

**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) **May 8, 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 May 8, 2015, GTx, Inc. issued its financial press release for the first quarter ended March 31, 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**

Description

Exhibit Number	Description
99.1	Press Release issued by GTx, Inc. dated May 8, 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.

By: /s/ Henry P. Doggrell
Name: Henry P. Doggrell
Title: Vice President, Chief Legal Officer and Secretary

**GTx Provides Corporate Update and Reports
First Quarter 2015 Financial Results**

— Company to initiate two open-label Phase 2 clinical trials of enobosarm in breast cancer —

— Company undertakes studies to optimize SARD compounds for further development —

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

MEMPHIS, TN. — May 8, 2015 — GTx, Inc. (Nasdaq: GTXI) today reported financial results for the first quarter ended March 31, 2015, and highlighted recent accomplishments and upcoming milestones. The Company remains primarily focused on targeting the androgen receptor in women with advanced breast cancer using enobosarm, the Company's oral, nonsteroidal selective androgen receptor modulator.

The Company also outlined the strategic rationale for the recent license agreement with the University of Tennessee Research Foundation (UTRF) to develop selective androgen receptor degrader (SARD) compounds that may be capable of degrading multiple forms of androgen receptor (AR). The Company envisions initially developing SARDs for those patients who do not respond or are resistant to currently approved therapies to inhibit tumor growth in patients with progressive castration-resistant prostate cancer (CRPC).

"I am pleased that we have been able to add to our platform of agents targeting hormonal receptors by successfully licensing the exclusive rights to the University of Tennessee Research Foundation's SARD technology. We now have the opportunity to develop a potentially novel therapy to treat men with castration-resistant prostate cancer who do not respond or become resistant to currently approved therapies," said Marc S. Hanover, CEO of GTx. "Additionally, our team continues to make good progress towards initiating our two planned Phase 2 clinical studies of enobosarm to treat advanced breast cancer, with the study in AR+ triple negative breast cancer expected to commence enrollment next month and our study of

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ER+/AR+ advanced breast cancer expected to start enrolling patients soon thereafter."

Corporate Highlights

Enobosarm is the Company's lead product candidate and is being developed for two breast cancer indications: as a targeted treatment for (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 objective will be clinical benefit, which is defined as a complete response, partial response or stable disease.

- Next month, the Company plans to commence enrollment in an open-label, proof-of-concept Phase 2 clinical trial of enobosarm in patients with advanced AR+ TNBC. The study will enroll up to 55 patients with the primary efficacy objective defined as clinical benefit at 16 weeks.
- Soon thereafter, in the third quarter of 2015, the Company plans to initiate enrollment in an open-label Phase 2 clinical trial of enobosarm in patients with ER+/AR+ advanced breast cancer. The study will enroll up to 118 patients with the primary efficacy objective defined as clinical benefit at 24 weeks.

Selective Androgen Receptor Degradator (SARD) technology is being evaluated as a potentially novel treatment for men with castration-resistant prostate cancer (CRPC) who do not respond or are resistant to currently approved therapies.

- The Company is conducting research through the University of Tennessee Health Science Center this year to select and optimize appropriate clinical candidates for the requisite preclinical studies to support initial human clinical studies. The Company expects to initiate the first facet of this preclinical development later this year. Additional preclinical studies and the undertaking of human clinical studies will require further funding which the Company may raise through the licensing or sale of certain assets, including GTx-758 and its ER alpha agonist family of compounds, or through a strategic partnership or collaboration for the development and commercialization of SARDs.

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

- The Company has completed enrollment of its open-label Phase 2 study of GTx-758 in men with metastatic and non-metastatic castration-resistant prostate cancer (CRPC). Both the 125 mg and 250 mg doses have demonstrated dose dependent increases in serum hormone binding globulin (SHBG), reductions in free testosterone and reductions in prostate specific antigen (PSA), confirming the mechanism of action of the compound.
- The Company is gauging third party interest in partnering or acquiring this asset and the library of ER alpha agonist compounds. GTx-758 may potentially be utilized to optimize the suppression of testosterone as well as provide amelioration for the estrogen deficiency side effects that typically accompany ADT.

First Quarter 2015 Financial Results

- As of March 31, 2015, cash and short-term investments were \$44.6 million compared to \$49.3 million at December 31, 2014.
- Loss from operations for the quarter ended March 31, 2015 was \$5.1 million compared to \$9.0 million for the same period of 2014.
- Research and development expenses for the quarter ended March 31, 2015 were \$2.9 million compared to \$6.4 million for the same period of 2014.
- General and administrative expenses for the quarter ended March 31, 2015 were \$2.1 million compared to \$2.6 million for the same period of 2014.

- The Company recognized a non-cash gain of \$2.6 million during the first quarter of 2015 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 March 31, 2015 was \$2.4 million compared to a net loss of \$9.0 million for the same period in 2014. The quarter ended March 31, 2015 included the above mentioned non-cash gain of \$2.6 million related to the change in fair value of the Company's warrant liability.
- GTx had approximately 140.4 million shares outstanding as of March 31, 2015. Additionally, there were 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 25497458. A playback of the call will be available from approximately 1:00 p.m. Eastern Standard Time today through May 15, 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 25497458. 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 enobosarm (GTx-024) to treat breast cancer

Enobosarm, an oral nonsteroidal selective androgen receptor modulator, is being studied for the targeted treatment of androgen receptor positive advanced breast cancer (ER+/AR+ and AR+ TNBC). Prior clinical studies have shown that women with metastatic breast cancer who have been previously treated with tamoxifen and whose cancer has progressed have responded to treatment with steroidal androgens, with overall response rates ranging from 20 to 60 percent. Because steroidal androgens have unwanted virilizing side effects, they have limited widespread clinical use. GTx believes that a selective androgen receptor modulator, like

enobosarm, by targeting the androgen receptor in advanced breast cancer, has the potential to provide clinical benefit to women with advanced breast cancer while minimizing these unwanted side-effects associated with steroidal androgens. For more information about enobosarm and our SARM portfolio, please visit www.gtxinc.com.

About GTx-758 (Capesaris®) to treat men with castration resistant prostate cancer

GTx-758, an oral nonsteroidal selective estrogen receptor alpha agonist, is being studied for secondary hormonal therapy in men with castration resistant prostate cancer (CRPC) and, potentially, as a secondary hormonal treatment for advanced prostate cancer used in combination with androgen deprivation treatment (ADT). For more information about GTx-758, please visit www.gtxinc.com.

About Selective Androgen Receptor Degraders (SARD) to treat men with castration resistant prostate cancer

The SARD program was in-licensed from the University of Tennessee Research Foundation in March 2015. Although current therapies have improved overall survival in men with CRPC, approximately one-third of the CRPC patients do not respond to these therapies, due in part to the presence of splice variants, including ARv7. Splice variants of the androgen receptor have been identified in which the binding site for androgens, the ligand binding domain, necessary for the action of many of the current therapies, is lost. In addition, most patients who do initially respond to available treatments eventually progress due to the emergence of resistance to these therapies. It is believed that CRPC growth remains highly dependent on androgen receptor activity, although the mechanisms which underlie this resistance are not fully understood. A therapeutic agent that would safely degrade multiple forms of the androgen receptor, including those without the ligand binding domain, may be uniquely positioned to address this patient population. For more information about the GTx SARD program, please visit 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 potential preclinical and other future development of GTx's licensed SARD technology and the timing thereof, including the anticipated identification of clinical SARD candidates and the potential evaluation thereof in human clinical studies; the potential for GTx to raise additional funds for SARD development, whether through the licensing or sale of certain assets, a strategic partnership or

collaboration for SARDs or otherwise; GTx's planned Phase 2 clinical trials for enobosarm (GTx-024), including the anticipated timing of initiation of such trials; 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 is at a very early stage and it is possible that GTx may determine not to move forward with any meaningful development of its SARD program; (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 initial human studies and 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 human clinical studies or the clinical product candidate may fail such clinical studies; (iv) that the clinical trials 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

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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 GTx-758 and other preclinical ER alpha agonist compounds in which case, GTx may be forced to abandon the development of GTx-758 and may otherwise not receive any return on its investment in GTx-758; 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 annual report on Form 10-K for the year ended December 31, 2014 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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Source: GTx, Inc.

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

	<u>March 31, 2015</u>	<u>December 31, 2014</u>
	<u>(unaudited)</u>	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 14,163	\$ 17,880
Short-term investments	30,437	31,415
Prepaid expenses and other current assets	743	856
Total current assets	<u>45,343</u>	<u>50,151</u>
Property and equipment, net	16	29
Intangible and other assets, net	423	471
Total assets	<u>\$ 45,782</u>	<u>\$ 50,651</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 438	\$ 512
Warrant liability	27,782	30,430
Accrued expenses and other current liabilities	1,647	1,850
Total current liabilities	<u>29,867</u>	<u>32,792</u>
Other long-term liabilities	20	30
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 200,000,000 shares authorized at March 31, 2015 and December 31, 2014; 140,374,112 and 140,325,643 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	140	140
Additional paid-in capital	512,910	512,460
Accumulated deficit	<u>(497,155)</u>	<u>(494,771)</u>

Total stockholders' equity	15,895	17,829
Total liabilities and stockholders' equity	<u>\$ 45,782</u>	<u>\$ 50,651</u>

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

	Three Months Ended	
	March 31,	
	2015	2014
Expenses:		
Research and development expenses	\$ 2,948	\$ 6,360
General and administrative expenses	2,111	2,629
Total expenses	<u>5,059</u>	<u>8,989</u>
Loss from operations	(5,059)	(8,989)
Other income, net	27	2
Gain on change in fair value of warrant liability	2,648	—
Net loss	<u>\$ (2,384)</u>	<u>\$ (8,987)</u>
Net loss per share — basic and diluted	<u>\$ (0.02)</u>	<u>\$ (0.14)</u>
Weighted average shares outstanding:		
Basic and diluted	<u>140,335,875</u>	<u>66,512,069</u>

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