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) **November 12, 2013**

GTx, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**000-50549**	**62-1715807**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

175 Toyota Plaza 7th Floor Memphis, Tennessee	**38103**
(Address of Principal Executive Offices)	(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 November 12, 2013, GTx, Inc. issued its financial press release for the third quarter ended September 30, 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	**Description**
99.1	Press Release issued by GTx, Inc. dated November 12, 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: November 12, 2013

GTx, Inc.

By: /s/ Mark E. Mosteller
Name: Mark E. Mosteller
Title: Vice President and Chief Financial Officer

Exhibit 99.1

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

GTx PROVIDES CORPORATE UPDATE AND REPORTS THIRD QUARTER 2013 FINANCIAL RESULTS

Further POWER Trial Analyses Add Support for Potential Regulatory Path for Enobosarm

MEMPHIS, TN. — November 12, 2013 — GTx, Inc. (Nasdaq: GTXI) today provided a Company update and reported financial results for the third quarter of 2013. The Company summarized additional analyses it has undertaken of the POWER1 and POWER2 clinical trials evaluating enobosarm 3 mg for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer (NSCLC). Using longitudinal continuous variable analyses, which was the statistical analysis pre-specified by the Company for submission of its data to the European regulatory authorities, enobosarm 3 mg demonstrated significant improvement in stair climb power, compared to placebo, in the POWER1 (platinum plus taxane) trial. While the same analyses showed unequivocal improvements in lean body mass, compared to placebo, in both POWER trials, enobosarm 3 mg did not show statistically significant improvements in stair climb power in the POWER2 (platinum + non-taxane) trial. The Company is continuing to consider the reasons that maintaining or improving lean body mass in the POWER2 trial did not translate into similar improvements in stair climb power, compared to placebo, but it believes it may be associated with the side effects of the non-taxane chemotherapy received by the patients in the study, including anemia in many of the patients.

“Since August, when we reported topline results from our two Phase 3 clinical trials of enobosarm to prevent and treat muscle wasting in non-small cell lung cancer patients, we have learned a good deal more from the POWER results and remain encouraged by enobosarm’s potential,” said Mitchell S. Steiner, MD, CEO of GTx. “We look forward to upcoming regulatory discussions and to potentially clarifying a path to market approval for this important new drug product candidate.”

The Company plans to meet with representatives from select member countries of the European Medicines Agency (EMA) and with the United States Food and Drug Administration (FDA) to review and discuss the results of the clinical trials as well as a feasible regulatory path forward.

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 recently announced 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. However, data from the studies have demonstrated enobosarm’s consistent effect on maintaining or improving lean body mass, compared to placebo. Pursuant to responder analyses, a larger proportion of patients receiving enobosarm maintained or increased lean body mass at both Day 84 and Day 147 in both clinical trials, compared to placebo. Using longitudinal continuous variable statistical analyses, which is the analysis the Company pre-specified in its statistical analysis plan for data to be submitted to the European regulatory authorities, enobosarm 3 mg had a significant effect on lean body mass through Day 84 and Day 147 in both clinical trials, compared to placebo (POWER1: p=0.0002 and <0.0001, respectively, and POWER2: p=0.0227 and 0.0036, respectively). Using this analysis, the POWER1 (platinum plus taxane) clinical study met the pre-specified primary endpoint of physical function for stair climb power through Day 84 (p=0.0147) and the secondary endpoint of stair climb power through Day 147 (p=0.0492).

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 March or April of 2014. To date, the Company has seen no adverse effect on survival from enobosarm treatment from pooled survival data. However, post-hoc landmark survival analyses of lean body mass responders at Day 84 suggest

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improved survival in patients who maintained or increased lean body mass in both clinical studies, regardless of treatment, potentially reinforcing the importance of building lean body mass in this patient population.

Enobosarm was well tolerated in both clinical studies. Although only minor differences in adverse events were observed between the groups with enobosarm 3 mg 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 and nausea and vomiting being more prevalent in the POWER2 (platinum plus non-taxane) clinical trial.

The POWER trials were designed to study the effectiveness and safety of a 3 mg dose of enobosarm to prevent and treat muscle wasting in patients with NSCLC. In each of these placebo controlled, double blind, add-on clinical trials, approximately 325 patients with stage III or IV NSCLC were randomized to oral daily doses of placebo or enobosarm 3 mg at the time they began first-line standard platinum doublet chemotherapy. The effect of enobosarm versus placebo on the maintenance or improvement of total lean body mass (muscle) was assessed by Dual-energy X-ray Absorptiometry and patients’ improvement in physical function was measured by stair climb power. Durability of enobosarm treatment was assessed at five months. Secondary endpoints included an assessment of whether enobosarm-treated patients had an improved quality of life and reduced healthcare resource utilization compared to placebo. Overall survival is being assessed as an additional safety endpoint.

Enobosarm 9 mg, being studied for the treatment of advanced breast cancer: GTx has initiated 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 is enrolling approximately 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 in the study are receiving an oral 9 mg dose of enobosarm once a day until they show evidence of clinical progression or have completed 336 days of treatment with enobosarm. The primary endpoint of the study is clinical benefit response, 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 percent 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 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.

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, 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 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-758 125 mg 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 125 mg and 250 mg dosing arms to 38 patients per arm. Enrollment in the 125 mg cohort is continuing with no reported venous thromboembolic events (VTEs) or other significant adverse events to date. Assuming there continues to be no unacceptable incidence of VTEs observed in the patients being dosed at 125 mg of GTx-758, the Company will then determine whether it will proceed with the dosing of the 250 mg cohort.

Upcoming Milestones

- Meet with European and U.S. regulatory authorities in the coming months to clarify enobosarm regulatory requirements
- Report survival results from enobosarm POWER trials (survival is being assessed as a safety endpoint and is expected mid way through the first half of 2014)
- Complete enrollment this quarter of a Phase 2, open-label clinical study to evaluate enobosarm 9 mg for the potential treatment of metastatic breast cancer (primary endpoint assessment of clinical response is expected in the second quarter of 2014)
- Complete enrollment this quarter of the expanded 125 mg dosing arm for the Phase 2, open-label clinical study to evaluate GTx-758 for the treatment of men with metastatic, castration-resistant prostate cancer

Financial highlights for the quarter ended September 30, 2013

The Company reported a net loss for the quarter ended September 30, 2013 of $8.9 million compared to net income of $5.1 million for the same period in 2012. The net income for the quarter ended September 30, 2012 resulted 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, for which the Company recognized a gain of $18.8 million. For the nine months ended September 30, 2013, the

Company reported a net loss of $34.3 million compared to a net loss of $16.4 million for the same period of 2012.

Research and development expenses for the quarter ended September 30, 2013 were $6.5 million compared to $9.8 million for the same period of 2012. General and administrative expenses for the quarter ended September 30, 2013 were $2.5 million compared to $3.0 million for the same period of 2012.

At September 30, 2013, GTx had cash and short-term investments of $21.0 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 800-706-7745 from the United States or Canada or 617-614-3472 from other international locations. The access code for the call is 23964715. A playback of the call will be available from approximately 1:00 p.m. Eastern Time today through November 26, 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 68864622. 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; (ii) that clinical trials being conducted by GTx may not be completed on schedule, or at all, or may otherwise be suspended or terminated; or (iii) 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. 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 being filed with the Securities and Exchange Commission later today 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)

	September 30, 2013 (unaudited)	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,283	$ 48,044
Short-term investments	1,675	8,045
Prepaid expenses and other current assets	830	726
Total current assets	21,788	56,815
Property and equipment, net	217	507
Intangible and other assets, net	487	452
Total assets	$ 22,492	$ 57,774
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,253	$ 1,707
Accrued expenses and other current liabilities	3,912	7,788
Total current liabilities	5,165	9,495
Other long-term liabilities	389	578
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value: 120,000,000 shares authorized at both September 30, 2013 and December 31, 2012; 63,185,389 and 62,818,424 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	63	63
Additional paid-in capital	464,445	460,887
Accumulated deficit	(447,570)	(413,249)
Total stockholders' equity	16,938	47,701
Total liabilities and stockholders' equity	$ 22,492	$ 57,774

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Expenses:				
Research and development expenses	$ 6,477	$ 9,764	$ 26,230	$ 28,836
General and administrative expenses	2,483	2,999	8,190	7,987
Total expenses	8,960	12,763	34,420	36,823
Loss from operations	(8,960)	(12,763)	(34,420)	(36,823)
Other income, net	23	(47)	99	14
Loss from operations before income taxes	(8,937)	(12,810)	(34,321)	(36,809)
Income tax benefit	—	5,812	—	6,548
Net loss from continuing operations	(8,937)	(6,998)	(34,321)	(30,261)

Income from discontinued operations before income taxes	—	20,214	—	22,752
Income tax expense	—	(8,115)	—	(8,851)
Net income from discontinued operations	—	12,099	—	13,901
Net income (loss)	$ (8,937)	$ 5,101	$ (34,321)	$ (16,360)
Net income (loss) per share - basic and diluted:				
Net loss from continuing operations	$ (0.14)	$ (0.11)	$ (0.54)	$ (0.48)
Net income from discontinued operations	—	0.19	—	0.22
Net income (loss) per share	$ (0.14)	$ 0.08	$ (0.54)	$ (0.26)
Weighted average shares outstanding:				
Basic and diluted	63,179,394	62,815,549	63,013,923	62,806,440