

**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 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))

ITEM 2.02 Results of Operations and Financial Condition.

On March 15, 2017, GTx, Inc. issued its financial press release for the fourth quarter and year ended December 31, 2016, 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.*

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release issued by GTx, Inc. dated March 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: March 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
Fourth Quarter and Year-End 2016 Financial Results**

— *Enobosarm demonstrated clinical benefit and met the primary efficacy endpoint for the 9 mg dose cohort in GTx's ongoing ER+/AR+ Phase 2 breast cancer trial* —

— *Company expects to report preliminary results from its Phase 2 clinical trial of enobosarm to treat Stress Urinary Incontinence (SUI) in the third quarter of 2017* —

— *Company expects to begin an initial clinical study of a Selective Androgen Receptor Degradator (SARD) in men with castration-resistant prostate cancer in the second half of 2017* —

MEMPHIS, Tenn. — March 15, 2017 — GTx, Inc. (Nasdaq: GTXI) today reported financial results for the fourth quarter and year ended December 31, 2016, and highlighted recent accomplishments and upcoming milestones. The Company has two ongoing clinical trials of enobosarm (GTx-024) 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 has identified lead compounds from its selective androgen receptor degrader (SARD) portfolio and has preclinical studies underway that are required prior to initiating a clinical trial in men with castration-resistant prostate cancer (CRPC) during the second half of 2017.

“In 2016, we broadened our clinical development efforts for enobosarm beyond breast cancer with the initiation of our clinical trial in SUI in postmenopausal women. Early results in this study are very promising, and we have added additional clinical sites and expect to receive top-line results from this trial in the third quarter. Later this year, we also expect to initiate a first in human clinical trial of a SARD in men with advanced prostate cancer,” said Robert J. Wills, Ph.D., Executive Chairman of GTx. “There is a great deal of interest in our SARD program based on data we have generated that demonstrate our SARD compounds degrade and inhibit multiple forms of the androgen receptor, including AR splice variants, and may therefore potentially treat CRPC in men who are non-responsive to current androgen therapy.”

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 first stage of evaluation was assessed among the first 18 evaluable patients for each cohort. At least 3 of 18 patients per cohort achieved CB at week 24, and the trial has proceeded to the second stage of enrollment. In Stage 2, if at least 9 of 44 evaluable patients achieve CB at week 24, the trial will have successfully demonstrated its primary endpoint, and those patients achieving CB at 24 weeks will be able to continue treatment for a total of up to 24 months. The two dose cohorts in the trial are being treated independently for the purpose of assessing efficacy. To date, in this ongoing clinical trial:

- CB has been demonstrated in both the 9 mg and 18 mg dose cohorts in Stage 1 of the trial, allowing both cohorts to advance to Stage 2 of the trial.
- A sufficient number of evaluable patients have already demonstrated CB at week 24 in the 9 mg dose group for the study to achieve the pre-specified primary efficacy endpoint in this ongoing clinical trial. Of the 40 patients in the 9 mg dose cohort whose AR status has been confirmed AR+, 10 patients have demonstrated CB at week 24, 23 patients have discontinued either at or prior to week 24, and 7 patients remain on study and have not yet reached week 24. There are another 5 patients who have been enrolled to the 9 mg cohort whose AR status has not yet been confirmed. Of the 10 evaluable patients achieving CB, 2 had a partial response and 8 had stable disease. The majority of adverse events are grade 1 and 2, and the most common adverse events reported (occurring in $\geq 10\%$ of patients) include nausea (31%), fatigue (18%), and arthralgias (13%). Elevations in transaminases (ALT and AST) during enobosarm treatment were mild with the majority being grade 1 or 2.

An abstract submitted by Dr. Beth Overmoyer, the lead principal investigator for the clinical trial and a medical oncologist with the Dana-Farber Cancer Center Institute, detailing data from Stage 1 of the 9 mg cohort, has been accepted for the “poster walk” at the European Society for Medical Oncology IMPAKT Breast Cancer Conference, which is being held May 4-6, 2017, in Brussels, Belgium.

Enobosarm appears to be safe and generally well tolerated. The independent Safety Monitoring Committee met in December 2016, and recommended that the clinical trial continue as planned. The trial will continue with a daily dose of either enobosarm 9 mg or 18 mg until 44 evaluable patients in each cohort have completed treatment in order to better characterize the CB response. 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 orally-administered enobosarm in up to 55 women with advanced, AR+ TNBC. Patients receive 18 mg of enobosarm once daily for up to 12 months. Stage 1 of the trial is being assessed among the first 21 evaluable patients, and if at least 2 of

21 patients achieve CB at week 16, then the trial can proceed to Stage 2 of enrollment of up to a total of 41 evaluable patients. 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 by the second quarter of 2017 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: Enrollment continues in the Company's ongoing Phase 2 proof-of-concept clinical trial of 3 mg of enobosarm in postmenopausal women with SUI. The Company expects to have top-line results from the trial in the third quarter of 2017.

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.

SARDs in Prostate Cancer: *the Company's selective androgen receptor degrader (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 dozens of compounds from its extensive patented SARD portfolio and has now selected lead compounds that are undergoing further preclinical studies required for a first in human clinical trial, including toxicology studies. It is anticipated that a first in human clinical trial of a SARD will be initiated during the second half of 2017.

The preclinical studies supporting the SARD program have been accepted for presentation and received recognition of merit at several upcoming international meetings, including the Endocrine Society's annual meeting, ENDO 2017, from April 1-4, 2017, and the annual meeting of the European Association of Urology being held from March 24-28, 2017.

Fourth Quarter and Year-End 2016 Financial Results

- As of December 31, 2016, cash and short-term investments were \$21.9 million compared to \$29.3 million at December 31, 2015.
- Research and development expenses for the quarter ended December 31, 2016 were \$4.6 million compared to \$3.9 million for the same period of 2015. Research and development expenses for the year ended December 31, 2016 were \$17.2 million compared to \$13.6 million for the year ended December 31, 2015.
- General and administrative expenses for the quarter ended December 31, 2016 were \$2.3 million compared to \$2.1 million for the same period of 2015. General and administrative expenses for the year ended December 31, 2016 were \$8.7 million compared to \$8.2 million for the year ended December 31, 2015.
- The net loss for the quarter ended December 31, 2016 was \$6.9 million compared to a net loss of \$3.2 million for the same period in 2015. The net loss for the quarter ended December 31, 2015 included a non-cash gain of \$2.7 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 subsequent to the first quarter of 2016.
- The net loss for the year ended December 31, 2016 was \$17.7 million compared to a net loss of \$18.7 million for the year ended December 31, 2015. The net loss for the years ended December 31, 2016 and December 31, 2015 included a non-cash gain of \$8.2 million and \$3.1 million, respectively, related to the change in the fair value of the Company's warrant liability.
- GTx had approximately 15.9 million shares of common stock outstanding as of December 31, 2016. 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 quarterly report on Form 10-Q for the period ending September 30, 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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Source: GTx, Inc.

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

	December 31,	
	2016 (unaudited)	2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 8,910	\$ 14,056
Short-term investments	12,959	15,200
Prepaid expenses and other current assets	2,429	2,633
Total current assets	24,298	31,889
Property and equipment, net	81	5
Intangible assets, net	123	137
Total assets	<u>\$ 24,502</u>	<u>\$ 32,031</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,220	\$ 382
Warrant liability	—	27,349
Accrued expenses and other current liabilities	3,391	2,441
Total current liabilities	4,611	30,172
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 60,000,000 and 400,000,000 shares authorized at December 31, 2016 and December 31, 2015, respectively; 15,919,572 and 14,037,411 shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively	16	14
Additional paid-in capital	551,073	515,319
Accumulated deficit	(531,198)	(513,474)
Total stockholders' equity	19,891	1,859
Total liabilities and stockholders' equity	<u>\$ 24,502</u>	<u>\$ 32,031</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,	
	2016	2015	2016	2015
Expenses:				
Research and development expenses	\$ 4,585	\$ 3,879	\$ 17,228	\$ 13,607
General and administrative expenses	2,279	2,079	8,705	8,234
Total expenses	6,864	5,958	25,933	21,841
Loss from operations	(6,864)	(5,958)	(25,933)	(21,841)
Other (expense) income, net	—	(4)	46	57
Gain on change in fair value of warrant liability	—	2,729	8,163	3,081
Net loss	<u>\$ (6,864)</u>	<u>\$ (3,233)</u>	<u>\$ (17,724)</u>	<u>\$ (18,703)</u>

Net loss per share:

Basic	<u>\$ (0.44)</u>	<u>\$ (0.23)</u>	<u>\$ (1.22)</u>	<u>\$ (1.33)</u>
Diluted	<u>\$ (0.44)</u>	<u>\$ (0.40)</u>	<u>\$ (1.22)</u>	<u>\$ (1.47)</u>

Weighted average shares outstanding:

Basic	<u>15,713,210</u>	<u>14,037,411</u>	<u>14,559,541</u>	<u>14,036,468</u>
Diluted	<u>15,713,210</u>	<u>14,952,920</u>	<u>14,559,541</u>	<u>14,777,404</u>
