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): May 23, 2008

GTx, Inc.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

005-79588

(Commission File Number)

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

3 N. Dunlap Street Van Vleet Building Memphis, Tennessee 38163 (901) 523-9700

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

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

ITEM 8.01 Other Events.

On May 23, 2008, GTx, Inc. issued a press release announcing the continuation of its Phase III PIN clinical trial, a copy of which is furnished as Exhibit 99.1 to this Current Report.

ITEM 9.01 Financial Statements and Exhibits.

(c) Exhibits

Exhibit Number 99.1

Description

Press Release issued by GTx, Inc. dated May 23, 2008

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.

GTx, Inc.

Date: May 23, 2008

By: <u>/s/ Henry P. Doggrell</u>
Name: Henry P. Doggrell
Title: Vice President, General Counsel/Secretary

Contact: McDavid Stilwell GTx, Inc. Director, Corporate Communications & Financial Analysis 901-523-9700

GTx Announces Phase III PIN Clinical Trial Will Continue As Planned

Memphis, TN — May 23, 2008 — GTx, Inc. (Nasdaq: GTXI) today announced that an independent biometrics group recommended that the Phase III clinical trial evaluating toremifene 20 mg in men with high grade prostatic intraepithelial neoplasia, or PIN, who are at increased risk for prostate cancer should continue as planned following an interim efficacy analysis. In order to preserve the integrity of the clinical trial and allow the study to continue without introducing bias, GTx did not receive data from the interim efficacy analysis.

This update does not change GTx's assessment of the study's probability of success.

"The interim efficacy analysis was an opportunity for an early look in this landmark Phase III PIN clinical trial," said Mitchell S. Steiner, MD, CEO of GTx. "Based on the strong supportive science and the fact that time is an important factor in cancer prevention studies, we are confident that the Phase III PIN clinical trial will demonstrate that toremifene 20 mg compared to placebo reduces prostate cancer. Additionally, the prespecified level of statistical significance required in the final efficacy decision is a lower statistical hurdle than was required in the interim analysis."

GTx will make a final determination about the toremifene 20 mg Phase III clinical trial after an efficacy analysis in the summer of 2009.

About the study

The three year, double blind, placebo controlled Phase III PIN clinical trial randomized 1,590 men with high grade PIN at 150 clinical sites in the United States and Canada. The primary endpoint of the event driven study is prostate cancer incidence.

About GTx

GTx, Inc., headquartered in Memphis, Tenn., is a biopharmaceutical company dedicated to the discovery, development, and commercialization of small molecules that selectively target hormone pathways to treat cancer, osteoporosis and bone loss, muscle wasting and other serious medical conditions. GTx is developing toremifene citrate, a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: first, a completed pivotal Phase III clinical trial evaluating toremifene citrate 80 mg for the treatment of serious side effects of androgen deprivation therapy for advanced prostate cancer, and second, an ongoing pivotal Phase III clinical trial evaluating toremifene citrate 20 mg for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia, or PIN. In 2006, GTx and Ipsen Group entered into a development and collaboration agreement for toremifene citrate in all indications except breast cancer for Europe and the Commonwealth of Independent States (CIS). GTx will file for marketing approval and, if approved, plans to commercialize toremifene citrate 80 mg in the United States. In December 2007, GTx and Merck & Co., Inc. formed a collaboration to discover and develop selective androgen receptor modulators (SARMs), a new class of drugs with the potential to treat sarcopenia, which is the loss of skeletal muscle mass resulting in reduced physical strength and ability to perform activities of daily living, cancer

cachexia (muscle wasting), as well as other musculoskeletal conditions. Merck and GTx are conducting several Phase I and Phase II clinical trials evaluating multiple SARM product candidates including Ostarine™ (also designated as MK-2866) for sarcopenia. Ostarine is also in a Phase II clinical trial for cancer cachexia which will be completed during the third quarter of 2008. Merck and GTx are evaluating additional muscle loss indications for potential SARM clinical development. GTx also is developing its preclinical compounds, GTx-758, an oral LH inhibitor for advanced prostate cancer, and GTx-878, an estrogen receptor beta agonist for the treatment of benign prostatic hyperplasia and chronic prostatitis.

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. 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 that (i) GTx and its collaboration partners will not be able to commercialize their product candidates if clinical trials do not demonstrate safety and efficacy in humans; (ii) GTx may not able to obtain required regulatory approvals to commercialize product candidates; (iii) clinical trials being conducted by GTx and its collaboration partners may not be completed on schedule, or at all, or may otherwise be suspended or terminated; and (iv) 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 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 May 12, 2008 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.