

**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 14, 2017**

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 August 14, 2017, GTx, Inc. issued its financial press release for the second quarter ended June 30, 2017, 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 August 14, 2017

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 14, 2017

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 2017 Financial Results

— Clinically significant reduction in incontinence episodes outlined in preliminary results from ongoing Phase 2 proof-of-concept clinical trial in stress urinary incontinence —

— Additional data from ongoing SUI clinical trial to be released in conjunction with podium presentation at International Continence Society meeting in September 2017 —

MEMPHIS, Tenn. — August 14, 2017 — GTx, Inc. (Nasdaq: GTXI) today reported financial results for the second quarter of 2017 and highlighted recent accomplishments and upcoming milestones.

During the quarter, GTx announced positive preliminary clinical data from an ongoing, open-label, Phase 2 proof-of-concept clinical trial of enobosarm in postmenopausal women with stress urinary incontinence (SUI). The Company also has continued to advance two additional R&D programs which are outlined below.

“We are impressed with the positive results in the first seven patients dosed in the SUI study. Stress urinary incontinence is a serious and often embarrassing condition which can have a significant negative impact on a patient’s quality of life. We are focused on potentially addressing this prevalent condition with a first-in-class, orally-administered therapy,” said Robert J. Wills, Ph.D., Executive Chairman of GTx.

Corporate Highlights and Anticipated Milestones

Enobosarm in Stress Urinary Incontinence: *The Company has an ongoing Phase 2 proof-of-concept clinical trial of enobosarm 3 mg in postmenopausal women with SUI. This open-label, non-placebo controlled proof-of-concept clinical trial is the first of its kind to evaluate an orally-administered selective androgen receptor modulator (SARM) for SUI.*

- In June 2017, the Company announced preliminary results from the first seven women in the ongoing trial, in which all of the women treated with enobosarm showed a clinically significant reduction (50 percent or greater) in incontinence episodes per day, as measured by mean stress leaks from baseline to week 12 of the trial.
- Mean stress leaks decreased by 80.9 percent overall; stress leaks dropped from 5.7 to 1.1 leaks per day.
- These results, as well as data from additional patients, will be presented at the International Continence Society (ICS) annual meeting in September 2017. The results from the first seven patients can be found [here](#).

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- Encouraged by the results to date from its SUI proof-of-concept clinical trial, the Company is planning to initiate in the second half of 2017 a randomized, double-blinded Phase 2 clinical trial to assess the efficacy and safety of two doses of enobosarm (3 mg and 1 mg) per day against placebo with the expectation that top-line data from this trial will be available by the end of 2018.

Enobosarm in Breast Cancer:

The Company has an ongoing Phase 2 clinical trial of enobosarm in estrogen receptor positive (ER+) and androgen receptor positive (AR+) breast cancer.

- The Company reported in November 2016 that the pre-specified threshold for success of the trial was already attained in the 9 mg cohort, with nine patients achieving a clinical benefit response (CBR) at 24 weeks among the first 22 evaluable patients in that cohort.
- CBR is defined as a complete response, partial response or stable disease, as measured by Response Evaluation Criteria in Solid Tumors (RECIST) at 24 weeks of treatment.
- The Phase 2 clinical trial is fully enrolled with at least 44 evaluable patients enrolled in each of the 9 mg and 18 mg cohorts of the trial, and the Company expects to report top-line results in the third quarter of 2017.
- The independent Safety Monitoring Committee established to monitor the safety of this clinical trial met on August 11, 2017, and recommended that the trial continue as planned.

The Company’s Phase 2 clinical trial of enobosarm in AR+ triple negative breast cancer completed the first stage of the two stage trial. Since there was insufficient CBR demonstrated among patients enrolled in the first stage of the trial, the Company has determined that the second and final stage of the trial will not continue.

- One patient who achieved stable disease remains on study for approximately 10 months from the initiation of treatment.

Enobosarm in Duchenne muscular dystrophy (DMD): *The Company has conducted preclinical studies evaluating SARMs in DMD. In preclinical models of DMD, GTx SARMs have increased body weight, lean mass and physical function.*

- The Company is pursuing a potential strategic collaboration with biopharma companies experienced in orphan drug development to continue the development of a SARM for the treatment of DMD.

SARDs in Prostate Cancer: *The Company has a Selective Androgen Receptor Degradator (SARD) preclinical program to evaluate its novel SARD technology in castration-resistant prostate cancer (CRPC).*

- The Company has ongoing preclinical studies to select the most appropriate compound to advance into a first-in-human clinical trial.

Second Quarter 2017 Financial Results

- As of June 30, 2017, cash and short-term investments were \$11.4 million compared to \$21.9 million at December 31, 2016. On August 10, 2017, the Company entered into a loan agreement (the “Loan Agreement”) with J.R. Hyde, III, the largest shareholder of the Company and its Lead Director of its Board of Directors, and The Pyramid Peak Foundation, another large shareholder of the Company, (the “Lenders”) for the Lenders to make available to the Company from time to time during the term of the Loan Agreement up to \$15 million at an interest rate of 8% per annum (the “Loan”). The term of the Loan Agreement is for a period of nine (9) months and is unsecured. The Lenders have agreed that they will participate in any “qualified” financing (defined as the sale of equity by the Company during the term of the Loan Agreement which equals or exceeds \$15 million) at least to the extent of any outstanding indebtedness under the Loan.
- Research and development expenses for the quarter ended June 30, 2017 were \$4.4 million compared to \$4.1 million for the same period of 2016.
- General and administrative expenses were \$2.0 million for both the quarter ended June 30, 2017 and June 30, 2016.
- Net loss for the quarter ended June 30, 2017 was \$6.4 million compared to a net loss of \$6.1 million for the same period in 2016.
- Net loss for the six months ended June 30, 2017 was \$12.7 million compared to a net loss of \$3.9 million for the same period in 2016. The six months ended June 30, 2016 included a non-cash gain of \$8.2 million due to the change in fair value of the Company’s warrant liability, recorded in the first quarter of 2016. During the first quarter of 2016, the Company modified its outstanding warrants with no further adjustment to the fair value of these warrants being required.
- GTx had approximately 16 million shares of common stock outstanding as of June 30, 2017. Additionally, there remain warrants outstanding to purchase approximately 6.4 million shares of GTx common stock at an exercise price of \$8.50 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 trial of enobosarm for the treatment of advanced breast cancer, as well as GTx’s plans to initiate a Phase 2 placebo-controlled clinical trial of enobosarm to treat SUI and the potential preclinical and other future development of GTx’s licensed selective androgen receptor degrader (SARD) technology and the development of selective androgen receptor modulators (SARMs) for the treatment of Duchenne muscular dystrophy (DMD) and the timing thereof; 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 its 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 or the Phase 2 placebo-controlled clinical trial GTx plans to initiate may not be completed or initiated 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 ending June 30, 2017, which is being filed subsequent to this release, 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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GTx, Inc.
Condensed Balance Sheets
(in thousands, except share data)

	June 30, 2017 (unaudited)	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 5,156	\$ 8,910
Short-term investments	6,200	12,959
Prepaid expenses and other current assets	2,130	2,429
Total current assets	13,486	24,298
Property and equipment, net	65	81
Intangible assets, net	116	123
Total assets	<u>\$ 13,667</u>	<u>\$ 24,502</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 603	\$ 1,220
Accrued expenses and other current liabilities	4,582	3,391
Total current liabilities	5,185	4,611
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 60,000,000 shares authorized at June 30, 2017 and December 31, 2016; 16,041,923 and 15,919,572 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	16	16
Additional paid-in capital	552,322	551,073
Accumulated deficit	(543,856)	(531,198)
Total stockholders' equity	8,482	19,891
Total liabilities and stockholders' equity	<u>\$ 13,667</u>	<u>\$ 24,502</u>

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,	
	2017	2016	2017	2016
Expenses:				
Research and development expenses	\$ 4,448	\$ 4,058	\$ 8,641	\$ 8,029
General and administrative expenses	1,997	1,999	4,084	4,113
Total expenses	6,445	6,057	12,725	12,142
Loss from operations	(6,445)	(6,057)	(12,725)	(12,142)
Other income, net	40	5	67	33
Gain on change in fair value of warrant liability	—	—	—	8,163
Net loss	<u>\$ (6,405)</u>	<u>\$ (6,052)</u>	<u>\$ (12,658)</u>	<u>\$ (3,946)</u>
Net loss per share — basic and diluted	<u>\$ (0.40)</u>	<u>\$ (0.43)</u>	<u>\$ (0.79)</u>	<u>\$ (0.28)</u>
Weighted average shares outstanding:				
Basic and diluted	<u>16,041,923</u>	<u>14,174,914</u>	<u>16,030,689</u>	<u>14,163,559</u>