
**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, 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 August 14, 2018, GTx, Inc. issued its financial press release for the second quarter ended June 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.*

Exhibit Number	Description
99.1	Press Release issued by GTx, Inc. dated August 14, 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: August 14, 2018

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 2018 Financial Results

— Completed patient enrollment in the ASTRID Trial, a Phase 2 double-blinded, placebo-controlled clinical trial of enobosarm in Stress Urinary Incontinence —

— Top-line results from the ASTRID Trial expected early in the fourth quarter of 2018 —

— Updated results from Phase 2 proof-of-concept (POC) clinical trial of enobosarm were presented at the 2018 American Urological Association (AUA) meeting in May —

MEMPHIS, Tenn. — August 14, 2018 — GTx, Inc. (Nasdaq:GTXI) today reported financial results for the second quarter ended June 30, 2018 and highlighted recent accomplishments and upcoming milestones.

“During the second quarter, we achieved a key milestone for the company when we completed patient enrollment in our placebo-controlled, Phase 2 ASTRID Trial of enobosarm in postmenopausal women with stress urinary incontinence (SUI),” said Robert J. Wills, Ph.D., Executive Chairman of GTx. “Due to overwhelming interest from women wanting to participate in the clinical trial, we completed enrollment several months ahead of schedule and exceeded the 400 patients planned. We look forward to reporting top-line results early in the fourth quarter of 2018.”

Clinical Highlights and Anticipated Milestones

Stress Urinary Incontinence (SUI):

Enobosarm, a Selective Androgen Receptor Modulator (SARM), is being evaluated in Phase 2 clinical development for SUI. Recent and upcoming important milestones are summarized as follows:

- The Company has an ongoing randomized, double-blinded, placebo-controlled, Phase 2 trial to assess the efficacy and safety of enobosarm administered orally in post-menopausal women with SUI compared to placebo. More information about the ASTRID (Assessing Enobosarm for Stress Urinary Incontinence Disorder) Trial can be found [here](#).
 - In April, the Company completed patient enrollment in the ASTRID Trial several months ahead of schedule, enrolling 493 women at over 60 clinical trial centers across the United States. Top-line results are expected early in the fourth quarter of 2018.
 - On May 18, 2018, a podium presentation entitled “Oral Enobosarm Shows Promising Activity in Post-Menopausal Women with Stress Urinary Incontinence: Results of a Phase 2 Study,” took place at the 2018 American Urological Association (AUA) annual meeting. The presentation updated results from the Phase 2 POC clinical trial of enobosarm. Details of the AUA presentation can be found [here](#) and are summarized below:
 - At the end of the 12-week treatment period, all 18 enobosarm-treated women showed clinically meaningful (50 percent or greater) reductions in stress urinary incontinence episodes per day compared to baseline.
 - The reduction in incontinence episodes was sustained, or durable, well beyond the 12-week treatment period.
 - There were no serious adverse events reported and reported adverse events were minimal and included headaches, nausea, fatigue, hot flashes, insomnia, muscle weakness and acne. Mild transient elevations in liver enzymes that were within normal limits were observed, except for one patient with levels greater than 1.5 times the upper limit of normal which returned to normal following her 12-week treatment period. Reductions in total cholesterol, LDL-C, HDL-C and triglycerides were also observed.
 - The ASTRID Trial protocol includes a four-month, off-drug durability assessment in the first 225 patients enrolled. These data will be announced simultaneously with the ASTRID results. Once the 225-patient cohort completes the four-month, off-drug durability assessment, those patients will have, at their discretion, the option to enter
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an additional five-month, off-drug extension study to provide a total of nine months of off-drug durability assessment.

- The Company also has initiated an open-label safety extension study. Each participating patient will receive 3 mg of oral enobosarm on a daily basis.

Prostate Cancer:

The Company has a Selective Androgen Receptor Degradar (SARD) preclinical program to evaluate its novel SARD technology in castration-resistant prostate cancer (CRPC). The Company has ongoing mechanistic preclinical studies designed to select the most appropriate compound to potentially advance into a first-in-human clinical trial.

Second Quarter 2018 Financial Results

- As of June 30, 2018, cash and short-term investments were \$45.7 million compared to \$43.9 million at December 31, 2017.
 - Research and development expenses for the quarter ended June 30, 2018 were \$8.0 million compared to \$4.4 million for the same period of 2017.
 - General and administrative expenses for the quarter ended June 30, 2018 were \$2.2 million compared to \$2.0 million for the same period of 2017.
 - The net loss for the quarter ended June 30, 2018 was \$10.0 million compared to a net loss of \$6.4 million for the same period in 2017.
 - Net loss for the six months ended June 30, 2018 was \$23.6 million compared to a net loss of \$12.7 million for the same period in 2017.
 - GTx had approximately 24.0 million shares of common stock outstanding as of June 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 the Phase 2 Proof-of-Concept Clinical Trial

The single-arm, open-label Phase 2 clinical trial is evaluating enobosarm in postmenopausal women with SUI, and is the first clinical trial to evaluate an orally-administered selective androgen receptor modulator (SARM) for SUI. This clinical trial is closed to enrollment; more information about the clinical trial can be found [here](#).

About the Phase 2 ASTRID Clinical Trial

In addition to the Phase 2 proof-of-concept clinical trial that was presented at AUA, GTX also has a larger, ongoing, placebo-controlled Phase 2 clinical trial evaluating enobosarm in postmenopausal women with SUI. The study, called ASTRID (Assessing Enobosarm for **S**tress **U**rinary **I**ncontinence **D**isorder), completed enrollment (n=493) and is being conducted at over 60 clinical trial centers across the United States. Top-line results are expected early in the fourth quarter of this year. More information about the ASTRID clinical trial can be found [here](#).

About Enobosarm and SUI

Enobosarm (GTX-024), a selective androgen receptor modulator (SARM), has been evaluated in 27 completed or ongoing clinical trials enrolling over 2,100 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. The rationale for evaluating enobosarm as a treatment for SUI is supported by preclinical *in vivo* data demonstrating increases in pelvic floor muscle mass following treatment with GTX's SARM compounds, including enobosarm, and the proof-of-concept Phase 2 clinical trial of enobosarm 3 mg for the treatment of postmenopausal women with SUI.

About Stress Urinary Incontinence

Stress urinary incontinence (SUI) refers to the unintentional leakage of urine during activities that increase abdominal pressure such as coughing, sneezing or physical exercise. SUI, the most common type of incontinence suffered by women, affects up to 35 percent of adult women. There are a variety of treatments that are used to treat SUI in women, such as behavioral

modification and pelvic floor physical therapy, especially as initial treatment options. As the condition worsens however, bulking agents and surgical procedures are often the most widely used treatments.

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 stress urinary incontinence and 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 clinical development of its selective androgen receptor modulator (SARM) compounds. 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 Phase 2 placebo-controlled clinical study being conducted by GTx for the treatment of stress urinary incontinence (SUI) may not be completed on schedule; (ii) that additional clinical development of GTx's SARM compound for the treatment of SUI will be required beyond the ongoing study; and (iii) any future development of SARMs in SUI is contingent on obtaining sufficient additional capital to permit such development, which it may be unable to do. 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 ended March 31, 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.

Investors:

Argot Partners

Kimberly Minarovich or Sam Martin

212-600-1902

Or

Media:

Red House Consulting

Denise Powell, 510-703-9491

denise@redhousecomms.com

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

	<u>June 30, 2018</u>	<u>December 31, 2017</u>
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 16,511	\$ 15,816
Short-term investments	29,205	28,083
Prepaid expenses and other current assets	1,864	2,178
Total current assets	47,580	46,077
Property and equipment, net	35	51
Intangible assets, net	101	108
Total assets	<u>\$ 47,716</u>	<u>\$ 46,236</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,473	\$ 2,604
Accrued expenses and other current liabilities	6,404	5,371
Total current liabilities	7,877	7,975
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 60,000,000 shares authorized at June 30, 2018 and December 31, 2017; 24,031,191 and 21,541,909 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	24	22
Additional paid-in capital	625,024	599,876
Accumulated deficit	(585,209)	(561,637)
Total stockholders' equity	39,839	38,261
Total liabilities and stockholders' equity	<u>\$ 47,716</u>	<u>\$ 46,236</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,	
	2018	2017	2018	2017
Expenses:				
Research and development expenses	\$ 7,962	\$ 4,448	\$ 18,962	\$ 8,641
General and administrative expenses	2,196	1,997	4,884	4,084
Total expenses	10,158	6,445	23,846	12,725
Loss from operations	(10,158)	(6,445)	(23,846)	(12,725)
Other income, net	143	40	274	67
Net loss	<u>\$ (10,015)</u>	<u>\$ (6,405)</u>	<u>\$ (23,572)</u>	<u>\$ (12,658)</u>
Net loss per share — basic and diluted	<u>\$ (0.43)</u>	<u>\$ (0.40)</u>	<u>\$ (1.04)</u>	<u>\$ (0.79)</u>
Weighted average shares outstanding:				
Basic and diluted	<u>23,288,691</u>	<u>16,041,923</u>	<u>22,623,601</u>	<u>16,030,689</u>