GTX INC /DE/
Form 8-K
February 10, 2014

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 10, 2014**

GTx, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-50549**	**62-1715807**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. 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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01. Regulation FD Disclosure.

On February 10, 2014 at 3:30 p.m. Eastern Time, management of GTx, Inc. (the GTx or the Company) will present a company overview at the Bio CEO & Investor Conference in New York City (the Conference). At the Conference, GTx management will provide a business update that includes the information set forth below:

The Company announced in August 2013 that the POWER1 and POWER2 Phase 3 clinical trials (the POWER trials) evaluating enobosarm 3mg 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 assessed by responders analysis as agreed upon by the U.S. Food and Drug Administration (FDA). 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 for the prevention and treatment of muscle wasting in patients with advanced NSCLC. Based on input from the two national authorities, the Company is preparing to initiate seven Phase 1 studies and to develop a pediatric investigation plan (PIP) necessary for submission of the MAA. The Company currently expects to submit the MAA to the EMA for enobosarm 3mg by the first quarter of 2015, assuming successful completion of the Phase 1 studies and acceptance of the PIP by the EMA s Pediatric Committee. The Company also plans to meet with FDA later this calendar quarter to discuss an appropriate regulatory path forward in the U.S. for enobosarm 3mg for the prevention and treatment of NSCLC.

GTx also will provide an update on its Phase 2, open label study evaluating enobosarm 9mg oral daily for the treatment of estrogen receptor positive and androgen receptor (AR) 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). The Company will report that enobosarm 9mg continues to be well tolerated by patients in the study, and that the Company expects to meet the pre-specified goal of demonstrating, after six months of treatment, at least three clinical benefit responses in at least 14 patients with AR positive breast cancer. The study is ongoing and data from all patients in the study is expected late in the second quarter of 2014.

A simultaneous webcast of the presentation will be accessible from the Company s website at http://www.gtxinc.com. An archived replay of the presentation will be available on the Company s website until February 24, 2014.

The information in this Current Report on Form 8-K shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by GTx, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Forward-Looking Information is Subject to Risk and Uncertainty

This Current Report on Form 8-K 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 the potential submission of a MAA to the EMA for enobosarm 3mg and the timing thereof, the initiation of Phase 1 studies of enobosarm 3mg and the development of a PIP necessary for the potential submission of the MAA, GTx s plans to meet with the FDA, and GTx s expectations with respect to certain results of and the timing of reporting data from its Phase 2 study evaluating enobosarm 9mg. 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 be unable to successfully complete or develop, in a timely manner or at all, the Phase 1 studies and PIP necessary to enable the submission of the planned MAA; (ii) that the EMA may determine that the safety and efficacy data from the Company s POWER1 and POWER2 Phase 3 clinical trials evaluating enobosarm 3 mg for the prevention and treatment of muscle wasting in patients with advanced NSCLC are insufficient to support approval of the planned MAA submission and that one or more additional Phase 3 clinical trials of enobosarm 3mg would be required to be successfully conducted by GTx in order to support any such approval, which would severely harm GTx s prospects; (iii) related to the uncertain and time-consuming regulatory approval process, including the risk that GTx may not be able to obtain any regulatory approvals to commercialize enobosarm 3mg in a timely manner or at all; (iv) associated with the difficulty and uncertainty of pharmaceutical product development, including the timing and cost thereof, and the inherent uncertainty of clinical success and regulatory approval; (v) related to GTx s need for substantial additional capital, including the risk that GTx s existing capital resources are insufficient to support any additional Phase 3 clinical trials of enobosarm 3 mg; and (vi) that GTx could utilize its available cash resources sooner than it currently expects and may be unable to raise additional capital, 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 Current Report on Form 8-K. 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GTx, Inc.

Date:	February 10, 2014	By:	/s/ Henry P. Doggrell
		Name:	Henry P. Doggrell
		Title:	Vice President, Chief Legal Officer and Secretary