

**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 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
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 3, 2016, GTx, Inc. issued its financial press release for the fourth quarter and year ended December 31, 2015, 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 March 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: March 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 Fourth Quarter and Year-End 2015 Financial Results

— Patient enrollment underway in two Phase 2 clinical trials of enobosarm for the treatment of advanced breast cancer; preliminary data from first stage of both trials expected by end of 2016 —

— Lead SARD candidates have been selected for additional preclinical studies necessary to initiate first in human clinical trials —

— Patient enrollment underway in Phase 2 proof-of-concept clinical trial of enobosarm in women with Stress Urinary Incontinence; anticipate top-line data in 2016 —

— Conference call today at 9:00 a.m. Eastern Time —

MEMPHIS, Tenn. — Mar. 3, 2016 — GTx, Inc. (Nasdaq: GTXI) today reported financial results for the fourth quarter and year ended December 31, 2015, 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.

“In 2015, we continued to make important progress across our pipeline assets, and while our primary focus continues to be the development of enobosarm to potentially treat advanced breast cancer and our SARD technology, we have diversified our therapeutic opportunities to include SARMs for stress urinary incontinence and Duchenne muscular dystrophy,” said Dr. Robert J. Wills, Executive Chairman of GTx.

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: currently expect to enroll the first stage of the open-label, Phase 2 clinical trial of enobosarm in women with metastatic or locally advanced, ER+/AR+ breast cancer by mid-year in order to report preliminary results by the end of 2016. 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: currently expect to enroll 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 by mid-year in order to report preliminary results by the end of 2016. 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: enrolled first patient 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.
 - DMD mice were treated with one of three different SARM compounds, including enobosarm, and each SARM cohort demonstrated increases in body weight, muscle mass, muscle performance (grip strength) and cardiac function, compared to control groups;
 - Histologically, in SARM-treated mice, skeletal muscles demonstrated a reduction in necrosis, fibrosis, and centrally nucleated cells, which are accepted markers of skeletal muscle atrophy; and
 - A SARM also markedly reduced the fibrosis of cardiac muscle, which is relevant since most DMD patients will develop cardiomyopathy as the disease progresses.

SARDs in Prostate Cancer: *Selective Androgen Receptor Degradation (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: lead SARD compounds are currently being evaluated in additional 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.

Fourth Quarter and Year-End 2015 Financial Results

- As of December 31, 2015, cash and short-term investments were \$29.3 million compared to \$49.3 million at December 31, 2014.

- Research and development expenses for the quarter ended December 31, 2015 were \$3.9 million compared to \$3.3 million for the same period of 2014. Research and development expenses for the year ended December 31, 2015 were \$13.6 million compared to \$20.9 million for the year ended December 31, 2014.
- General and administrative expenses for the quarter ended December 31, 2015 were \$2.1 million compared to \$2.2 million for the same period of 2014. General and administrative expenses for the year ended December 31, 2015 were \$8.2 million compared to \$9.5 million for the year ended December 31, 2014.
- The net loss for the quarter ended December 31, 2015 was \$3.2 million compared to a net loss of \$14.5 million for the same period in 2014. The net loss for the quarters ended December 31, 2015 and December 31, 2014 included a non-cash gain of \$2.7 million and a non-cash loss of \$8.8 million, respectively, related to the change in the fair value of the Company's warrant liability. The net loss for the year ended December 31, 2015 was \$18.7 million compared to a net loss of \$39.4 million for the year ended December 31, 2014. The net loss for the years ended December 31, 2015 and December 31, 2014 included a non-cash gain of \$3.1 million and a non-cash loss of \$8.8 million, respectively, related to the change in the fair value of the Company's warrant liability.
- GTx had approximately 140.4 million shares of common stock outstanding as of December 31, 2015. 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.

Conference Call and Webcast

There will be a conference call today at 9:00 a.m. Eastern Standard Time. To listen to the conference call, please dial 877-930-8288 from the United States or Canada or 253-336-8703 from other international locations. The access code for the call is 35776523. A playback of the call will be available from approximately 12:00 p.m. Eastern Standard Time today through March 10, 2016 and may be accessed by dialing 855-859-2056 from the United States or Canada or 800-585-8367 from other international locations and referencing reservation number 35776523. Additionally, you may access the live and subsequently archived webcast of the conference call from the Investor Relations section of the Company's website at <http://www.gtxinc.com>.

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; 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 quarterly report on Form 10-Q for the quarter ended September 30, 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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GTx, Inc.
Condensed Balance Sheets
(in thousands, except share data)

	December 31,	
	2015 (unaudited)	2014
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 14,056	\$ 17,880
Short-term investments	15,200	31,415
Prepaid expenses and other current assets	2,633	856
Total current assets	31,889	50,151
Property and equipment, net	5	29
Intangible and other assets, net	137	471
Total assets	<u>\$ 32,031</u>	<u>\$ 50,651</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 382	\$ 512
Warrant liability	27,349	30,430
Accrued expenses and other current liabilities	2,441	1,850
Total current liabilities	30,172	32,792
Other long-term liabilities	—	30
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 400,000,000 and 200,000,000 shares authorized at December 31, 2015 and December 31, 2014, respectively; 140,374,112 and 140,325,643 shares issued and outstanding at December 31, 2015 and December 31, 2014, respectively	141	140
Additional paid-in capital	515,192	512,460
Accumulated deficit	(513,474)	(494,771)
Total stockholders' equity	1,859	17,829
Total liabilities and stockholders' equity	<u>\$ 32,031</u>	<u>\$ 50,651</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,	
	2015	2014	2015	2014
Expenses:				
Research and development expenses	\$ 3,879	\$ 3,254	\$ 13,607	\$ 20,870
General and administrative expenses	2,079	2,203	8,234	9,478
Total expenses	5,958	5,457	21,841	30,348
Loss from operations	(5,958)	(5,457)	(21,841)	(30,348)
Other (expense) income, net	(4)	(284)	57	(259)
Gain (loss) on change in fair value of warrant liability	2,729	(8,804)	3,081	(8,804)
Net loss	<u>\$ (3,233)</u>	<u>\$ (14,545)</u>	<u>\$ (18,703)</u>	<u>\$ (39,411)</u>
Net loss per share:				
Basic	<u>\$ (0.02)</u>	<u>\$ (0.13)</u>	<u>\$ (0.13)</u>	<u>\$ (0.48)</u>
Diluted	<u>\$ (0.04)</u>	<u>\$ (0.13)</u>	<u>\$ (0.15)</u>	<u>\$ (0.48)</u>
Weighted average shares outstanding:				
Basic	<u>140,374,112</u>	<u>108,869,121</u>	<u>140,364,684</u>	<u>81,807,706</u>
Diluted	<u>149,529,197</u>	<u>108,869,121</u>	<u>147,774,040</u>	<u>81,807,706</u>