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) **August 5, 2014**

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 August 5, 2014, GTx, Inc. issued its financial press release for the second quarter ended June 30, 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	**Description**
99.1	Press Release issued by GTx, Inc. dated August 5, 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: August 5, 2014

GTx, Inc.

By: /s/ Henry P. Doggrell
Name: Henry P. Doggrell
Title: Vice President, Chief Legal Officer and Secretary

GTx PROVIDES CORPORATE UPDATE AND REPORTS SECOND QUARTER 2014 FINANCIAL RESULTS

MEMPHIS, TN. — August 5, 2014 — GTx, Inc. (Nasdaq: GTXI) today reported financial results for the quarter and six months ended June 30, 2014. The Company also highlighted clinical development progress with enobosarm, an oral selective androgen receptor modulator, as well as progress with GTx-758, its oral nonsteroidal selective estrogen receptor alpha agonist, being studied for secondary hormonal therapy in men with castration-resistant prostate cancer.

Recent Highlights

Enobosarm 9 mg is being developed for the targeted treatment of androgen receptor positive and estrogen receptor positive metastatic breast cancer: At the American Society of Clinical Oncology (ASCO) 50th Annual Meeting, GTx reported positive preliminary results from a Phase 2 trial of enobosarm 9 mg, currently in development for the treatment of patients with androgen receptor (AR) positive and estrogen receptor (ER) positive metastatic breast cancer who have previously responded to hormonal therapy. The primary endpoint of the Phase 2 trial is the proportion of subjects with clinical benefit at 6 months in subjects with AR positive metastatic lesions. Clinical benefit is defined as those patients who have either stable disease, a complete response, or a partial response as defined in the modified RECIST 1.1 criteria.

- The primary endpoint was assessed in 17 AR positive patients, with 6 patients demonstrating clinical benefit at six months, exceeding the pre-defined statistical threshold requiring that at least 3 of 14 patients with an AR positive metastatic lesion demonstrate clinical benefit.
- Of the 6 patients that have demonstrated clinical benefit, 3 patients currently remain on study with each surpassing 270 days with stable disease.
- The results also demonstrated that, after a median duration on study of 81 days, 41 percent of all patients (9/22) achieved clinical benefit as best response and also had increased prostate specific antigen, or PSA, which appears to be an indicator of AR activity.
- Enobosarm was well tolerated; the most common adverse events were pain, fatigue, nausea, hot flash/night sweats, and arthralgia.
- The Company plans to conduct additional clinical development of enobosarm 9 mg in patients with AR positive metastatic breast cancer, subject to the ability to obtain additional funding.

Enobosarm 3 mg is being developed for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer: GTx continues to evaluate whether data from the POWER trials are sufficient to support a filing of a Marketing Authorization Application (MAA) with the European Medicines Agency, as well as the commercial prospects for enobosarm 3 mg for the indication of prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer (NSCLC) treated with platinum plus taxane chemotherapy.

- In the POWER trials, survival was assessed as a safety endpoint to determine that enobosarm treatment did not adversely affect survival. This quarter, a final analysis for survival was performed following 450 deaths in patients in both studies. There were no statistical differences in survival between subjects in the placebo and enobosarm arms.

GTx-758 (Capesaris®) is 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 continues to enroll patients in an open-label, Phase 2 clinical study of GTx-758 to treat men with metastatic and non-metastatic castration-resistant prostate cancer (CRPC) and is evaluating the safety and efficacy of two doses (125 mg and 250 mg oral daily dosing) 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. Enrollment in the 125 mg arm has been completed and, after a pre-specified safety review by the independent Data Safety Monitoring Board identified no safety concerns, the Company commenced enrollment in the 250 mg arm.

- The Company is enrolling the 250 mg arm with both high risk non-metastatic and metastatic CRPC patients.
- The Company expects enrollment to be completed in 2014 and top-line results to be available during the first quarter of 2015.

Second Quarter and Six Months 2014 Financial Results

The net loss for the quarter ended June 30, 2014 was $10.9 million compared to a net loss of $12.8 million for the same period in 2013. The net loss for the six months ended June 30, 2014 was $19.9 million compared to a net loss of $25.4 million for the same period in 2013.

Research and development expenses for the quarter ended June 30, 2014 were $7.9 million compared to $10.1 million for the same period of 2013. General and administrative expenses for the quarter ended June 30, 2014 were $3.1 million compared to $2.7 million for the same period of 2013.

At June 30, 2014, GTx had cash and short-term investments of $17.3 million.

About enobosarm (GTx-024) 9 mg

Enobosarm 9 mg, an oral selective androgen receptor modulator, is being studied for the targeted treatment of androgen receptor positive and estrogen receptor positive metastatic breast cancer. 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 treatment with 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. Additionally, women with metastatic breast cancer receiving treatment with enobosarm may receive the benefit of increased lean body mass, reduction in fat mass and improvement in physical function.

In the enobosarm 9 mg Phase 2 proof-of-concept, open-label clinical trial in the US, we enrolled 22 postmenopausal women with advanced breast cancer to assess clinical benefit response after six months of enobosarm 9 mg treatment, which was defined as those women receiving treatment who have

demonstrated (i) a complete response (disappearance of all targeted lesions), (ii) a partial response (at least a 30 percent decrease in the sum of the diameters of the targeted lesions), or (iii) stable disease (no disease progression from baseline). Of the 22 patients enrolled in the study, a total of 20 patients had one or more scheduled assessments for determination of clinical benefit. The primary endpoint was assessed in 17 AR positive patients, with 6 patients demonstrating clinical benefit at six months, exceeding the pre-defined statistical threshold requiring that at least 3 of 14 patients with an AR positive metastatic lesion demonstrate clinical benefit. A total of 7 patients achieved clinical benefit at six months, which includes one patient whose AR status could not be determined. The results also demonstrated that, after a median duration on study of 81 days, 41 percent of all patients (9/22) achieved clinical benefit as best response and also had increased prostate specific antigen, or PSA, which appears to be an indicator of AR activity. The 7 patients achieving clinical benefit (which included 6 of the 17 patients with AR positive metastatic lesions, or 35 percent) had stable disease. No confirmed complete or partial responses have been observed in the study, although 3 patients currently remain on study past 270 days as their disease has continued to remain stable. Enobosarm was well tolerated. The most common adverse events, or AEs, reported were pain, fatigue, nausea, hot flash/night sweats, and arthralgia. The majority of AEs were Grade 1. There were two serious adverse events, or SAEs, reported during the study. Only one of the SAEs, bone pain of the chest cage, was assessed as possibly related to enobosarm.

About enobosarm (GTx-024) 3 mg

Enobosarm 3 mg, an oral selective androgen receptor modulator, is being developed for the prevention and treatment of muscle wasting in patients with advanced NSCLC. 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 3 mg for the prevention and treatment of muscle wasting in patients with advanced NSCLC failed to achieve the statistical significance required by the Food and Drug Administration (FDA) for marketing approval in the US, GTx 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.

Enobosarm 3 mg demonstrated a statistically significant effect versus placebo on the primary endpoint of physical function through Day 84 in the POWER 1 clinical trial as assessed by continuous variable analysis, as pre-specified in our statistical analysis plan for the European Medicines Agency (EMA). Therefore, we met with representatives from two member countries to the EMA in January 2014 to review and discuss the results of the POWER trials to determine an appropriate path forward for submitting a MAA in the EU for enobosarm 3 mg for the prevention and treatment of muscle wasting in patients with advanced NSCLC. 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 for enobosarm 3 mg in the more narrow indication of the prevention and treatment of muscle wasting in patients with advanced NSCLC treated with platinum plus taxane chemotherapy. Although we have undertaken certain activities which are required for the submission of a MAA, we are continuing to evaluate whether data from the POWER trials are sufficient to support the filing of a MAA and whether the commercial prospects for enobosarm 3 mg warrant the filing of a MAA for this indication.

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, 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 the FDA. The Company is evaluating options for further development of enobosarm 3 mg in the US.

Enobosarm was well tolerated in both POWER trials. 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 being more prevalent in the POWER2 (platinum plus non-taxane) clinical trial. Survival was assessed as another safety endpoint to determine that enobosarm treatment did not adversely affect survival. A final analysis for survival was performed following 450 deaths in patients in both studies, which occurred in June of 2014. There were no statistical differences in survival between subjects in the placebo and enobosarm arms.

About GTx-758 (Capesaris®)

GTx-758, an oral nonsteroidal selective estrogen receptor alpha agonist, is 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 efficacy of two doses (125 mg and 250 mg 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 125 mg arm has been completed without any incidences of venous thromboembolic events (VTEs) and, after a pre-specified safety review by the independent Data Safety Monitoring Board, the Company is now enrolling subjects in the 250 mg arm. Based upon the observed safety and efficacy in the 125 mg arm and with no safety issues having been observed in the first ten metastatic patients enrolled in the 250 mg arm, the Company is enrolling the remainder of the 250 mg arm with both high risk non-metastatic and metastatic CRPC patients, with the expectation that enrollment will be completed later this year. Data from the study is expected during the first quarter of 2015.

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, including treatments for breast and prostate 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 quarterly report on Form 10-Q, which is expected to be filed with the Securities and Exchange Commission on August 5, 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.

Contact:
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GTx, Inc.
901-523-9700

Source: GTx, Inc.

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

	June 30, 2014 (unaudited)	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,178	$ 14,529
Short-term investments	6,080	200
Prepaid expenses and other current assets	1,194	442
Total current assets	18,452	15,171
Property and equipment, net	58	112
Intangible and other assets, net	625	322
Total assets	$ 19,135	$ 15,605
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 992	$ 808
Accrued expenses and other current liabilities	2,711	3,759
Total current liabilities	3,703	4,567
Other long-term liabilities	147	354
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value: 200,000,000 and 120,000,000 shares authorized at both June 30, 2014 and December 31, 2013, respectively; 76,014,531 and 63,185,389 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively	76	63
Additional paid-in capital	490,500	465,981
Accumulated deficit	(475,291)	(455,360)
Total stockholders' equity	15,285	10,684
Total liabilities and stockholders' equity	$ 19,135	$ 15,605

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Expenses:				
Research and development expenses	$ 7,894	$ 10,139	$ 14,254	$ 19,753
General and administrative expenses	3,052	2,684	5,681	5,707

Total expenses	10,946	12,823	19,935	25,460
Loss from operations	(10,946)	(12,823)	(19,935)	(25,460)
Other income, net	2	21	4	76
Net loss	$ (10,944)	$ (12,802)	$ (19,931)	$ (25,384)
Net loss per share:				
Basic and diluted	$ (0.15)	$ (0.20)	$ (0.28)	$ (0.40)
Weighted average shares outstanding:				
Basic and diluted	75,433,302	62,994,771	70,997,330	62,929,816