

**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, 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
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, 2014, GTx, Inc. issued its financial press release for the fourth quarter and year ended December 31, 2013, 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, 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: March 4, 2014

GTx, Inc.

By: /s/ Henry P. Doggrell

Name: Henry P. Doggrell

Title: Vice President, Chief Legal Officer and Secretary

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

GTx PROVIDES CORPORATE UPDATE AND REPORTS 2013 FINANCIAL RESULTS

Plans to file MAA for enobosarm 3mg by first quarter 2015

MEMPHIS, TN. — March 4, 2014 — GTx, Inc. (Nasdaq: GTXI) today provided a Company update and reported financial results for the fourth quarter and full year 2013.

Clinical updates

Enobosarm (GTx-024) 3 mg, 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: GTx announced in August 2013 that the POWER1 (platinum plus taxane) and POWER2 (platinum plus non-taxane) Phase 3 clinical trials evaluating enobosarm 3 mg for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer (NSCLC) failed to meet the co-primary endpoints of lean body mass and physical function that were assessed statistically using responder analyses, as agreed upon with the Food and Drug Administration (FDA). In a recent meeting with FDA, the Company learned that because the POWER trials did not meet the pre-specified statistical criterion for the co-primary endpoints, the current data from the POWER trials are insufficient to support the filing of a new drug application (NDA). However, the Company believes there is a regulatory path forward for enobosarm 3mg and plans to meet again with FDA to seek agreement on the Phase 3 program required to provide the efficacy and safety data required by FDA for the filing of a NDA.

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 recently met with representatives from two member countries to the EMA to review and discuss the results of the POWER trials to determine an appropriate path forward for potentially submitting a marketing authorization application (MAA) in the European Union (EU) for enobosarm 3mg. Based on input from the two national authorities, the Company currently expects to submit by the first quarter of 2015 the MAA for enobosarm 3mg for the prevention and treatment of muscle wasting in patients with advanced NSCLC treated with platinum plus taxane chemotherapy.

Enobosarm was well tolerated in both clinical studies. 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, survival will be assessed after 450 of the approximately 650 patients in the two studies have died, which currently is expected to have occurred by late April of 2014. To date, the Company has seen no adverse effect on survival from enobosarm treatment from pooled survival data.

Enobosarm 9 mg, 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 enobosarm 9mg oral daily 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 U.S. 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. The Company expects to 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 data from all patients in the study is expected late in the second quarter of 2014.

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. Enobosarm 9mg has the potential to be a novel, targeted hormonal therapy for AR positive, ER positive metastatic 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 nonmetastatic 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.

After reviewing data collected to date from the GTx-758 125mg dosing arm indicating the ability of the drug to substantially increase SHBG and lower free testosterone without any unexpected side-effects occurring, the clinical trial protocol was amended to eliminate the third dosing arm of 500 mg originally designed for the study and to increase the number of subjects to be enrolled in the 125mg and 250mg dosing arms to 38 patients per arm. 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 assuming no safety issues are

Financing update

In a separate press release issued this morning, GTx announced that it has signed a definitive purchase agreement providing for the private placement of its securities. The private placement would, subject to the satisfaction of customary closing conditions, generate gross proceeds to GTx of approximately \$21.3 million. Additional details regarding the private placement are included in a current report of the company on Form 8-K, to be filed with the SEC.

Financial highlights for the quarter and year ended December 31, 2013

The Company reported a net loss for the quarter ended December 31, 2013 of \$7.8 million compared to a net loss of \$10.7 million for the same period in 2012. For the year ended December 31, 2013, the Company reported a net loss of \$42.1 million compared to a net loss of \$27.1 million for the year ended December 31, 2012. The net loss for the year ended December 31, 2012 included a gain of \$18.8 million from the sale of the Company's rights and certain assets related to FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of metastatic breast cancer in postmenopausal women in the United States.

Research and development expenses for the quarter and year ended December 31, 2013 were \$6.1 million and \$32.3 million, respectively, compared to \$10.1 million and \$38.9 million for the same periods of 2012. General and administrative expenses for the quarter and year ended December 31, 2013 were \$3.1 million and \$11.3 million, respectively, compared to \$2.9 million and \$10.8 million for the same periods of 2012.

At December 31, 2013, GTx had cash and short-term investments of \$14.7 million, and with proceeds from the recently announced financing, GTx's cash position will increase by approximately \$21 million.

Conference call

There will be a conference call today at 9:00 a.m. Eastern Time. To listen to the conference call, please dial 877-280-4957 from the United States or Canada or 857-244-7314 from other international locations. The access code for the call is 86747366. A playback of the call will be available from approximately 5:00 p.m. Eastern Time today through March 18, 2014 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 25033543. 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, 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. Additionally, forward looking statements include those relating to the anticipated closing of its private placement of GTx common stock, and the amount and proposed use of proceeds of the private placement. 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, risks and uncertainties associated with market conditions, whether GTx will be able to consummate the private placement and the satisfaction of closing conditions related to the private placement. There can be no assurance that GTx will be able to complete the private placement on the terms described herein or in a timely manner, if at all. Regardless of whether the private placement is consummated, 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 quarterly report on Form 10-Q filed with the Securities and Exchange Commission on November 12, 2013 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, Inc.
Condensed Balance Sheets
(in thousands, except share data)

	December 31,
	<u>2013</u> <u>2012</u>

(unaudited)

ASSETS

Current assets:

Cash and cash equivalents	\$	14,529	\$	48,044
Short-term investments		200		8,045
Prepaid expenses and other current assets		442		726
Total current assets		15,171		56,815
Property and equipment, net		112		507
Intangible and other assets, net		322		452
Total assets	\$	15,605	\$	57,774

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable	\$	808	\$	1,707
Accrued expenses and other current liabilities		3,759		7,788
Total current liabilities		4,567		9,495
Other long-term liabilities		354		578

Commitments and contingencies

Stockholders' equity:

Common stock, \$0.001 par value: 120,000,000 shares authorized at both December 31, 2013 and December 31, 2012; 63,185,389 and 62,818,424 shares issued and outstanding at December 31, 2013 and December 31, 2012, respectively		63		63
Additional paid-in capital		465,981		460,887
Accumulated deficit		(455,360)		(413,249)
Total stockholders' equity		10,684		47,701
Total liabilities and stockholders' equity	\$	15,605	\$	57,774

5

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

	Three Months Ended December 31,		Year Ended December 31,	
	2013	2012	2013	2012
Expenses:				
Research and development expenses	\$	6,088	\$	10,051
General and administrative expenses		3,091		2,858
Total expenses		9,179		12,909
Loss from operations		(9,179)		(12,909)
Other income (expense), net		1,389		(33)
Loss from operations before income taxes		(7,790)		(12,942)
Income tax benefit		—		2,273
Net loss from continuing operations		(7,790)		(10,669)
Income (loss) from discontinued operations before income taxes		—		(76)
Income tax benefit (expense)		—		30
Net income (loss) from discontinued operations		—		(46)
Net loss	\$	(7,790)	\$	(10,715)
Net income (loss) per share - basic and diluted:				
Net loss from continuing operations	\$	(0.12)	\$	(0.17)
Net income from discontinued operations		—		—
Net loss per share	\$	(0.12)	\$	(0.17)
Weighted average shares outstanding:				
Basic and diluted		63,185,389		62,817,495

6