

**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, 2017**

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On May 3, 2017, GTx, Inc. issued a press release announcing the publication in the journal Human Molecular Genetics of results from preclinical studies supporting the potential efficacy of GTx's SARMS, including GTx-026, for DMD treatment.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|---|
| 99.1 | Press Release issued by GTx, Inc. dated May 3, 2017 |

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, 2017

GTx, Inc.

By: /s/ Henry P. Doggrell

Name: Henry P. Doggrell

Title: Vice President, Chief Legal Officer and Secretary

3

EXHIBIT INDEX

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|---|
| 99.1 | Press Release issued by GTx, Inc. dated May 3, 2017 |

4

GTx Announces Results from Preclinical Studies of SARMs in Duchenne Muscular Dystrophy Models Published in Human Molecular Genetics

— *GTx non-steroidal selective-androgen receptor modulators (SARMs) increased body weight, lean mass and physical function in preclinical models of Duchenne Muscular Dystrophy (DMD)* —

MEMPHIS, Tenn.—(BUSINESS WIRE)— May 3, 2017— GTx, Inc. (Nasdaq: GTXI) today announced the publication in the journal *Human Molecular Genetics* of results from preclinical studies supporting the potential efficacy of the Company's SARMs, and in particular GTx-026, for Duchenne Muscular Dystrophy (DMD) treatment. DMD is a rare genetic disorder characterized by progressive muscle degeneration and weakness, affecting approximately 18,000 boys in the United States.

Studies examined the treatment of castrated wildtype mice, x-linked muscular dystrophy (*mdx*) mice, and dystrophin and utrophin double mutant (*mdx-dm*) mice with GTx-026.

- In *mdx* mice, compared to vehicle-treated mice, GTx-026 treatment led to increased body weight (62% vs. 31%), lean mass (60% vs 20%), grip strength, and improved cardiac and pulmonary function
- In *mdx-dm* mice, compared to vehicle-treated mice, GTx-026 led to improved body weight, lean mass, and grip strength above baseline levels, leading to a 50 to 70% improvement in survival

Other SARMs in the Company's portfolio, GTx-024 (enobosarm) and GTx-027, showed similar positive effects on muscle mass, function, and histological characteristics.

"DMD typically afflicts boys around three to five years of age followed by declining physical functions before attaining puberty. Current treatment options for DMD rely on corticosteroids to reduce inflammation, but unfortunately the prolonged use of corticosteroids results in hyperglycemia, osteoporosis, and muscle wasting, which are all counterproductive in this disease," said Ramesh Narayanan, Ph.D., Director, Center for Cancer Drug Discovery and Associate Professor, Department of Medicine, University of Tennessee and a consultant for GTx, Inc. "We hypothesize that an androgen receptor agonist may reverse musculoskeletal complications and extend survival in these boys, and in preclinical models, GTx-026 increased muscle mass, function, and survival, therefore supporting the concept of a SARM to treat DMD-affected boys."

The Company's preclinical studies have continued to confirm beneficial effects from SARMs in mice genetically altered to simulate DMD, compared to control groups. The Company is pursuing a potential strategic collaboration with biopharma companies experienced in orphan drug development to advance the development of a SARM for the treatment of DMD.

The peer-reviewed article, "Androgen Receptor Agonists Increase Lean Mass, Improve Cardiopulmonary Functions, and Extend Survival in Preclinical Models of Duchenne Muscular Dystrophy" appears in the journal *Human Molecular Genetics* (April 27, 2017).

About SARMs

A selective androgen receptor modulator, or SARM, is a class of compound that can bind to the androgen receptor, but is not actually a steroid hormone. Enobosarm, one of the Company's SARMs, has been shown to increase muscle mass in patients with non-small cell lung cancer, and is currently being evaluated as a possible treatment of stress urinary incontinence in postmenopausal

women. Enobosarm has been evaluated in 24 completed or ongoing clinical trials, enrolling over 1,700 subjects, of which approximately 1,200 subjects were treated with enobosarm at doses ranging from 0.1 mg to 100 mg.

About DMD

Duchenne Muscular Dystrophy (DMD), is a rare, genetic disorder characterized by progressive muscle degeneration and weakness. It is caused by mutation(s) in dystrophin, a protein that helps to keep muscle cells intact. Symptom onset is in early childhood, usually between the ages of three and five, and the disease primarily affects boys. Until recently, boys with DMD did not survive much beyond their teen years or twenties, but with advances in cardiac and respiratory care, survival into the early thirties is becoming more common.

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, 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 the preclinical and potential future development of selective androgen receptor modulators (SARMs) for the treatment of Duchenne muscular dystrophy (DMD), as well as GTx's ongoing Phase 2 proof-of-concept clinical trial of enobosarm (GTx-024) to treat stress urinary incontinence (SUI). 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's evaluation of a SARM for the treatment of DMD is at a very early stage and it is possible that GTx may determine not to move forward with any meaningful development of the program; (ii) that if GTx determines to move forward with additional development of enobosarm for the treatment of SUI or if GTx does determine to move forward with meaningful development of a SARM for the treatment of DMD, GTx will require additional funding, which it may be unable to raise, in which case, GTx may fail to realize the anticipated benefits from its SARM technology; (iii) that GTx may not be successful in developing a SARM for the treatment of DMD to advance into clinical studies or the clinical product candidate may fail such clinical studies; (iv) that the clinical trial of enobosarm to treat SUI being conducted by GTx may not be completed on schedule, or at all, or may otherwise be suspended or terminated; (v) related to the difficulty and uncertainty of pharmaceutical product development, including the time and expense required to conduct preclinical and clinical trials and analyze data, and the uncertainty of preclinical

and clinical success; and (vi) related to issues arising during the uncertain and time-consuming regulatory process, including the risk that GTx may not receive any approvals to advance the clinical development of one or more potential clinical SARM candidates. In addition, 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. 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. 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 March 24, 2017, 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 Contacts

Lauren Crosby (Investors)
GTx, Inc.
901.271.8622
lcrosby@gtxinc.com

Denise Powell (Media)
Red House Consulting
510.703.9491
denise@redhousecomms.com

Source: GTx, Inc.
