

**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, 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 May 15, 2017, GTx, Inc. issued its financial press release for the first quarter ended March 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 May 15, 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: May 15, 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
First Quarter 2017 Financial Results**

- *Company expects to report topline results from its Phase 2 clinical trial of enobosarm to treat Stress Urinary Incontinence (SUI) in the third quarter of 2017 —*
- *Abstract on preliminary results from the Phase 2 SUI clinical trial has been accepted for a podium presentation at the International Continence Society Annual Meeting —*
- *Results published in Human Molecular Genetics demonstrate SARMs' ability to increase body weight, lean mass and physical function in preclinical models of Duchenne Muscular Dystrophy —*
- *Company continues to advance its SARD preclinical program to begin first in human clinical study in men with castration-resistant prostate cancer —*

MEMPHIS, Tenn. — May 15, 2017 — GTx, Inc. (Nasdaq: GTXI) today reported financial results for the first quarter of 2017, and highlighted recent accomplishments and upcoming milestones. The Company has two ongoing clinical trials of enobosarm (GTx-024) as a potential treatment in women with advanced breast cancer and one ongoing trial with enobosarm as a potential treatment for stress urinary incontinence (SUI) in postmenopausal women. The Company is also completing preclinical studies in its Selective Androgen Receptor Degradator (SARD) program that are required prior to initiating a clinical trial in men with castration-resistant prostate cancer (CRPC), which is planned for the first half of 2018.

“We look forward to several important data milestones during this year. This includes top-line results which we expect to announce in the third quarter of this year from an ongoing Phase 2 trial of enobosarm in women with advanced, ER+, AR+ breast cancer and from our clinical trial to treat postmenopausal women with SUI. We also continue to generate interest in the SARD program, which is focused on developing a novel treatment for advanced prostate cancer.” said Robert J. Wills, Ph.D., Executive Chairman of GTx.

Corporate Highlights and Anticipated Milestones

Enobosarm in Breast Cancer: *The Company's lead product candidate, enobosarm, a selective androgen receptor modulator (SARM), is being developed as a targeted treatment for two advanced breast cancer indications: (i) estrogen receptor positive (ER+) and androgen receptor positive (AR+) breast cancer, and (ii) AR+ triple negative breast cancer (TNBC). For both clinical trials, the primary efficacy endpoint is a determination of clinical benefit (CB), which is defined as a complete response, partial response or stable disease.*

ER+/AR+ breast cancer: The Company has an ongoing open-label, multi-center Phase 2 clinical trial of enobosarm in women with advanced, ER+, AR+ breast cancer. Patients receive orally-administered enobosarm (9 mg or 18 mg) daily for up to 24 months. The two dose cohorts in the trial are being treated independently for the purpose of assessing efficacy. The study is fully enrolled and the Company expects to report top-line results from this study in the third quarter of 2017.

AR+ TNBC: The Company also has an ongoing open-label, multi-center Phase 2 clinical trial to evaluate the efficacy and safety of an orally-administered 18 mg dose of enobosarm in up to 55 women with advanced, AR+ TNBC. The primary efficacy objective of the trial is CB response following 16 weeks of treatment in 41 evaluable patients. The Company expects to have sufficient data from Stage 1 of the trial later this quarter to determine if patient enrollment should continue into Stage 2 of the trial.

SARMs in Non-Oncologic Indications: *The Company also is developing SARMs as potential treatments for both stress urinary incontinence (SUI) in postmenopausal women and Duchenne muscular dystrophy (DMD), a rare disease characterized by progressive muscle degeneration and weakness.*

Stress Urinary Incontinence: Earlier this year, the Company announced it has added additional clinical sites to its ongoing Phase 2 proof-of-concept clinical trial of 3 mg of enobosarm in postmenopausal women with SUI. These sites are now enrolling patients, and the Company expects to announce top-line results from this trial in the third quarter of 2017.

- An abstract on preliminary data from the ongoing Phase 2 clinical trial has been accepted for podium presentation at the annual meeting of the International Continence Society in Florence, Italy on September 13, 2017. The principal investigator, Dr. Kenneth Peters, will present these encouraging data from the first cohort of patients enrolled in the study.

Duchenne muscular dystrophy: Utilizing data developed from its preclinical development efforts, 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.

- Results from preclinical studies to support the potential efficacy of the SARM GTx-026, GTx-027 and enobosarm for DMD treatment were published in the journal Human Molecular Genetics; GTx SARMs increased body weight, lean mass and physical function in preclinical models of DMD.

SARDs in Prostate Cancer: *The Company's Selective Androgen Receptor Degradator (SARD) technology is being evaluated as a potentially novel treatment for men with castration-resistant prostate cancer (CRPC), including those who do not respond or are resistant to currently*

approved therapies. The Company believes that its SARD compounds will degrade multiple forms of the androgen receptor, including AR splice variants, such as AR-V7, along with mutant versions of the receptor.

Castration-Resistant Prostate Cancer: The Company has screened compounds from its extensive patented SARD portfolio and has now selected lead compounds that are undergoing further preclinical studies including toxicology studies required for a first in human clinical trial which is planned during

the first half of 2018. Preclinical SARD data recently were presented at the following medical meetings:

- The discovery and early mechanistic evaluation studies were presented at the Endocrine Society's annual meeting, ENDO 2017.
- Data on the effect of SARDs on enzalutamide-resistant prostate cancer were presented at the annual meeting of the European Association of Urology.
- Data confirming N-terminal domain binding and efficacy, in preclinical models of AR-SV-expressing castration-resistant prostate cancer, was presented this week at the American Urological Association Meeting, 2017, in Boston. N-terminal binding facilitates inhibition of androgen-mediated cancer proliferation in both native and mutant receptors.

First Quarter 2017 Financial Results

- As of March 31, 2017, cash and short-term investments were \$16.5 million compared to \$21.9 million at December 31, 2016.
- Research and development expenses for the quarter ended March 31, 2017 were \$4.2 million compared to \$4.0 million for the same period of 2016.
- General and administrative expenses were \$2.1 million for both the quarter ended March 31, 2017 and March 31, 2016.
- The Company recognized a non-cash gain of \$8.2 million for the quarter ended March 31, 2016 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 subsequent to the first quarter of 2016.
- Net loss for the quarter ended March 31, 2017 was \$6.3 million compared to net income of \$2.1 million for the same period in 2016. Net income for the quarter ended March 31, 2016 included the non-cash gain of \$8.2 million related to the revaluation of the Company's warrant liability.
- GTx had approximately 16.0 million shares of common stock outstanding as of March 31, 2017. Additionally, there remain warrants outstanding to purchase approximately 6.4 million shares of GTx common stock at an exercise price of \$8.50 per share.

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 the enrollment and conduct of GTx's ongoing Phase 2 proof-of-concept clinical trial of enobosarm (GTx-024) to treat stress urinary incontinence (SUI) and its Phase 2 clinical trials of enobosarm for the treatment of advanced breast cancer, as well as the potential preclinical and other future development of GTx's licensed SARD technology and the development of selective androgen receptor modulators (SARMs) for the treatment of Duchenne muscular dystrophy (DMD) and the timing thereof, including the identification of lead SARD clinical candidates and the potential evaluation thereof for the initiation of a first-in-man clinical study; 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 advanced breast cancer or for the treatment of SUI or if GTx does determine to move forward with meaningful development of its SARD program or a SARM for the treatment of DMD, 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 or a SARM for the treatment of DMD to advance into clinical studies or the clinical product candidate may fail such clinical studies; (iv) that the clinical trials of enobosarm to treat advanced breast cancer or 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, 2016, 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.
Condensed Balance Sheets
(in thousands, except share data)

	March 31, 2017 (unaudited)	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 7,771	\$ 8,910
Short-term investments	8,740	12,959
Prepaid expenses and other current assets	2,240	2,429
Total current assets	18,751	24,298
Property and equipment, net	73	81
Intangible assets, net	119	123
Total assets	<u>\$ 18,943</u>	<u>\$ 24,502</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 514	\$ 1,220
Accrued expenses and other current liabilities	4,243	3,391
Total current liabilities	4,757	4,611
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 60,000,000 shares authorized at March 31, 2017 and December 31, 2016; 16,041,923 and 15,919,572 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	16	16
Additional paid-in capital	551,621	551,073
Accumulated deficit	(537,451)	(531,198)
Total stockholders' equity	14,186	19,891
Total liabilities and stockholders' equity	<u>\$ 18,943</u>	<u>\$ 24,502</u>

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

	Three Months Ended March 31,	
	2017	2016
Expenses:		
Research and development expenses	\$ 4,193	\$ 3,971
General and administrative expenses	2,087	2,114
Total expenses	6,280	6,085
Loss from operations	(6,280)	(6,085)
Other income, net	27	28
Gain on change in fair value of warrant liability	—	8,163
Net income (loss)	<u>\$ (6,253)</u>	<u>\$ 2,106</u>
Net income (loss) per share — basic and diluted	<u>\$ (0.39)</u>	<u>\$ 0.15</u>
Weighted average shares outstanding:		
Basic	16,018,342	14,152,204
Diluted	<u>16,018,342</u>	<u>14,344,816</u>