

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 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) **February 21, 2013**

GTx, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

000-50549
(Commission
File Number)

62-1715807
(I.R.S. Employer
Identification No.)

**175 Toyota Plaza
7th Floor
Memphis, Tennessee 38103
(901) 523-9700**

(Address, including zip code, and telephone number,
including area code, of registrant's principal executive offices)

(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 communications 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 February 21, 2013, GTx, Inc. issued its financial press release for the fourth quarter and year ended December 31, 2012, 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

99.1 Press Release issued by GTx, Inc. dated February 21, 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: February 21, 2013

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 2012 FINANCIAL RESULTS

MEMPHIS, TN. — February 21, 2013 — GTx, Inc. (Nasdaq: GTXI) today provided a Company update and reported financial results for the fourth quarter and full year 2012.

“We have completed enrollment of our two pivotal Phase III clinical trials evaluating enobosarm for the prevention and treatment of muscle wasting in non-small cell lung cancer patients,” said Mitchell S. Steiner, MD, CEO of GTx. “We are pleased that FDA has recognized enobosarm as a potentially important new drug product to address the serious and unmet medical need of muscle wasting in this lung cancer population by recently granting enobosarm fast track designation.”

Clinical updates

Enobosarm (Ostarine®, GTx-024), 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 completed enrollment in late December of subjects with advanced non-small cell lung cancer in two pivotal Phase III clinical trials, POWER 1 and POWER 2. These international Phase III studies 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 response rates of enobosarm 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. 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 and safety assessments, as well as an update on survival.

In January, GTx announced that the FDA has designated enobosarm 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.

Capesaris® (GTx-758), 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 has initiated an open-label, Phase II clinical study of Capesaris to treat men with metastatic castration resistant prostate cancer. The Phase II study will evaluate the safety and effectiveness of three lower doses of Capesaris. 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 Capesaris to treat certain estrogen deficiency side effects associated with LHRH agonists such as hot flashes, bone loss, and insulin resistance.

Seventy-five men with metastatic castration resistant prostate cancer will be randomized into one of three cohorts of 125 mg, 250 mg or 500 mg daily dose of Capesaris. 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 Capesaris will commence if an acceptable incidence of venous thromboembolic events is observed among randomized patients for 30 days following enrollment of the last patient in the previous cohort.

Capesaris is an oral nonsteroidal selective estrogen receptor alpha agonist which GTx is developing for the treatment of advanced prostate cancer. Data from previous clinical and preclinical studies have demonstrated the ability of Capesaris 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 Capesaris 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 Capesaris may be effective, in combination with ADT, as a primary treatment of advanced prostate cancer by reducing free testosterone to levels lower than what is attainable with ADT alone and potentially reducing the estrogen deficiency side effects caused by the use of ADT.

Financial highlights for the quarter and year ended December 31, 2012

The Company reported a net loss of \$10.7 million for both the quarter ended December 31, 2012 and the quarter ended December 31, 2011. For the year ended December 31, 2012, the Company reported a net loss of \$27.1 million, which included a gain of \$18.8 million on 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. The Company reported a net loss of \$33.3 million for the year ended December 31, 2011, which included collaboration revenue of \$8.1 million.

Research and development expenses for the quarter and year ended December 31, 2012 were \$10.1 million and \$38.9 million, respectively, compared to \$8.9 million and \$31.9 million for the same periods of 2011. General and administrative expenses for the quarter and year ended December 31, 2012 were \$2.9 million and \$10.8 million, respectively, compared to \$3.1 million and \$12.0 million for the same periods of 2011.

At December 31, 2012, GTx had cash and short-term investments of \$56.1 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 866-203-2528 from the United States or Canada or 617-213-8847 from other international locations. The access code for the call is 43547305. A playback of the call will be available from approximately 11:00 a.m. Eastern Time today through March 7, 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 89559013. 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, 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 (also known as Ostarine[®] or GTx-024) and its clinical trial of Capesaris[®] (GTx-758). 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 quarterly report on Form 10-Q filed with the Securities and Exchange Commission on November 8, 2012 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 and per share data)
(unaudited)

	<u>December 31,</u>	
	<u>2012</u>	<u>2011</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 48,044	\$ 63,745
Short-term investments	8,045	10,695
Accounts receivable, net	9	981
Inventory	—	161
Prepaid expenses and other current assets	717	1,266
Total current assets	<u>56,815</u>	<u>76,848</u>
Property and equipment, net	507	1,096
Intangible and other assets, net	452	712
Total assets	<u>\$ 57,774</u>	<u>\$ 78,656</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,707	\$ 1,219
Accrued expenses and other current liabilities	7,788	4,614
Total current liabilities	<u>9,495</u>	<u>5,833</u>
Other long-term liabilities	578	949
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 120,000,000 shares authorized at both December 31, 2012 and December 31, 2011; 62,818,424 and 62,790,223 shares issued and outstanding at December 31, 2012 and December 31, 2011, respectively	63	63
Additional paid-in capital	460,887	457,985
Accumulated deficit	(413,249)	(386,174)
Total stockholders' equity	<u>47,701</u>	<u>71,874</u>
Total liabilities and stockholders' equity	<u>\$ 57,774</u>	<u>\$ 78,656</u>

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

	Three Months Ended December 31,		Year Ended December 31,	
	2012	2011	2012	2011
Revenues:				
Collaboration revenue	\$ —	\$ —	\$ —	\$ 8,066
Expenses:				
Research and development expenses	10,051	8,863	38,887	31,938
General and administrative expenses	2,858	3,141	10,845	12,027
Total expenses	12,909	12,004	49,732	43,965
Loss from operations	(12,909)	(12,004)	(49,732)	(35,899)
Other (expense) income, net	(33)	66	(19)	398
Loss from operations before income taxes	(12,942)	(11,938)	(49,751)	(35,501)
Income tax benefit	2,273	298	8,821	886
Net loss from continuing operations	(10,669)	(11,640)	(40,930)	(34,615)
Income (loss) from discontinued operations before income taxes	(76)	1,256	22,676	2,207
Income tax benefit (expense)	30	(298)	(8,821)	(886)
Net (loss) income from discontinued operations	(46)	958	13,855	1,321
Net loss	\$ (10,715)	\$ (10,682)	\$ (27,075)	\$ (33,294)
Net (loss) income per share - basic and diluted:				
Net loss from continuing operations	\$ (0.17)	\$ (0.19)	\$ (0.65)	\$ (0.60)
Net income from discontinued operations	—	0.02	0.22	0.02
Net loss per share	\$ (0.17)	\$ (0.17)	\$ (0.43)	\$ (0.58)
Weighted average shares outstanding:				
Basic and diluted	62,817,495	62,790,223	62,809,219	57,359,466