

**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) **March 4, 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 March 4, 2015, GTx, Inc. issued its financial press release for the fourth quarter and year ended December 31, 2014, 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 March 4, 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 Fourth Quarter and Year-End 2014 Financial Results

- Company to initiate two open-label Phase 2 clinical trials of enobosarm for two breast cancer indications -

- Conference call today at 9:00 a.m. ET -

MEMPHIS, TN. — March 4, 2015 — GTx, Inc. (Nasdaq: GTXI) today reported financial results for the fourth quarter and year ended December 31, 2014, and highlighted recent accomplishments and upcoming milestones. The Company remains 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 highlighted clinical progress with GTx-758, its oral nonsteroidal selective estrogen receptor alpha agonist, being studied for secondary hormonal therapy in men with castration resistant prostate cancer.

"We are pleased to now be working with Rob Wills, our new Executive Chairman, an industry executive with solid operational experience, to help us execute on our business objectives," said Marc S. Hanover, CEO of GTx. "Initiating and enrolling our two new breast cancer trials is of utmost importance to our Company as we remain dedicated to treating women with advanced breast cancer."

Recent Highlights and Upcoming Activities

- In February 2015, appointed Robert J. Wills, Ph.D., to the Company's Board of Directors, effective March 2, 2015, to serve as its Executive Chairman as well as Chairman of the Scientific and Development Committee of the Board. Dr. Wills will support the Company's clinical trials and business development activities, as well as the Company's external communications with shareholders, investors and analysts.
- In November 2014, closed a private placement financing that resulted in the Company raising approximately \$43 million.

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).

- During the fourth quarter of 2014, presented updated results from an ongoing Phase 2 trial of enobosarm 9 mg for the treatment of patients with ER+/AR+ metastatic breast cancer at the San Antonio Breast Cancer Symposium. The results showed

clinical benefit at six months that exceeded the pre-defined statistical threshold requiring that at least 3 of 14 AR+ patients demonstrate clinical benefit.

- In the second quarter of 2015, the Company plans to initiate 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.
- In the third quarter of 2015, the Company plans to initiate 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.
- For each of these two phase 2 clinical trials, clinical benefit is defined as a complete response, partial response or stable disease.

GTx-758 (Capesaris®) is being developed as a secondary hormonal treatment for men with castration resistant prostate cancer (CRPC).

- We continue to enroll patients in an open-label Phase 2 study of GTx-758 in men with metastatic and non-metastatic CRPC. The 125 mg arm is enrolled and the 250 mg dose is expected to be fully enrolled by the end of the first quarter of 2015.
- Men on androgen deprivation therapy (ADT) who fail to reach castrate levels of testosterone remain at high risk for progression of their prostate cancer. GTx-758, in combination with ADT in these patients, may reduce this risk by lowering testosterone to accepted castrate levels, as well as ameliorating the estrogen deficiency side effects associated with ADT. Upon completion of our ongoing Phase 2 clinical study, we will evaluate potential next steps in the clinical development of GTx-758, including potentially seeking a partnering or collaborative arrangement in order to fund additional clinical development.

Fourth Quarter and Year-End 2014 Financial Results

- As of December 31, 2014, cash and short-term investments were \$49.3 million compared to \$14.7 million at December 31, 2013. Reported year-end cash and short-term investments include \$42.8 million in net proceeds the Company received upon closing of the private placement of common stock and warrants in November 2014.
- Loss from operations for the quarter ended December 31, 2014 was \$5.5 million compared to \$9.2 million for the same period of 2013. Loss from operations for the year ended December 31, 2014 was \$30.3 million compared to \$43.6 million for the year ended December 31, 2013.

- Research and development expenses for the quarter ended December 31, 2014 were \$3.3 million compared to \$6.1 million for the same period of 2013. Research and development expenses for the year ended December 31, 2014 were \$20.9 million compared to \$32.3 million for the year ended December 31, 2013.
- General and administrative expenses for the quarter ended December 31, 2014 were \$2.2 million compared to \$3.1 million for the same period of 2013. General and administrative expenses for the year ended December 31, 2014 were \$9.5 million compared to \$11.3 million for the year ended December 31, 2013.

- The Company incurred a non-cash loss of \$8.8 million during the fourth quarter of 2014 due to the change in fair value of the Company's warrant liability. The Company classified the warrants issued in the November 2014 private placement as a liability due to certain provisions of the warrants that may require the Company, or its successor, to cash settle the warrants or otherwise 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 December 31, 2014 was \$14.5 million compared to a net loss of \$7.8 million for the same period in 2013. The net loss for the year ended December 31, 2014 was \$39.4 million compared to a net loss of \$42.1 million for the same period in 2013. Both the quarter and year ended December 31, 2014 included the above mentioned non-cash loss of \$8.8 million related to the change in fair value of the Company's warrant liability.
- GTx had approximately 140.3 million shares outstanding as of December 31, 2014.

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 866-314-5232 from the United States or Canada or 617-213-8052 from other international locations. The access code for the call is 85796452. A playback of the call will be available from approximately 1:00 p.m. Eastern Standard Time today through March 18, 2015 and may be accessed by dialing 888-286-8010 from the United States or Canada or 617-801-6888 from other international locations and referencing reservation number 56856619. 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

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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, 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). GTx is enrolling an open-label, Phase 2 clinical study of GTx-758 to treat men with metastatic and non-metastatic CRPC. Data from the study is expected in the third quarter of 2015. For more information about GTx-758, 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 GTx's planned clinical trials for enobosarm (GTx-024) and its ongoing clinical trial of GTx-758 (Capesaris®), including the anticipated timing of initiation and expected data from such trials, statements related to the potential to undertake additional development of GTx-758 and GTx's plans or possible plans related thereto, 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 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; (ii) that any additional clinical development of GTx's product candidates beyond the two planned Phase 2 clinical trials of enobosarm in patients with AR positive advanced

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breast cancer 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; (iii) that GTx may not be able to obtain required regulatory approvals to commercialize its product candidates in a timely manner or at all; or (iv) that GTx may be unable to take appropriate action to increase its authorized and unreserved shares of common stock to an amount sufficient to remove GTx's cash settlement obligations under the November 2014 warrants and/or that GTx could otherwise remain subject to liability accounting with respect to these 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 September 30, 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.

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.

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

| | December 31, | |
|--|---------------------|------------------|
| | 2014 (unaudited) | 2013 |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 17,880 | \$ 14,529 |
| Short-term investments | 31,415 | 200 |
| Prepaid expenses and other current assets | 856 | 442 |
| Total current assets | 50,151 | 15,171 |
| Property and equipment, net | 29 | 112 |
| Intangible and other assets, net | 471 | 322 |
| Total assets | <u>\$ 50,651</u> | <u>\$ 15,605</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 512 | \$ 808 |
| Warrant liability | 30,430 | — |
| Accrued expenses and other current liabilities | 1,850 | 3,759 |
| Total current liabilities | 32,792 | 4,567 |
| Other long-term liabilities | 30 | 354 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Common stock, \$0.001 par value: 200,000,000 and 120,000,000 shares authorized at December 31, 2014 and December 31, 2013, respectively; 140,325,643 and 63,185,389 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively | 140 | 63 |
| Additional paid-in capital | 512,460 | 465,981 |
| Accumulated deficit | (494,771) | (455,360) |
| Total stockholders' equity | 17,829 | 10,684 |
| Total liabilities and stockholders' equity | <u>\$ 50,651</u> | <u>\$ 15,605</u> |

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

| | Three Months Ended December 31, | | Year Ended December 31, | |
|---|------------------------------------|-------------------|----------------------------|--------------------|
| | 2014 | 2013 | 2014 | 2013 |
| Expenses: | | | | |
| Research and development expenses | \$ 3,254 | \$ 6,088 | \$ 20,870 | \$ 32,318 |
| General and administrative expenses | 2,203 | 3,091 | 9,478 | 11,281 |
| Total expenses | 5,457 | 9,179 | 30,348 | 43,599 |
| Loss from operations | (5,457) | (9,179) | (30,348) | (43,599) |
| Other (expense) income, net | (284) | 1,389 | (259) | 1,488 |
| Loss on change in fair value of warrant liability | (8,804) | — | (8,804) | — |
| Net loss | <u>\$ (14,545)</u> | <u>\$ (7,790)</u> | <u>\$ (39,411)</u> | <u>\$ (42,111)</u> |
| Net loss per share — basic and diluted | <u>\$ (0.13)</u> | <u>\$ (0.12)</u> | <u>\$ (0.48)</u> | <u>\$ (0.67)</u> |
| Weighted average shares outstanding: | | | | |
| Basic and diluted | <u>108,869,121</u> | <u>63,185,389</u> | <u>81,807,706</u> | <u>63,057,142</u> |

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