

**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 6, 2015**

**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**  
**7<sup>th</sup> 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 6, 2015, GTx, Inc. issued its financial press release for the second quarter ended June 30, 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 August 6, 2015

**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 6, 2015

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 2015 Financial Results**

– *Company initiates Phase 2 clinical trial of enobosarm in patients with advanced androgen receptor positive triple negative breast cancer* –

– *Company explores the potential of SARMs to treat Duchenne muscular dystrophy* –

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

MEMPHIS, Tenn. — August 6, 2015 — GTx, Inc. (Nasdaq: GTXI) today reported financial results for the quarter and six months ended June 30, 2015, and highlighted recent accomplishments and developments. The Company has initiated its Phase 2 clinical trial of enobosarm in androgen receptor positive (AR+) triple negative breast cancer (TNBC) and anticipates initiating this quarter an additional Phase 2 clinical study of enobosarm to treat AR+ and estrogen receptor positive (ER+) breast cancer. The Company also is evaluating several selective androgen receptor modulator (SARM) compounds in preclinical models of Duchenne muscular dystrophy (DMD) where a SARM's ability to increase muscle mass may prove beneficial to patients suffering from DMD.

"I am pleased that we have initiated our Phase 2 clinical study of AR+ triple negative breast cancer, and I look forward to having our first patient enrolled this quarter," said Marc S. Hanover, CEO of GTx.

"Our primary focus continues to be developing enobosarm for the treatment of advanced breast cancer and the preclinical development of our newly licensed selective androgen receptor degrader program," said Dr. Robert J. Wills, Executive Chairman of GTx. "In addition, the extensive SARM data from our preclinical and clinical development efforts, together with input from leading experts in areas of muscle disorders, has encouraged us to undertake preclinical studies to determine whether SARMs offer a treatment option for DMD."

## Corporate Highlights

*Enobosarm, a SARM, is the Company's lead product candidate and is being developed as a targeted treatment for two advanced breast cancer indications for (i) AR+ TNBC and (ii) ER+ and AR+ breast cancer. For both clinical trials, the primary efficacy objective will be clinical benefit, which is defined as a complete response, partial response or stable disease by Response Evaluation Criteria in Solid Tumors 1.1.*

- The Company initiated its open-label, proof-of-concept Phase 2 clinical trial of a daily dose of 18 mg of enobosarm in patients with advanced AR+ TNBC. The study will enroll up to 55 patients to obtain 41 evaluable patients for the primary efficacy objective defined as clinical benefit at 16 weeks. There will be two stages of evaluation in the clinical trial with the first stage assessment occurring following 16 weeks of treatment for the first 21 evaluable patients. If at least 2 of the 21 patients achieve clinical benefit, the trial will continue to enroll the second stage of the study.
- In the third quarter of 2015, the Company plans to initiate an open-label Phase 2 clinical trial of enobosarm to assess clinical benefit in patients with ER+/AR+ advanced breast cancer. The study will enroll up to 118 patients to obtain 44 evaluable patients in each of two cohorts. One cohort will receive a daily dose of 9 mg of enobosarm and the other cohort a daily dose of 18 mg of enobosarm. There will be two stages of evaluation in the clinical trial with the first stage assessment occurring following 24 weeks of treatment for the first 18 evaluable patients in each of the two cohorts. If at least 3 of the 18 patients achieve clinical benefit in one or both cohorts, the trial will continue through the second stage for that cohort.
- The Company is expecting data from the first stage of each Phase 2 clinical trial by the end of 2016.

*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 variants, such as ARv-7.
- The Company is conducting research in collaboration with the University of Tennessee Health Science Center to select and optimize appropriate drug development candidates to move into the preclinical studies required to support initial clinical trials.

*SARM's ability to increase muscle mass may prove beneficial as a treatment for DMD.*

- DMD is a rare genetic disorder affecting approximately one in 3,000 boys. DMD is characterized by progressive muscle degeneration and weakness and represents a serious unmet medical need.
- The Company is undertaking preclinical studies and has initiated discussions with experts to better understand the potential of SARMs as a treatment for DMD.

*GTx-758 (Capesaris®) for the treatment of advanced prostate cancer.*

- All patients in the Company's open-label Phase 2 clinical trial of GTx-758 in men with metastatic and high risk non-metastatic CRPC have reached the primary endpoint assessment. Both the 125 mg and 250 mg doses have demonstrated dose dependent increases from baseline in sex hormone binding globulin (SHBG), reductions in free testosterone and reductions in prostate specific antigen (PSA), confirming the mechanism of action of GTx-758. Efficacy and safety data from the clinical trial will be presented at an appropriate scientific meeting and submitted for publication.
- The Company is discussing this data with potential strategic partners to determine their interest in partnering or acquiring this asset, as well as the library of ER alpha agonist compounds.

## Second Quarter and Six Months 2015 Financial Results

- As of June 30, 2015, cash and short-term investments were \$39.4 million compared to \$49.3 million at December 31, 2014.
- Loss from operations for the quarter ended June 30, 2015 was \$5.0 million compared to \$10.9 million for the same period of 2014. Loss from operations for the six months ended June 30, 2015 was \$10.0 million compared to \$19.9 million for the same period of 2014.
- Research and development expenses for the quarter ended June 30, 2015 were \$3.0 million compared to \$7.9 million for the same period of 2014.
- General and administrative expenses for the quarter ended June 30, 2015 were \$2.0 million compared to \$3.1 million for the same period of 2014.
- The Company recognized a non-cash loss of \$43.0 million and \$40.4 million for the quarter and six months ended June 30, 2015, respectively, due to the change in fair value of the Company's warrant liability. The Company classified the warrants issued in its November 2014 private placement as a liability due to certain provisions of the warrants that may require the Company, or its successor, to pay cash to warrant holders under certain circumstances through December 31, 2016. The Company anticipates recognizing non-cash gains or losses resulting from the revaluation of these warrants to fair value each reporting period through the earlier of December 31, 2016 or the exercise in full of these warrants.
- The net loss for the quarter ended June 30, 2015 was \$48.0 million compared to a net loss of \$10.9 million for the same period in 2014. The net loss for the quarter ended June 30, 2015 included the above mentioned non-cash loss of \$43.0 million related to the change in the fair value of the Company's warrant liability. The net loss for the six months ended June 30, 2015 was \$50.3 million compared to \$19.9 million for the same period of 2014. The net loss for the six months ended June 30, 2015 included a non-cash loss of \$40.4 million related to the change in fair value of the Company's warrant liability.

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- GTx had approximately 140.4 million shares outstanding as of June 30, 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 80918724. A playback of the call will be available from approximately 12:00 p.m. Eastern Standard Time today through August 13, 2015 and may be accessed by dialing 855-859-2056 from the United States or Canada or 404-537-3406 from other international locations and referencing reservation number 80918724. 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.gtxic.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 initiation and enrollment of GTx's Phase 2 clinical studies of enobosarm (GTx-024) for the treatment of advanced breast cancer, 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 for GTx to raise additional funds for further SARD development; GTx's plans to partner the development of a GTx SARM for the treatment of DMD; GTx's ability to demonstrate sufficient efficacy and safety in its*

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*Phase 2 clinical trials for enobosarm to continue development of the compound for one or both advanced breast cancer indications; potential third party interest in partnering or acquiring GTx-758 (Capesaris®) and other preclinical ER alpha agonist compounds; GTx's expectation that it will recognize non-cash gains or losses resulting from the revaluation of the warrants issued in November 2014 to fair value each reporting period through the earlier of December 31, 2016 or the exercise in full of these warrants; and the potential therapeutic applications for, and potential benefits of, enobosarm, GTx-758 and the licensed 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 even if GTx does determine to move forward with meaningful development of its SARD program, to advance preclinical development of its SARD program sufficient to support the initiation of clinical studies, GTx will require additional funding, which it may be unable to raise, in which case, GTx may fail to realize the anticipated benefits of its licensing of the SARD technology; (iii) that GTx may not be successful in developing a clinical SARD product candidate 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 being conducted or planned to be conducted by GTx may not be initiated or 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; (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 SARD candidates; (vii) that any additional clinical development of GTx's product candidates beyond the two planned Phase 2 clinical trials of enobosarm is contingent on GTx entering into new collaborative arrangements with third parties for such development or otherwise obtaining*

sufficient additional capital to permit such development, which it may be unable to do; (viii) that GTx may be unsuccessful in developing any third party interest in partnering or acquiring a SARM for the treatment of DMD or GTx-758 and other preclinical ER alpha agonist

compounds in which case, GTx may be forced to abandon the development of a SARM for the treatment of DMD and/or GTx-758 and may otherwise not receive any return on its investment for one or both compounds; and (ix) that GTx could remain subject to liability accounting with respect to the November 2014 warrants for the full terms of these warrants. 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 March 31, 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.

#### GTx Contacts

Lauren Crosby (Investors)  
GTx, Inc.  
901.271.8622  
lcrosby@gtxinc.com

Denise Powell (Media)  
Red House Consulting  
510.703.9491  
denise@redhousecomms.com

Source: GTx, Inc.

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

	June 30, 2015 (unaudited)	December 31, 2014
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 14,323	\$ 17,880
Short-term investments	25,111	31,415
Prepaid expenses and other current assets	1,856	856
Total current assets	41,290	50,151
Property and equipment, net	12	29
Intangible and other assets, net	558	471
Total assets	<u>\$ 41,860</u>	<u>\$ 50,651</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 797	\$ 512
Warrant liability	70,798	30,430
Accrued expenses and other current liabilities	1,573	1,850
Total current liabilities	73,168	32,792
Other long-term liabilities	—	30
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 400,000,000 shares and 200,000,000 shares authorized at June 30, 2015 and December 31, 2014, respectively; 140,374,112 and 140,325,643 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively	140	140
Additional paid-in capital	513,659	512,460
Accumulated deficit	(545,107)	(494,771)
Total stockholders' (deficit) equity	(31,308)	17,829
Total liabilities and stockholders' equity	<u>\$ 41,860</u>	<u>\$ 50,651</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,	
	2015	2014	2015	2014
Expenses:				
Research and development expenses	\$ 2,956	\$ 7,894	\$ 5,904	\$ 14,254
General and administrative expenses	2,005	3,052	4,116	5,681

Total expenses	4,961	10,946	10,020	19,935
Loss from operations	(4,961)	(10,946)	(10,020)	(19,935)
Other income, net	25	2	52	4
Loss on change in fair value of warrant liability	(43,016)	—	(40,368)	—
Net loss	<u>\$ (47,952)</u>	<u>\$ (10,944)</u>	<u>\$ (50,336)</u>	<u>\$ (19,931)</u>
Net loss per share:				
Basic and diluted	<u>\$ (0.34)</u>	<u>\$ (0.15)</u>	<u>\$ (0.36)</u>	<u>\$ (0.28)</u>
Weighted average shares outstanding:				
Basic and diluted	<u>140,374,112</u>	<u>75,433,302</u>	<u>140,355,099</u>	<u>70,997,330</u>

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