

**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 29, 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
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 October 29, 2015, GTx, Inc. issued its financial press release for the third quarter ended September 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 October 29, 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: October 29, 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 Third Quarter 2015 Financial Results

— Two Phase 2 clinical trials of enobosarm are enrolling patients for the treatment of advanced breast cancer —

— FDA clearance enables GTx to initiate clinical trial of enobosarm in women with Stress Urinary Incontinence —

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

MEMPHIS, Tenn. — October 29, 2015 — GTx, Inc. (Nasdaq: GTXI) today reported financial results for the quarter and nine months ended September 30, 2015, and highlighted recent accomplishments and developments. The Company's lead program has patients enrolling in two Phase 2 clinical trials of enobosarm: one in women with estrogen receptor positive (ER+) and androgen receptor positive (AR+) breast cancer, and another in women with AR+ triple negative breast cancer (TNBC).

In October, the Company received FDA clearance to initiate a Phase 2 proof-of-concept clinical trial of enobosarm to treat postmenopausal women with stress urinary incontinence (SUI) and plans to initiate the trial in the first quarter of 2016.

"While our primary focus continues to be the development of enobosarm to treat advanced breast cancer, we are expanding the potential utility of our SARM portfolio with the initiation of a proof of concept trial in SUI," said Dr. Robert J. Wills, Executive Chairman of GTx. "Together with our preclinical development in Duchenne muscular dystrophy, we hope to leverage other SARM compounds in our portfolio to create near term value for indications outside of oncology."

Corporate Highlights

Enobosarm, a selective androgen receptor modulator (SARM), is the Company's lead product candidate and is being developed as a targeted treatment for two advanced breast cancer indications for (i) estrogen receptor positive (ER+) and androgen receptor positive (AR+) breast cancer, and (ii) AR+ triple negative breast cancer (TNBC). For both clinical studies, the primary efficacy objective will be clinical benefit, which is defined as a complete response, partial response or stable disease. Preliminary data from the first stage of both Phase 2 clinical trials are expected by the end of 2016.

- Initiated enrollment of an open-label, Phase 2 clinical trial of enobosarm to assess clinical benefit in women with metastatic or locally advanced, ER+/AR+ breast cancer. The study will enroll up to 118 patients to obtain data from 88 evaluable patients to assess the primary efficacy objective of clinical benefit following 24 weeks of treatment.
- Initiated enrollment of an open-label, proof-of-concept Phase 2 clinical trial of enobosarm in women with advanced AR+ TNBC. The study will enroll up to 55

patients to obtain data from 41 evaluable patients to assess the primary efficacy objective of clinical benefit following 16 weeks of treatment.

SARMs ability to increase muscle mass may prove beneficial in other non-oncology indications. The Company is exploring SARMs as potential treatments for stress urinary incontinence (SUI) in postmenopausal women where pelvic floor muscle weakness leads to incontinence, as well as Duchenne muscular dystrophy (DMD), a rare genetic disorder characterized by progressive muscle degeneration and weakness.

- The FDA has accepted the investigational new drug (IND) application for a Phase 2 proof-of-concept clinical trial of enobosarm to treat postmenopausal women with SUI. The Company plans to initiate the trial in the first quarter of 2016 and anticipates top-line data by the end of 2016.
- The Company's preclinical studies have continued to confirm beneficial effects from SARMs in mice genetically altered to simulate DMD, compared to control groups. DMD mice were treated with three different SARM compounds, including enobosarm, and each cohort demonstrated increases in body weight, muscle mass, muscle performance (grip strength) and cardiac function compared to control groups. The Company has initiated discussions with potential strategic partners who have proven experience in developing and commercializing therapies for DMD.

Selective Androgen Receptor Degradar (SARD) technology is being evaluated as a potentially novel treatment for men with castration-resistant prostate cancer, 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 AR-V7.

- The Company continues to make progress towards identifying potential clinical SARD candidates with the goal of initiating preclinical studies in the first quarter of 2016.

Third Quarter and Nine Months 2015 Financial Results

- As of September 30, 2015, cash and short-term investments were \$34.5 million compared to \$49.3 million at December 31, 2014.
- Research and development expenses for the quarter ended September 30, 2015 were \$3.8 million compared to \$3.4 million for the same period of 2014.
- General and administrative expenses for the quarter ended September 30, 2015 were \$2.0 million compared to \$1.6 million for the same period of 2014.

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- The Company recognized a non-cash gain of \$40.7 million and \$352,000 for the quarter and nine months ended September 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.

- Net income for the quarter ended September 30, 2015 was \$34.9 million compared to a net loss of \$4.9 million for the same period in 2014. Net income for the quarter ended September 30, 2015 included the above mentioned non-cash gain of \$40.7 million related to the change in the fair value of the Company's warrant liability. The net loss for the nine months ended September 30, 2015 was \$15.5 million compared to \$24.9 million for the same period of 2014. The net loss for the nine months ended September 30, 2015 included a non-cash gain of \$352,000 related to the change in fair value of the Company's warrant liability.
- GTx had approximately 140.4 million shares outstanding as of September 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 58836318. A playback of the call will be available from approximately 12:00 p.m. Eastern Standard Time today through November 5, 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 58836318. 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.gtxinc.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 commencement and enrollment of GTx's planned clinical study of enobosarm (GTx-024) to treat stress urinary incontinence (SUI) and GTx's ongoing 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; the potential therapeutic applications for, and potential benefits of SARM (including enobosarm) and SARD technology; and 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. 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 or a SARM for the treatment of DMD, to advance preclinical development of its SARD or SARM 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 and/or SARM 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 being conducted by GTx or the planned clinical trial of enobosarm to be conducted by GTx in SUI 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 SARM or SARD candidates; (vii) that any additional clinical development of GTx's product candidates beyond the Phase 2 clinical trials of enobosarm for the treatment of advanced breast cancer or the planned Phase 2 clinical trial of enobosarm for the treatment of SUI 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 SUI, in which case GTx may be forced to abandon the development of a SARM for the treatment of DMD and/or SUI and may

otherwise not receive any return on its investment for these SARM 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 June 30, 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.

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

	September 30, 2015 (unaudited)	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 11,797	\$ 17,880
Short-term investments	22,663	31,415
Prepaid expenses and other current assets	2,458	856
Total current assets	36,918	50,151
Property and equipment, net	8	29
Intangible and other assets, net	852	471
Total assets	\$ 37,778	\$ 50,651
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 184	\$ 512
Warrant liability	30,078	30,430
Accrued expenses and other current liabilities	3,204	1,850
Total current liabilities	33,466	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 September 30, 2015 and December 31, 2014, respectively; 140,374,112 and 140,325,643 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	140	140
Additional paid-in capital	514,413	512,460
Accumulated deficit	(510,241)	(494,771)
Total stockholders' equity	4,312	17,829
Total liabilities and stockholders' equity	\$ 37,778	\$ 50,651

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,	
	2015	2014	2015	2014
Expenses:				
Research and development expenses	\$ 3,824	\$ 3,362	\$ 9,728	\$ 17,616
General and administrative expenses	2,039	1,594	6,155	7,275
Total expenses	5,863	4,956	15,883	24,891
Loss from operations	(5,863)	(4,956)	(15,883)	(24,891)
Other income, net	9	21	61	25
Gain on change in fair value of warrant liability	40,720	—	352	—
Net income (loss)	\$ 34,866	\$ (4,935)	\$ (15,470)	\$ (24,866)
Net income (loss) per share:				
Basic	\$ 0.25	\$ (0.06)	\$ (0.11)	\$ (0.34)
Diluted	\$ (0.04)	\$ (0.06)	\$ (0.11)	\$ (0.34)
Weighted average shares outstanding:				
Basic	140,374,112	76,014,531	140,361,507	72,688,108
Diluted	154,852,127	76,014,531	140,361,507	72,688,108