

**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) **August 9, 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 August 9, 2016, GTx, Inc. issued its financial press release for the second quarter ended June 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 August 9, 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: August 9, 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 Second Quarter 2016 Financial Results

— *Enobosarm breast cancer clinical trials ongoing; plan to have preliminary data by end of 2016 to evaluate advancing to the second and final stage of both trials* —

— *Data from enobosarm clinical trial in post-menopausal women with SUI is expected in the first half of 2017* —

— *Lead SARD candidates have been selected and are undergoing preclinical testing required to commence first human clinical trial in 2017* —

MEMPHIS, Tenn. — August 9, 2016 — GTx, Inc. (Nasdaq: GTXI) today reported financial results for the second quarter ended June 30, 2016 and highlighted upcoming milestones. The Company is currently enrolling patients in three Phase 2 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.

“We have maintained considerable momentum in our lead enobosarm programs as well as our emerging SARD program. In the coming months, I look forward to reporting preliminary data from our two Phase 2 clinical trials of enobosarm in women with advanced breast cancer, which should enable us to determine if the clinical benefit response will permit each trial to advance to the second and final stage of the trial,” said Dr. Robert J. Wills, Executive Chairman of GTx. “In addition, the clinical trial of enobosarm to treat stress urinary incontinence in postmenopausal women has continued to enroll and we expect data from this trial during the first half of 2017.”

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, which is defined as a complete response, partial response or stable disease.*

- **ER+/AR+ breast cancer:** We currently expect to have sufficient data from the first stage of this open-label, Phase 2 clinical trial of enobosarm in women with metastatic or locally advanced, ER+/AR+ breast cancer before the end of 2016 to allow us to make a determination as to whether we will enroll additional patients in each of the two study cohorts for the second stage of the trial. 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 in total in order to obtain

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data from 88 evaluable patients (44 evaluable patients in each dose group) to assess the primary efficacy objective of clinical benefit response following 24 weeks of treatment.

- **AR+ TNBC:** We expect to have sufficient data from the first stage of this open-label, proof-of-concept Phase 2 clinical trial of 18 mg of enobosarm in women with advanced AR+ TNBC by the end of 2016 to allow us to make a determination as to whether we will continue enrolling patients into the second stage of the trial. 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:** Enrollment in the Phase 2 proof-of-concept clinical trial of 3 mg of enobosarm in postmenopausal women with SUI is ongoing. This trial, in up to 35 women, is the first clinical trial to evaluate a SARM for SUI. Data from the trial is expected during the first half of 2017, at which point we plan to determine if continued development of enobosarm or another of our SARM compounds in SUI is warranted.
- **DMD:** 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 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 androgen receptor, including AR splice variants, such as AR-V7, along with mutant versions of the receptor.*

- **CRPC:** Lead SARD compounds are undergoing required preclinical development, including formulation and metabolism studies. The Company’s plan is to initiate its first human clinical trial with a SARD in 2017.
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Second Quarter 2016 Financial Results

- As of June 30, 2016, cash and short-term investments were \$19.8 million compared to \$29.3 million at December 31, 2015.
- Research and development expenses for the quarter ended June 30, 2016 were \$4.1 million compared to \$3.0 million for the same period of 2015.
- General and administrative expenses were \$2.0 million for both the quarter ended June 30, 2016 and June 30, 2015.

- The net loss for the quarter ended June 30, 2016 was \$6.1 million compared to a net loss of \$48.0 million for the same period in 2015. The second quarter of 2015 included a non-cash loss of \$43.0 million 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 are required subsequent to the first quarter of 2016.
- The net loss for the six months ended June 30, 2016 was \$4.0 million compared to a net loss of \$50.3 million for the same period of 2015. The six months ended June 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 six months ended June 30, 2015 included a non-cash loss of \$40.4 million due to the change in fair value of the Company's warrant liability.
- GTx had approximately 141.7 million shares of common stock outstanding as of June 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 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 March 31, 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 such statements are based.

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

	June 30, 2016 (unaudited)	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 9,572	\$ 14,056
Short-term investments	10,200	15,200
Prepaid expenses and other current assets	2,064	2,633
Total current assets	21,836	31,889
Property and equipment, net	11	5
Intangible assets, net	130	137

Total assets	\$	21,977	\$	32,031
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	1,387	\$	382
Warrant liability		—		27,349
Accrued expenses and other current liabilities		2,143		2,441
Total current liabilities		3,530		30,172
Commitments and contingencies				
Stockholders' equity:				
Common stock, \$0.001 par value: 400,000,000 shares authorized at June 30, 2016 and December 31, 2015; 141,749,150 and 140,374,112 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively				
		142		141
Additional paid-in capital		535,725		515,192
Accumulated deficit		(517,420)		(513,474)
Total stockholders' equity		18,447		1,859
Total liabilities and stockholders' equity	\$	21,977	\$	32,031

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Expenses:				
Research and development expenses	\$ 4,058	\$ 2,956	\$ 8,029	\$ 5,904
General and administrative expenses	1,999	2,005	4,113	4,116
Total expenses	6,057	4,961	12,142	10,020
Loss from operations	(6,057)	(4,961)	(12,142)	(10,020)
Other income, net	5	25	33	52
Gain (loss) on change in fair value of warrant liability	—	(43,016)	8,163	(40,368)
Net loss	\$ (6,052)	\$ (47,952)	\$ (3,946)	\$ (50,336)
Net loss per share — basic and diluted	\$ (0.04)	\$ (0.34)	\$ (0.03)	\$ (0.36)
Weighted average shares outstanding:				
Basic and diluted	141,749,150	140,374,112	141,635,597	140,355,099