq:GTXI) today reported financial results for the third quarter of 2017 and highlighted recent accomplishments and upcoming milestones.

“During the quarter, we achieved a key milestone for the company when we reported positive results from our first clinical trial in stress urinary incontinence,” said Robert J. Wills, Ph.D., Executive Chairman of GTx. “Remarkably, 18 out of 18 women who received enobosarm for 12 weeks responded. These responses also appear to be durable, lasting months after dosing. These exciting results provided the basis for our recently initiated, placebo-controlled clinical trial of enobosarm for the treatment of SUI.”

“Recent data suggests 50 percent of women report SUI, for which there are no FDA-approved pharmaceutical therapies. An orally-available therapy would offer numerous advantages over existing treatments including surgery, and would provide a significant new option that many women would choose in order to address this medical condition,” said Kenneth M. Peters, M.D., Chairman of Urology, Oakland University William Beaumont School of Medicine and the principal investigator in the trial.

Third Quarter 2017 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 important milestones are summarized as follows:

- Reported positive results from the Phase 2 proof-of-concept (POC) clinical trial of enobosarm 3 mg administered orally in post-menopausal women with SUI. With the inclusion of the final patient completing treatment in the POC clinical trial, data from the 18 evaluable patients completing the required 12 weeks of daily treatment showed a clinically meaningful reduction (50 percent or greater) in stress leaks per day, compared to baseline. The mean decrease in stress leaks per day was 81 percent overall (5.17 mean leaks/day at baseline to 1.0 mean leaks/day at 12 weeks).
- Patients are being followed for an additional 28 weeks post-treatment to assess the durability of treatment effect. Durability of response for patients who completed the 28-week observation phase has resulted in a 41 to 100 percent reduction in stress leaks/day from baseline (N=6). For

those patients who have not completed the 28-week observation phase, the durability of response, measured beginning 4 weeks post dosing, continues to be sustained.

- Highlighted the Phase 2 POC results at the International Continence Society (ICS) annual meeting in a poster entitled, “Kegels in a Bottle: Preliminary Results of a Selective Androgen Receptor Modulator (GTx-024) for the Treatment of Stress Urinary Incontinence in Post-Menopausal Women”, which subsequently was voted best poster for the conference.
- Initiated a second clinical trial, Assessing Enobosarm for **Stress Urinary Incontinence Disorder (ASTRID)**: a randomized, double-blinded, placebo-controlled, Phase 2 trial to assess the efficacy and safety of two doses of enobosarm (1 mg and 3 mg) administered orally in post-menopausal woman with SUI compared to placebo. The primary endpoint of the trial is the percentage of patients with at least a 50 percent reduction in mean leaks/day, compared to baseline. This trial is expected to enroll approximately 400 patients across 70 clinical sites in the U.S. Top-line results are expected to be available by the end of 2018.

Breast Cancer:

Enobosarm is also being evaluated as a hormonal therapy for women with estrogen receptor positive (ER+) and androgen receptor positive (AR+) breast cancer in a Phase 2 clinical trial for this advanced breast cancer population. As reported earlier for the 9 mg cohort, the Phase 2 trial pre-specified threshold for success, clinical benefit response (CBR), was attained and therefore met the primary efficacy endpoint. In addition, the 18 mg cohort has also met the primary efficacy endpoint. The trial has now completed enrollment of the predefined number of evaluable patients in both dosage arms with at least 44 patients in each of two cohorts receiving 9 mg or 18 mg daily doses of enobosarm.

- In the 9 mg cohort, following 24 weeks of treatment, a total of 14 patients achieved a CBR out of 49 evaluable patients confirmed as AR positive (28.6%), with two patients achieving a partial response and 12 reporting stable disease. Currently, four patients in this cohort remain on study. In the 18 mg cohort, with 48 evaluable patients, 12 patients achieved a CBR (25%) at 24 weeks with one patient demonstrating a partial response and 11 patients reporting stable disease. Three patients remain on study in the 18 mg cohort. Both doses of enobosarm appear to be safe and generally well tolerated. A complete summary of the study results will be submitted for presentation or publication in 2018.
- Although both the 9 mg and 18 mg cohorts met the primary efficacy endpoint in the Phase 2 clinical trial, after evaluating the drug development environment for breast cancer, where treatment paradigms are shifting to immunotherapies and/or combination therapies, the Company has decided that the time and cost of conducting the necessary clinical trials for approval in this indication do not warrant further development of enobosarm in this indication at this time.

Duchenne Muscular Dystrophy (DMD):

SARMs have also been evaluated in preclinical models of DMD, in which GTx SARMs have increased lean muscle mass and physical function. The Company is pursuing a potential strategic collaboration with

biopharma companies experienced in orphan drug development to continue the development of a SARM for the treatment of DMD.

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 advance into a first-in-human clinical trial.

Third Quarter 2017 Corporate Highlights and Financial Results

- During the quarter, GTx raised net proceeds of \$45.6 million in a private placement of its common stock and warrants to purchase its common stock. GTx sold 5,483,320 immediately separable units, comprised of an aggregate of 5,483,320 newly-issued shares of common stock and warrants to purchase up to 3,289,988 additional shares of common stock. Both the common stock and warrants have been registered for resale with the Securities and Exchange Commission.
- As of September 30, 2017, cash and short-term investments were \$53.6 million compared to \$21.9 million at December 31, 2016.
- Research and development expenses for the quarter ended September 30, 2017 were \$5.9 million compared to \$4.6 million for the same period of 2016.
- General and administrative expenses for the quarter ended September 30, 2017 were \$2.6 million compared to \$2.3 million for the same period of 2016.
- Net loss for the three months ended September 30, 2017 was \$8.5 million compared to a net loss of \$6.9 million for the same period in 2016.
- Net loss for the nine months ended September 30, 2017 was \$21.2 million compared to a net loss of \$10.9 million for the same period in 2016. The nine months ended September 30, 2016 included a non-cash gain of \$8.2 million due to the change in 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 September 30, 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 is a biopharmaceutical company dedicated to the discovery, development and commercialization of medicines to treat serious 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 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, as well as the development of selective androgen receptor modulators (SARMs) for the treatment of Duchenne muscular dystrophy (DMD) 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 or a SARM for the treatment of DMD are at very early stages and it is possible that GTx may determine not to move forward with any meaningful development of one or both programs; (ii) that if GTx 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 or a SARM, 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 quarterly report on Form 10-Q for the quarter ending September 30, 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.

GTx, Inc.

Condensed Balance Sheets

(in thousands, except share data)

	September 30, 2017 (unaudited)	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 53,431	\$ 8,910
Short-term investments	200	12,959
Prepaid expenses and other current assets	2,049	2,429
Total current assets	55,680	24,298
Property and equipment, net	57	81
Intangible assets, net	112	123
Total assets	<u>\$ 55,849</u>	<u>\$ 24,502</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,451	\$ 1,220
Accrued expenses and other current liabilities	6,828	3,391
Total current liabilities	9,279	4,611
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 60,000,000 shares authorized at September 30, 2017 and December 31, 2016; 21,541,909 and 15,919,572 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	22	16
Additional paid-in capital	598,908	551,073
Accumulated deficit	(552,360)	(531,198)
Total stockholders' equity	46,570	19,891
Total liabilities and stockholders' equity	<u>\$ 55,849</u>	<u>\$ 24,502</u>

GTx, Inc.

Condensed Statements of Operations

(in thousands, except share and per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Expenses:				
Research and development expenses	\$ 5,914	\$ 4,614	\$ 14,555	\$ 12,643
General and administrative expenses	2,617	2,313	6,701	6,426
Total expenses	8,531	6,927	21,256	19,069
Loss from operations	(8,531)	(6,927)	(21,256)	(19,069)
Other income, net	27	13	94	46
Gain on change in fair value of warrant liability	—	—	—	8,163
Net loss	<u>\$ (8,504)</u>	<u>\$ (6,914)</u>	<u>\$ (21,162)</u>	<u>\$ (10,860)</u>
Net loss per share — basic and diluted	<u>\$ (0.53)</u>	<u>\$ (0.49)</u>	<u>\$ (1.32)</u>	<u>\$ (0.77)</u>
Weighted average shares outstanding:				
Basic and diluted	<u>16,115,835</u>	<u>14,189,226</u>	<u>16,059,383</u>	<u>14,172,177</u>

Investors:

Argot Partners

Kimberly Minarovich or Sam Martin

212-600-1902

or

Media:

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