

**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, 2014**

**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 May 8, 2014, GTx, Inc. issued its financial press release for the first quarter ended March 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 May 8, 2014

**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: May 8, 2014

GTx, Inc.

By: /s/ Henry P. Doggrell

Name: Henry P. Doggrell

Title: Vice President, Chief Legal Officer and Secretary

Contact:  
 Marc Hanover, interim CEO and President  
 GTx, Inc.  
 901-523-9700

## GTx PROVIDES CORPORATE UPDATE AND REPORTS FIRST QUARTER 2014 FINANCIAL RESULTS

MEMPHIS, TN. — May 8, 2014 — GTx, Inc. (Nasdaq: GTXI) today provided a Company update and reported financial results for the first quarter of 2014.

### Clinical updates

**Enobosarm (GTx-024) 3mg, an oral selective androgen receptor modulator, being developed for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer:** Following GTx's announcement in August 2013 that the POWER1 (platinum plus taxane) and POWER2 (platinum plus non-taxane) Phase 3 clinical trials evaluating enobosarm 3mg for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer (NSCLC) failed to achieve the statistical significance, as agreed upon with the Food and Drug Administration (FDA), GTx has met with regulators in both the US and Europe to better understand the prospects for commercializing its enobosarm product candidate as a treatment for muscle wasting in NSCLC patients. Since enobosarm 3mg demonstrated a statistically significant effect versus placebo on physical function at three months in the POWER1 Phase 3 clinical trial, assessed by continuous variable analysis as pre-specified in the statistical analysis plan for the European Medicines Agency (EMA), the Company believes data from the POWER trials may be sufficient to support the filing of a marketing authorization application (MAA) in the European Union (EU) for enobosarm 3mg for the prevention and treatment of muscle wasting in patients with advanced NSCLC treated with platinum plus taxane chemotherapy. The Company has retained experts in both the US and EU to work with its internal team to explore the option of submitting a MAA.

In a meeting with FDA earlier this year, the FDA confirmed that the current data from the POWER trials are insufficient to support the filing of a new drug application (NDA), as the POWER trials did not meet the pre-specified statistical criterion for the co-primary endpoints of lean body mass and stair climb power, using responder analyses, as agreed upon with FDA. The Company is evaluating options for further development of enobosarm 3 mg.

Enobosarm was well tolerated in both POWER trials. Although only minor differences in adverse events were observed between the groups with enobosarm 3mg and placebo in the POWER1 and POWER2 trials, there were notable differences in the adverse event profiles between studies, with anemia and other hematologic toxicities being more prevalent in the POWER2 (platinum plus non-taxane) clinical trial. Survival is being assessed as another safety endpoint to determine that enobosarm treatment is not adversely affecting survival. As specified in the Company's statistical analysis plan, the final analysis for survival superiority will be done at the time 450 deaths have been realized (pooled across both studies). The Company currently expects this to occur during the summer of 2014. To date, the Company has seen no adverse effect on survival from enobosarm treatment from pooled survival data.

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**Enobosarm 9mg, being studied for the targeted treatment of androgen receptor and estrogen receptor positive metastatic breast cancer:** GTx is conducting a Phase 2, open label clinical study evaluating an oral daily dose of 9mg enobosarm for the treatment of androgen receptor (AR) positive and estrogen receptor (ER) positive metastatic breast cancer in women who have previously responded to hormonal therapy for the treatment of their advanced breast cancer. Nine clinical study sites in the US have fully enrolled the study with 22 postmenopausal women with advanced breast cancer to assess clinical benefit response after six months of enobosarm 9mg treatment, which is defined as either those women receiving treatment who have demonstrated a complete response (disappearance of all targeted lesions), a partial response (at least a 30 percent decrease in the sum of the diameters of the targeted lesions) or stable disease (no disease progression from baseline). Enobosarm 9mg continues to be well tolerated by patients in the study.

In preclinical and clinical studies, androgens suppress breast cancer growth. Prior studies have shown that women with metastatic breast cancer who have been previously treated with tamoxifen and whose cancer has progressed have responded to non-selective androgens, with overall response rates ranging from 20 to 60 percent. Although these non-selective androgens have been used to treat breast cancer, the unwanted virilizing side effects, including facial and body hair, enlargement of voice box, acne, and edema have limited their widespread clinical use. GTx believes that a selective androgen receptor modulator, like enobosarm, by targeting the androgen receptor in metastatic breast cancer, has the potential to provide clinical benefit to women with advanced breast cancer by treating their disease while minimizing the unwanted masculinizing side-effects associated with steroidal androgens. Furthermore, unlike steroidal androgens, enobosarm cannot be converted to an estrogen that could be detrimental in breast cancer.

The Company has determined that the study will meet the pre-specified goal of demonstrating at least three clinical benefit responses in a minimum of 14 patients with AR positive metastatic breast cancer. The study is ongoing and the last study patient is expected to have her primary endpoint visit in June of this year, with data to assess the primary study endpoint expected in July 2014. Preliminary data from the study is being presented at the American Society of Clinical Oncology (ASCO) in Chicago, Illinois on June 2, 2014, in a poster presentation entitled, "Enobosarm: A targeted therapy for metastatic, androgen receptor positive breast cancer". The Company is planning to meet with key opinion leaders and other breast cancer specialists at ASCO to evaluate data then available from the study and discuss appropriate next steps for the development of this potential treatment option for women with advanced breast cancer.

**GTx-758 (Capesaris®), an oral nonsteroidal selective estrogen receptor alpha agonist, being studied for secondary hormonal therapy in men with castration-resistant prostate cancer and, potentially, as a secondary hormonal treatment for advanced prostate cancer used in combination with ADT:** GTx is enrolling an open-label, Phase 2 clinical study of GTx-758 to treat men with metastatic and non-metastatic castration-resistant prostate cancer (CRPC). GTx-758 has previously demonstrated the ability to increase the production of a protein called sex hormone binding globulin (SHBG) that binds testosterone and thereby reduces free testosterone. The Phase 2 study is evaluating the safety and effectiveness of two doses (125mg and 250mg oral daily dose) of GTx-758. The primary endpoint of the study is the proportion of patients with a  $\geq 50\%$  decline from baseline in serum PSA by Day 90. Other key endpoints include SHBG and total and free testosterone levels, as well as prostate cancer progression, in the study subjects. In addition, the clinical study is evaluating the ability of GTx-758 to treat certain estrogen deficiency side-effects associated with LHRH agonists, such as hot flashes, bone loss, and insulin resistance.

Enrollment in the 125mg cohort has been completed without any incidences of VTEs and, after a pre-specified safety review by the independent Data Safety Monitoring Board, we are now enrolling subjects in the 250mg arm. Based upon the observed safety and effectiveness in the 125mg cohort and with no

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safety issues having been observed in the first ten metastatic patients enrolled in the 250mg cohort, the Company plans to enroll the remainder of the 250mg cohort with both high risk non-metastatic and metastatic CRPC patients, with the expectation that enrollment will be completed later this summer. Data from the study is expected during the first quarter is 2015.

#### Financial highlights for the quarter ended March 31, 2014

The Company reported a net loss for the quarter ended March 31, 2014 of \$9.0 million compared to a net loss of \$12.6 million for the same period in 2013. Research and development expenses for the quarter ended March 31, 2014 were \$6.4 million compared to \$9.6 million for the same period of 2013. General and administrative expenses for the quarter ended March 31, 2014 were \$2.6 million compared to \$3.0 million for the same period of 2013.

At March 31, 2014, GTx had cash and short-term investments of \$27.8 million.

#### 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, cancer supportive care, including prevention and treatment of cancer-related muscle wasting, 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 clinical trials for enobosarm (GTx-024) and its clinical trial of GTx-758 (Capesaris®). 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 may not be able to obtain required regulatory approvals to commercialize its product candidates in a timely manner or at all; or (ii) that clinical trials being conducted by GTx may not be completed on schedule, or at all, or may otherwise be suspended or terminated. 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. 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. 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 filed with the Securities and Exchange Commission on March 12, 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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#### GTx, Inc. Condensed Balance Sheets (in thousands, except share data)

	March 31, 2014 (unaudited)	December 31, 2013
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 22,432	\$ 14,529
Short-term investments	5,345	200
Prepaid expenses and other current assets	1,278	442
Total current assets	29,055	15,171
Property and equipment, net	86	112
Intangible and other assets, net	652	322
Total assets	<u>\$ 29,793</u>	<u>\$ 15,605</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 619	\$ 808
Accrued expenses and other current liabilities	3,894	3,759
Total current liabilities	4,513	4,567
Other long-term liabilities	195	354
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 120,000,000 shares authorized at March 31, 2014 and December 31, 2013; 75,161,437 and 63,185,389 shares issued and outstanding at March 31, 2014 and December 31, 2013, respectively	75	63
Additional paid-in capital	489,357	465,981
Accumulated deficit	(464,347)	(455,360)
Total stockholders' equity	25,085	10,684
Total liabilities and stockholders' equity	<u>\$ 29,793</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	
	2014	2013
<b>Expenses:</b>		
Research and development expenses	\$ 6,360	\$ 9,614
General and administrative expenses	2,629	3,023
Total expenses	8,989	12,637
Loss from operations	(8,989)	(12,637)
Other income, net	2	55
Net loss	\$ (8,987)	\$ (12,582)
<b>Net loss per share:</b>		
Basic and diluted	\$ (0.14)	\$ (0.20)
<b>Weighted average shares outstanding:</b>		
Basic and diluted	66,512,069	62,864,140