

**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 3, 2013**

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 3, 2013, GTx, Inc. issued its financial press release for the first quarter ended March 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 May 3, 2013

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 3, 2013

GTx, Inc.

By: /s/ Mark E. Mosteller

Name: Mark E. Mosteller

Title: Vice President and Chief Financial Officer

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

GTx PROVIDES CORPORATE UPDATE AND REPORTS FIRST QUARTER 2013 FINANCIAL RESULTS

MEMPHIS, TN. — May 3, 2013 — GTx, Inc. (Nasdaq: GTXI) today provided a Company update and reported financial results for the first quarter of 2013.

“We expect the last patients to complete our two pivotal Phase 3 clinical studies of enobosarm to prevent and treat muscle wasting in non-small cell lung cancer by the end of this month, which should allow us to release topline data from the studies in the third quarter of this year,” said Mitchell S. Steiner, MD, CEO of GTx. “We are also initiating a new clinical study of enobosarm to treat women with metastatic breast cancer and believe that enobosarm offers the potential of a new hormonal therapy to treat this deadly disease.”

Clinical updates

Enobosarm (GTx-024) 3 mg, an oral selective androgen receptor modulator, being studied for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer: GTx has completed enrollment in its two pivotal Phase 3 clinical trials of enobosarm 3 mg to prevent and treat patients with advanced non-small cell lung cancer. These international Phase 3 studies (POWER 1 and POWER 2) are being conducted in approximately 80 clinical sites in the United States, Europe, Russia and South America. In each of the placebo-controlled, double-blind clinical trials, approximately 325 patients with Stage III or IV non-small cell lung cancer have been randomized to oral daily doses of placebo or enobosarm 3 mg at the time they began first line standard platinum doublet chemotherapy. The studies are evaluating as co-primary endpoints at three months of treatment the responder rates of enobosarm 3 mg versus placebo on maintaining or improving total lean body mass (muscle) assessed by dual x-ray absorptiometry and improving physical function assessed by the Stair Climb Test. Durability of the drug effect will be evaluated as a secondary endpoint at five months of treatment in those patients who responded at Day 84. Topline results will be presented for both studies at the same time in the third quarter of this year and will include the co-primary endpoints, safety assessments, and an update on survival.

In January, GTx announced that the FDA has designated enobosarm 3 mg for the prevention and treatment of muscle wasting in non-small cell lung cancer as a fast track development program. Fast track status is a process designed by the FDA to facilitate the development and expedite the review of new drug candidates that are intended to treat serious diseases and have the potential to fill an unmet medical need. With a fast track designation, there is an increased possibility for a priority review of a new drug application (NDA) filed for the drug candidate and the opportunity for more frequent interactions with the FDA both prior to and following the filing of a NDA.

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In April, GTx announced that a per protocol review of safety data from GTx’s two pivotal clinical trials of enobosarm 3 mg to prevent and treat muscle wasting in non-small cell lung cancer patients by an independent Data Safety Monitoring Board (DSMB) resulted in a determination that GTx continues as planned the two Phase 3 clinical trials. The DSMB has met every six months to review safety data from the studies and will not meet again until data from both studies are locked and unblinded for a final assessment of safety data from the two studies.

Enobosarm 9 mg, being studied for the treatment of advanced breast cancer: GTx is initiating a Phase 2, open label clinical study evaluating enobosarm 9 mg for the treatment of estrogen receptor (ER) positive metastatic breast cancer in women who have previously responded to hormonal therapy for the treatment of their advanced breast cancer. This proof of concept study will enroll twenty (20) postmenopausal women with ER positive metastatic breast cancer who have previously responded to hormone therapy at approximately six clinical sites in the United States. The women will receive oral 9 mg of enobosarm once a day until they show evidence of clinical progression or have completed 336 days of treatment with enobosarm. The primary endpoint is clinical benefit, which will be assessed at six months, and 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% decrease in the sum of the diameters of the targeted lesions) or stable disease (no disease progression from baseline).

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 nonselective androgens, with overall response rates ranging from 20 to 60%. Although these nonselective 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. Unlike steroidal androgens, enobosarm cannot be converted to an estrogen that could be detrimental in 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 primary 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 castration resistant prostate cancer. The Phase 2 study will evaluate the safety and effectiveness of three lower doses of GTx-758. The primary endpoint will be to reduce serum prostate specific antigen, or PSA, by day 90. Other key endpoints include serum sex hormone binding globulin (SHBG) levels, total and free testosterone levels, and progression free survival in the study subjects. In addition, the clinical study will evaluate 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.

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Seventy-five men with metastatic castration resistant prostate cancer are being enrolled into one of three cohorts of 125 mg, 250 mg or 500 mg daily dose of GTx-758. Each arm will have 25 patients and the enrollment will be conducted sequentially, with the 125 mg cohort being the first to be enrolled. The

enrollment into the next higher dose of GTx-758 will commence if an acceptable incidence of venous thromboembolic events is observed among patients for 30 days following enrollment of the last patient in the previous cohort and management decides to continue testing at the next higher dose.

Data from previous clinical and preclinical studies have demonstrated the ability of GTx-758 to increase the production of a protein called SHBG, thereby reducing free testosterone levels. By reducing free testosterone, GTx believes serum PSA will be reduced in men with castration resistant prostate cancer. GTx believes GTx-758 has the potential to reduce free testosterone without also causing certain estrogen deficiency side effects, such as bone loss, hot flashes and insulin resistance, which are common with current androgen deprivation therapies for prostate cancer. GTx also believes that GTx-758 may be effective, in combination with ADT, as a primary treatment of advanced prostate cancer by reducing free testosterone to levels lower than those attainable with ADT alone while potentially reducing the estrogen deficiency side effects caused by the use of ADT.

Financial highlights for the quarter ended March 31, 2013

The Company reported a net loss for the quarter ended March 31, 2013 of \$12.6 million compared to a net loss of \$11.1 million for the same period in 2012. The net loss for the first quarter of 2012 was partially offset by income from discontinued operations of \$1.3 million related to sales of FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of metastatic breast cancer in postmenopausal women in the United States. The Company sold its rights to FARESTON® in September 2012.

Research and development expenses for the quarter ended March 31, 2013 were \$9.6 million compared to \$9.8 million for the same period of 2012. General and administrative expenses for the quarter ended March 31, 2013 were \$3.0 million compared to \$2.6 million for the same period of 2012.

At March 31, 2013, GTx had cash and short-term investments of \$42.2 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 866-953-6857 from the United States or Canada or 617-399-3481 from other international locations. The access code for the call is 86834278. A playback of the call will be available from approximately 11:00 a.m. Eastern Time today through May 17, 2013 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 55193186. Additionally, you may

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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, 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 will not be able to commercialize its product candidates if clinical trials do not demonstrate safety and efficacy in humans; (ii) that GTx may not be able to obtain required regulatory approvals to commercialize its product candidates in a timely manner or at all; (iii) that clinical trials being conducted by GTx may not be completed on schedule, or at all, or may otherwise be suspended or terminated; or (iv) that GTx could utilize its available cash resources sooner than it currently expects and may be unable to raise capital when needed, which would force GTx to delay, reduce or eliminate its product candidate development programs or commercialization efforts. 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 5, 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.

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

	March 31, 2013 (unaudited)	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 36,136	\$ 48,044
Short-term investments	6,085	8,045
Prepaid expenses and other current assets	1,375	726
Total current assets	43,596	56,815
Property and equipment, net	389	507
Intangible and other assets, net	713	452

Total assets	\$ 44,698	\$ 57,774
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,100	\$ 1,707
Accrued expenses and other current liabilities	7,049	7,788
Total current liabilities	8,149	9,495
Other long-term liabilities	488	578
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 120,000,000 shares authorized at both March 31, 2013 and December 31, 2012; 62,893,791 and 62,818,424 shares issued and outstanding at March 31, 2013 and December 31, 2012, respectively	63	63
Additional paid-in capital	461,829	460,887
Accumulated deficit	(425,831)	(413,249)
Total stockholders' equity	36,061	47,701
Total liabilities and stockholders' equity	\$ 44,698	\$ 57,774

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

	Three Months Ended March 31,	
	2013	2012
Expenses:		
Research and development expenses	\$ 9,614	\$ 9,835
General and administrative expenses	3,023	2,588
Total expenses	12,637	12,423
Loss from operations	(12,637)	(12,423)
Other income, net	55	8
Loss from operations before income taxes	(12,582)	(12,415)
Income tax benefit	—	381
Net loss from continuing operations	(12,582)	(12,034)
Income from discontinued operations before income taxes	—	1,335
Income tax expense	—	(381)
Net income from discontinued operations	—	954
Net loss	\$ (12,582)	\$ (11,080)
Net loss per share - basic and diluted:		
Net loss from continuing operations	\$ (0.20)	\$ (0.19)
Net income from discontinued operations	—	0.01
Net loss per share	\$ (0.20)	\$ (0.18)
Weighted average shares outstanding:		
Basic and diluted	62,864,140	62,798,008

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