
**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) **October 22, 2018**

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 October 22, 2018, GTX, Inc. issued its financial press release for the third quarter ended September 30, 2018, 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 October 22, 2018

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: October 22, 2018

GTx, Inc.

By: /s/ Henry P. Doggrell

Name: Henry P. Doggrell

Title: Vice President, Chief Legal Officer and Secretary



GTx Reports Third Quarter 2018 Financial Results and Provides Corporate Update

MEMPHIS, Tenn. — October 22, 2018 — GTx, Inc. (Nasdaq: GTXI) today reported financial results for the third quarter ended September 30, 2018, and provided a corporate update.

“During the quarter, we turned our focus to the ongoing selective androgen receptor degrader program and the potential of our novel selective androgen receptor degrader to treat castration-resistant prostate cancer. We expect to select the most appropriate development compounds by year-end, which we plan to take into IND-enabling studies next year,” said Robert J. Wills, Ph.D., Executive Chairman of GTx. “Additionally, we are exploring other strategic options for the company with the goal of optimizing the full potential of our development pipeline.”

Corporate Development Update

Selective Androgen Receptor Degradator (SARD): Prostate Cancer

The Company has an ongoing preclinical program to evaluate its novel selective androgen receptor degrader (SARD) technology in castration-resistant prostate cancer (CRPC). In some men with CRPC, current prostate cancer therapy is not effective or subject to emerging resistance. The Company believes that its SARDs may be first-in-class dual-interacting androgen receptor (AR) antagonists and degraders, and may therefore potentially treat CRPC in men who are non-responsive to current androgen targeted therapies. Going forward, the Company plans to:

- Complete ongoing mechanistic preclinical studies by year-end or early in the first quarter of 2019;
- Select the most appropriate SARD compounds to move forward with IND-enabling studies in 2019; and
- Potentially advance one of its SARD compounds into a first-in-human clinical trial in 2020

Selective Androgen Receptor Modulator (SARM): Stress Urinary Incontinence (SUI), Breast Cancer

SUI: Enobosarm, a SARM, was evaluated in post-menopausal women with SUI compared to placebo. During the quarter, the Company announced that the ASTRID Trial, a Phase 2 double-blind, placebo-controlled clinical trial of orally-administered enobosarm (3 mg or 1 mg) in post-menopausal women with SUI, did not achieve statistical significance on the primary endpoint

for the trial. Enobosarm was generally safe and well tolerated, and reported adverse events were minimal and similar across all treatment groups. The Company is conducting a comprehensive review of all the ASTRID data and is consulting with key experts to fully understand the study outcomes.

Advanced Breast Cancer: Enobosarm was also evaluated as a hormonal therapy for women with estrogen receptor positive (ER+) and androgen receptor positive (AR+) breast cancer in a Phase 2 clinical trial. The trial met the primary efficacy endpoint in the trial; there are three women in the study who continue to respond to treatment after almost two years on enobosarm (two have stable disease, one now has a partial response). Approximately one year ago, the Company determined that treatment paradigms had shifted to immunotherapies and/or combination therapies, and that it was no longer feasible for GTx to conduct further development of enobosarm in breast cancer.

Enobosarm has been evaluated in more than two dozen clinical trials enrolling over 2,200 subjects, in which approximately 1,500 subjects were treated with enobosarm at doses ranging from 0.1 mg to 100 mg. At all evaluated dose levels, enobosarm was observed to be generally safe and well tolerated.

Third Quarter 2018 Financial Results

- As of September 30, 2018, cash and short-term investments were \$38.1 million compared to \$43.9 million at December 31, 2017.
 - Research and development expenses for the quarter ended September 30, 2018 were \$7.5 million compared to \$5.9 million for the same period of 2017.
 - General and administrative expenses for the quarter ended September 30, 2018 were \$2.2 million compared to \$2.6 million for the same period of 2017.
 - The net loss for the quarter ended September 30, 2018 was \$9.4 million compared to a net loss of \$8.5 million for the same period in 2017.
 - Net loss for the nine months ended September 30, 2018 was \$33.0 million compared to a net loss of \$21.2 million for the same period in 2017.
 - GTx had approximately 24.1 million shares of common stock outstanding as of September 30, 2018. Additionally, there are warrants outstanding to purchase approximately 5.3 million shares of GTx common stock at an exercise price of \$8.50 per share and approximately 3.3 million shares of GTx common stock at an exercise price of \$9.02.
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About GTx

GTx, Inc., headquartered in Memphis, Tenn., is a biopharmaceutical company dedicated to the discovery, development and commercialization of medicines to treat serious and/or significant unmet medical conditions, including prostate cancer.

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 GTx's ongoing preclinical development of its selective androgen receptor degrader (SARD) technology; GTx's plans to move forward with IND-enabling studies for its SARD technology and to potentially advance one of its SARD compounds into a first-in-human clinical trial, and the anticipated timing of such activities; statements related to the therapeutic potential of GTx's SARD technology, including to potentially treat CRPC in men who are non-responsive to current androgen targeted therapies; and statements related to optimizing the full potential of GTx's development pipeline. 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 the SARDs preclinical research being conducted and planned to be conducted by GTx may not be completed on schedule or at all; (ii) that additional preclinical development of GTx's SARD compound will be required beyond anticipated IND-enabling studies, whether to enable the submission of an IND application to the U.S. Food and Drug Administration or otherwise; (iii) that GTx's evaluation of its SARD technology is at an early stage and is subject to the substantial risk of failure inherent in the development of early-stage programs; (iv) that GTx's existing capital resources are insufficient to allow GTx to potentially advance a SARD compound into a first-in-human clinical trial and therefore any future clinical development of SARDs in prostate cancer, including any such first-in-human clinical trial, is contingent on GTx obtaining sufficient additional capital to permit such development, which it may be unable to do on acceptable terms, or at all; and (v) that GTx may be unable to preserve or realize any value from its SARD and SARM programs, whether through strategic transactions or alternatives or otherwise. In addition, GTx will otherwise need additional funding and may be unable to raise capital when needed, which would force GTx to delay, reduce or eliminate its development initiatives 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 ended June 30, 2018, 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.

Source: GTx, Inc.

GTx, Inc.

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

	September 30, 2018 (unaudited)	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 23,089	\$ 15,816
Short-term investments	14,984	28,083
Prepaid expenses and other current assets	2,071	2,178
Total current assets	40,144	46,077
Property and equipment, net	28	51
Intangible assets, net	97	108
Total assets	<u>\$ 40,269</u>	<u>\$ 46,236</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,121	\$ 2,604
Accrued expenses and other current liabilities	6,184	5,371
Total current liabilities	9,305	7,975
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 60,000,000 shares authorized at September 30, 2018 and December 31, 2017; 24,051,844 and 21,541,909 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	24	22
Additional paid-in capital	625,580	599,876
Accumulated deficit	(594,640)	(561,637)
Total stockholders' equity	30,964	38,261
Total liabilities and stockholders' equity	<u>\$ 40,269</u>	<u>\$ 46,236</u>

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,	
	2018	2017	2018	2017
Expenses:				
Research and development expenses	\$ 7,467	\$ 5,914	\$ 26,429	\$ 14,555
General and administrative expenses	2,160	2,617	7,044	6,701
Total expenses	<u>9,627</u>	<u>8,531</u>	<u>33,473</u>	<u>21,256</u>
Loss from operations	(9,627)	(8,531)	(33,473)	(21,256)
Other income, net	196	27	470	94
Net loss	<u>\$ (9,431)</u>	<u>\$ (8,504)</u>	<u>\$ (33,003)</u>	<u>\$ (21,162)</u>
Net loss per share — basic and diluted	<u>\$ (0.39)</u>	<u>\$ (0.53)</u>	<u>\$ (1.43)</u>	<u>\$ (1.32)</u>
Weighted average shares outstanding:				
Basic and diluted	<u>24,045,992</u>	<u>16,115,835</u>	<u>23,108,442</u>	<u>16,059,383</u>