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 10, 2016**

GTx, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**000-50549**	**62-1715807**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

175 Toyota Plaza 7th Floor Memphis, Tennessee	**38103**
(Address of Principal Executive Offices)	(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 May 10, 2016, GTx, Inc. issued its financial press release for the first quarter ended March 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*.

Exhibit Number	**Description**
99.1	Press Release issued by GTx, Inc. dated May 10, 2016

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 10, 2016

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 2016 Financial Results

MEMPHIS, Tenn. — May. 10, 2016 — GTx, Inc. (Nasdaq: GTXI) today reported financial results for the first quarter ended March 31, 2016, and highlighted recent accomplishments and upcoming milestones. The Company is currently enrolling patients in three clinical trials: two trials evaluating enobosarm as a potential treatment for women with advanced breast cancer and another assessing enobosarm as a potential treatment for stress urinary incontinence in postmenopausal women.

“During the first quarter, we executed on several ongoing initiatives that we expect will make 2016 a year of considerable progress,” said Dr. Robert J. Wills, Executive Chairman of GTx. “We have continued to make progress in the enrollment of our two advanced breast cancer clinical trials of enobosarm, with preliminary data from the first stage of each study expected by the end of 2016. Also, we are excited to be collaborating with doctors on a clinical trial that is the first clinical study to use a SARM to treat stress urinary incontinence in postmenopausal women and expect data from this study late in 2016.”

Corporate Highlights and Anticipated Milestones

Enobosarm in Breast Cancer: *The Company’s lead product candidate, 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 will be clinical benefit, which is defined as a complete response, partial response or stable disease.*

- **ER+/AR+ breast cancer:** We currently expect to complete enrollment in the first stage of the open-label, Phase 2 clinical trial of enobosarm in women with metastatic or locally advanced ER+/AR+ breast cancer in the second quarter of 2016, to allow us to determine during the fourth quarter of this year whether there is sufficient safety and efficacy data to warrant proceeding with the second stage of the clinical study. While the first stage of the trial will evaluate 18 patients for each of the two dosing arms, 9 mg and 18 mg of enobosarm, the trial is designed to enroll up to 118 patients to obtain data from 44 evaluable patients in each study arm (a total of 88 evaluable patients) to assess the primary efficacy objective of clinical benefit response following 24 weeks of treatment.

- **AR+ TNBC:** We currently expect to complete enrollment in the first stage of the open-label, proof-of-concept Phase 2 clinical trial of 18 mg of enobosarm in women with advanced AR+ TNBC in the third quarter of 2016, to allow us to determine by the end of 2016 whether there is sufficient safety and efficacy data to warrant proceeding with the second stage of the clinical study. While the first stage will

include 21 evaluable patients, the trial is designed to enroll up to 55 patients in total in order to obtain data from 41 evaluable patients to assess the primary efficacy objective of clinical benefit response following 16 weeks of treatment.

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

- **SUI:** We are currently enrolling patients in a Phase 2 proof-of-concept clinical trial of 3 mg of enobosarm to treat up to 35 postmenopausal women with SUI, the first clinical trial to evaluate a SARM for SUI. Top-line data from the Phase 2 clinical trial is anticipated by the end of 2016.

- **DMD:** The Company’s preclinical studies have continued to confirm beneficial effects from SARMs in mice genetically altered to simulate DMD, compared to control groups. The Company continues to advance its preclinical initiatives while pursuing a strategic collaboration with potential biopharma partners experienced in orphan drug development.

SARDs in Prostate Cancer: *Our 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.*

- **CRPC:** Several lead SARD compounds are currently being evaluated in preclinical studies to select the best SARD compounds for continued development, as well as to develop data necessary to initiate first in human clinical trials in 2017.

First Quarter 2016 Financial Results

- As of March 31, 2016, cash and short-term investments were $24.3 million compared to $29.3 million at December 31, 2015.

- Research and development expenses for the quarter ended March 31, 2016 were $4.0 million compared to $2.9 million for the same period of 2015.

- General and administrative expenses were $2.1 million for both the quarter ended March 31, 2016 and March 31, 2015.

- The Company recognized a non-cash gain of $8.2 million and $2.6 million for the quarter ended March 31, 2016 and 2015, respectively, due to the change in fair value of the Company’s warrant liability. During the first quarter of 2016, the

Company recorded a non-cash reclassification of this warrant liability to stockholders’ equity due to the modification of these warrants. No adjustments to the fair value of these warrants will be made in the future.

- Net income for the quarter ended March 31, 2016 was $2.1 million compared to a net loss of $2.4 million for the same period in 2015. Net income for the quarter ended March 31, 2016 included the non-cash gain of $8.2 million related the revaluation of our warrant liability. The net loss for the quarter

ended March 31, 2015 included a non-cash gain of $2.6 million related to the change in the fair value of the Company's warrant liability.

· GTx had approximately 141.7 million shares of common stock outstanding as of March 31, 2016. Additionally, there remain warrants outstanding to purchase approximately 64.3 million shares of GTx common stock at an exercise price of $0.85 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 anticipated identification of clinical SARD candidates and the potential evaluation thereof in clinical studies; 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 the 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 ended December 31, 2015 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)

	March 31, 2016 (unaudited)	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,063	$ 14,056
Short-term investments	12,200	15,200
Prepaid expenses and other current assets	2,295	2,633
Total current assets	26,558	31,889
Property and equipment, net	12	5
Intangible assets, net	134	137
Total assets	$ 26,704	$ 32,031
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 903	$ 382
Warrant liability	—	27,349

Accrued expenses and other current liabilities	2,116	2,441
Total current liabilities	3,019	30,172
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value: 400,000,000 shares authorized at March 31, 2016 and December 31, 2015; 141,749,150 and 140,374,112 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	142	141
Additional paid-in capital	534,911	515,192
Accumulated deficit	(511,368)	(513,474)
Total stockholders' equity	23,685	1,859
Total liabilities and stockholders' equity	$ 26,704	$ 32,031

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

	Three Months Ended March 31,	
	2016	2015
Expenses:		
Research and development expenses	$ 3,971	$ 2,948
General and administrative expenses	2,114	2,111
Total expenses	6,085	5,059
Loss from operations	(6,085)	(5,059)
Other income, net	28	27
Gain on change in fair value of warrant liability	8,163	2,648
Net income (loss)	$ 2,106	$ (2,384)
Net income (loss) per share — basic and diluted	$ 0.01	$ (0.02)
Weighted average shares outstanding:		
Basic	141,522,043	140,335,875
Diluted	143,448,168	140,335,875