
**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 26, 2010 (May 25, 2010)

GTx, Inc.

(Exact name of registrant as specified in its charter)

| | | |
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| 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:

- Written communications 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))
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ITEM 8.01 Other Events.

On May 25, 2010, GTx, Inc. issued a press release announcing top line results of the Phase III clinical trial evaluating toremifene 20 mg, a selective estrogen receptor modulator, for the prevention of prostate cancer in men with high grade prostatic intraepithelial neoplasia, or PIN, a premalignant lesion of the prostate, a copy of which is furnished as Exhibit 99.1 to this Current Report.

ITEM 9.01 Financial Statements and Exhibits.

(c) Exhibits

| <u>Exhibit Number</u> | <u>Description</u> |
|---------------------------|--|
| 99.1 | Press Release issued by GTx, Inc. dated May 25, 2010 |

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 26, 2010

By: Is/ Henry P. Doggrell _____
Name: Henry P. Doggrell
Title: Vice President, General Counsel/Secretary

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

GTx Announces Top Line Results of Phase III Clinical Trial Evaluating Toremifene 20 mg for the Prevention of Prostate Cancer in Men with High Grade PIN

Memphis, May 25, 2010 – GTx, Inc. (Nasdaq: GTXI) today announced top line results of the Phase III clinical trial evaluating toremifene 20 mg, a selective estrogen receptor modulator, for the prevention of prostate cancer in men with high grade prostatic intraepithelial neoplasia, or PIN, a premalignant lesion of the prostate.

Incidence of prostate cancer was lower in men receiving toremifene 20 mg compared to placebo but not statistically significantly different ($p=0.385$). A 10.2% relative risk reduction at three years was observed. The primary endpoint of the study was the development of prostate cancer among men who had received at least one dose of study drug and had undergone at least one on-study prostate biopsy.

GTx randomized 1,590 men with high grade PIN into the three year clinical trial. In the study, there were no clinically significant differences in the adverse event safety profile between men treated with toremifene 20 mg and men receiving placebo. Venous thromboembolic events were similar among men receiving placebo and men taking toremifene 20 mg. Cardiovascular adverse events were also similar between the two study arms.

“We designed the Phase III trial based upon the successful outcome of our Phase IIb clinical trial. Toremifene 20 mg did also reduce prostate cancer in our Phase III study but based on our review of the topline data, there is not a sufficient reduction in cancers compared to placebo over a three year period to demonstrate the statistical significance required for this study,” said Dr. Mitchell S. Steiner, CEO of GTx. “We intend to review all data from the study this summer to better understand the trial results and the ability of toremifene 20 mg to reduce cancer among these high risk men.

“We are grateful to the nearly 1,600 men with high grade PIN and the hundreds of physicians and site coordinators who participated in this clinical trial,” Steiner said. “The study demonstrated that these patients are indeed at high risk for prostate cancer, with 45.5% of men in the placebo group developing prostate cancer within three years.”

Steiner continued: “GTx and Ipsen will pursue their partnership to develop toremifene 80 mg and are planning a second Phase III clinical trial evaluating toremifene 80 mg to reduce fractures and treat other estrogen deficiency side effects of androgen deprivation therapy for prostate cancer.”

GTx has submitted to FDA a protocol for the second toremifene 80 mg Phase III clinical trial and will meet with FDA this summer to finalize the trial design. GTx has secured funding for this clinical study through the expansion of its partnership with Ipsen which was announced March 23, 2010. GTx expects to initiate the TREAT 2 (Toremifene for Reduction of fractures and other Estrogen deficiency side effects in men on Androgen deprivation Therapy) Phase III clinical trial by year end 2010.

GTx is continuing to develop its pipeline of product candidates to address unmet medical needs. In addition to advancing toremifene 80 mg in the second Phase III clinical trial, GTx is expecting results of the Phase II clinical trial evaluating GTx-758, an oral LH inhibitor for first line treatment of advanced prostate cancer this summer and is planning late stage clinical trials for Ostarine™ (GTx-024) for the prevention and treatment of cancer induced muscle wasting (cancer cachexia).

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 for the treatment and prevention of cancer, the treatment of side effects of anticancer therapy, cancer supportive care, and other serious medical conditions.

GTx is developing toremifene 80 mg for the reduction of fractures and treatment of other estrogen deficiency side effects of androgen deprivation therapy for prostate cancer. GTx has completed a successful toremifene 80 mg Phase III clinical trial and expects to initiate TREAT 2, the second Phase III clinical trial by year end 2010.

GTx is also developing Ostarine™ (GTx-024) and other selective androgen receptor modulators, or SARMs, for cancer cachexia and other muscle wasting diseases. GTx is meeting with the FDA this summer to discuss the late stage clinical development plan for Ostarine for cancer cachexia.

GTx's newest product candidate is GTx-758, an oral LH inhibitor, which is in a Phase II clinical trial. GTx-758 has the potential to achieve medical castration without causing bone loss, hot flashes, impotence and other serious side effects of currently available androgen deprivation therapy for prostate cancer. GTx expects to receive results of the Phase II clinical trial in the summer of 2010.

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 include, but are not limited to, statements relating to GTx's plans to continue to pursue the development of and marketing approval for, and the potential commercialization of, toremifene 80 mg, and the continued development and potential commercialization of GTx's other product candidates. 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 (i) that GTx and its collaboration partner will not be able to commercialize their product candidates if clinical trials do not demonstrate safety and efficacy in humans, including in any additional clinical trials that GTx may conduct for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT; (ii) that GTx may not be able to obtain required regulatory approvals to commercialize its product candidates, including toremifene 80 mg to reduce fractures in men with prostate cancer on ADT, in a timely manner or at all; (iii) that clinical trials being conducted or planned to be conducted by GTx and its collaboration partner may not be initiated or completed on schedule, or at all, or may otherwise be suspended or terminated; (iv) related to GTx's dependence on its collaboration partner for product candidate development and commercialization efforts; (v) related to GTx's reliance on third parties to manufacture its product candidates and to conduct its clinical trials; and (vi) 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 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 annual report on Form 10-Q filed with the SEC on May 4, 2010 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.