

**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 3, 2016**

**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))

ITEM 2.02 Results of Operations and Financial Condition.

On November 3, 2016, GTx, Inc. issued its financial press release for the third quarter ended September 30, 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**  
99.1

**Description**  
Press Release issued by GTx, Inc. dated November 3, 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: November 3, 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 Third Quarter 2016 Financial Results

— Announced achievement of Stage 1 milestone in Phase 2 clinical trial of enobosarm in ER+/AR+ breast cancer —

— Company raised \$14 million in a registered direct offering of its common stock —

MEMPHIS, Tenn. — November 3, 2016 — GTx, Inc. (Nasdaq: GTXI) today reported financial results for the third quarter ended September 30, 2016 and provided an update on the Company's clinical development activities. The Company has three ongoing Phase 2 clinical trials: two trials evaluating enobosarm as a potential treatment for women with advanced androgen receptor positive breast cancer and another trial assessing enobosarm as a potential treatment for stress urinary incontinence in postmenopausal women.

"We made excellent progress during the quarter, including demonstrating clinical benefit in Stage 1 of the 9 mg dose group which enabled us to advance this dose group to the second and final stage of the ER+/AR+ breast cancer trial," said Robert J. Wills, Ph.D., Executive Chairman of GTx. "In addition we are pleased with the continued financial support of key existing investors who participated in our equity offering last month which enables us to continue to pursue key milestones in the coming months for our breast cancer and stress urinary incontinence programs, as well as our SARD technology."

### 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 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 Phase 2 clinical trial of enobosarm (GTx-024) 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 will be assessed among the first 18 evaluable patients for each cohort. If at least 3 of 18 patients per cohort achieve CB at week 24, the trial will proceed to the second stage of enrollment. The primary efficacy objective of the trial is clinical benefit response following 24 weeks of treatment, which, under the clinical trial protocol, will be demonstrated if at least 9 of 44 evaluable patients achieve CB. Those patients demonstrating CB at week 24 will continue to

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receive treatment for up to 24 months. The two dose cohorts in the trial will be treated independently for the purpose of assessing efficacy.

- The Company announced in September 2016 that the 9 mg dose group demonstrated clinical benefit in Stage 1 of the trial allowing the 9 mg cohort to advance to Stage 2;
- The Company expects to announce top-line results from Stage 1 of the 9 mg cohort before the end of 2016.

**AR+ TNBC:** The Company has an ongoing open-label, multi-center, multinational Phase 2 clinical trial to evaluate the efficacy and safety of orally administered enobosarm in up to 55 women with advanced, AR+ TNBC. Patients will receive 18 mg of enobosarm once daily for up to 12 months. Stage 1 of the trial will be assessed among the first 21 evaluable patients. If at least 2 of 21 patients achieve clinical benefit at week 16, then the trial will proceed to Stage 2 of enrollment of up to a total of 41 evaluable patients. The primary efficacy objective of the trial is clinical benefit response following 16 weeks of treatment in 41 evaluable patients.

- The Company expects to have sufficient data from Stage 1 of the trial in the first quarter of 2017 to determine if patient enrollment should continue into Stage 2 of the trial.

**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.*

**Stress Urinary Incontinence:** Enrollment in the Phase 2 proof-of-concept clinical trial of 3 mg of enobosarm in women with SUI is ongoing. This is the first clinical trial to evaluate a SARM for SUI. The Company believes that developing an oral therapy to treat the growing number of women who suffer a diminished quality of life from stress urinary incontinence presents a unique commercial opportunity, especially since current therapies may sometimes involve invasive procedures. The Company expects to have data from the trial during the first half of 2017.

**Duchenne muscular dystrophy:** Preclinical studies have confirmed the beneficial effects from SARMs in mice genetically altered to simulate DMD, compared to control groups. The Company continues to pursue a potential strategic collaboration with biopharma companies experienced in orphan drug development.

**SARDs in Prostate Cancer:** *Our 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*

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*androgen receptor, including AR splice variants, such as AR-V7, along with mutant versions of the receptor.*

**Castration-Resistant Prostate Cancer:** Lead SARD compounds are undergoing further preclinical development, including formulation and pharmacokinetic studies. The Company plans to initiate its first human clinical trial with a SARD in 2017.

### Third Quarter and Nine Months 2016 Financial Results

- In October 2016, the Company completed a registered direct offering of its common stock resulting in net proceeds of approximately \$13.6 million. Under the terms of the offering, the Company sold 17.3 million shares of its common stock at a purchase price of \$0.81 per share, which was the consolidated closing bid price of the Company's common stock on October 11, 2016. The investors in the offering consisted of certain existing shareholders of the Company, including J.R. Hyde, III, its largest shareholder and Lead Director of the Company's Board of Directors (the "Board"), Robert J. Wills, the Board's Executive Chairman, and Marc S. Hanover, the Company's Chief Executive Officer and a member of the Board.
- As of September 30, 2016, cash and short-term investments were \$13.4 million, which does not include the proceeds noted above from our recent equity financing, compared to \$29.3 million at December 31, 2015.
- Research and development expenses for the quarter ended September 30, 2016 were \$4.6 million compared to \$3.8 million for the same period of 2015.
- General and administrative expenses were \$2.3 million for the quarter ended September 30, 2016 compared to \$2.0 million for the same period of 2015.
- The net loss for the quarter ended September 30, 2016 was \$6.9 million compared to net income of \$34.9 million for the same period in 2015. Net income for the quarter ended September 30, 2015 included a non-cash gain of \$40.7 million due to the change in the 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 modification of these warrants. No adjustments to the fair value of these warrants are required subsequent to the first quarter of 2016.
- The net loss for the nine months ended September 30, 2016 was \$10.9 million compared to a net loss of \$15.5 million for the same period of 2015. The nine months ended September 30, 2016 included a non-cash gain of \$8.2 million due to the change in the fair value of the Company's warrant liability, recorded during the first quarter of 2016. The nine months

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ended September 30, 2015 included a non-cash gain of \$352,000 due to the change in fair value of the Company's warrant liability.

- GTx had approximately 141.9 million shares of common stock outstanding as of September 30, 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*

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*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 June 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.*

### GTx Contacts

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Source: GTx, Inc.

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

	September 30, 2016 (unaudited)	December 31, 2015
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 8,238	\$ 14,056
Short-term investments	5,200	15,200
Prepaid expenses and other current assets	2,096	2,633
Total current assets	15,534	31,889
Property and equipment, net	89	5
Intangible assets, net	126	137
Total assets	<u>\$ 15,749</u>	<u>\$ 32,031</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,223	\$ 382
Warrant liability	—	27,349
Accrued expenses and other current liabilities	2,141	2,441
Total current liabilities	3,364	30,172
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 400,000,000 shares authorized at September 30, 2016 and December 31, 2015; 141,915,817 and 140,374,112 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	142	141
Additional paid-in capital	536,577	515,192
Accumulated deficit	(524,334)	(513,474)
Total stockholders' equity	12,385	1,859
Total liabilities and stockholders' equity	<u>\$ 15,749</u>	<u>\$ 32,031</u>

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**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,	
	2016	2015	2016	2015
<b>Expenses:</b>				
Research and development expenses	\$ 4,614	\$ 3,824	\$ 12,643	\$ 9,728
General and administrative expenses	2,313	2,039	6,426	6,155
Total expenses	6,927	5,863	19,069	15,883
Loss from operations	(6,927)	(5,863)	(19,069)	(15,883)
Other income, net	13	9	46	61
Gain on change in fair value of warrant liability	—	40,720	8,163	352
Net income (loss)	<u>\$ (6,914)</u>	<u>\$ 34,866</u>	<u>\$ (10,860)</u>	<u>\$ (15,470)</u>
Net income (loss) per share:				
Basic	<u>\$ (0.05)</u>	<u>\$ 0.25</u>	<u>\$ (0.08)</u>	<u>\$ (0.11)</u>
Diluted	<u>\$ (0.05)</u>	<u>\$ (0.04)</u>	<u>\$ (0.08)</u>	<u>\$ (0.11)</u>
Weighted average shares outstanding:				
Basic	<u>141,892,266</u>	<u>140,374,112</u>	<u>141,721,778</u>	<u>140,361,507</u>
Diluted	<u>141,892,266</u>	<u>154,852,127</u>	<u>141,721,778</u>	<u>140,361,507</u>

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