



**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**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 25, 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)

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(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)
  - 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 February 25, 2008, GTX, Inc. issued a press release announcing positive Phase III clinical trial results for toremifene citrate 80 mg, the Company's investigational therapy for the treatment of multiple side effects of androgen deprivation therapy (ADT) for advanced prostate cancer, 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 February 25, 2008

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**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: February 25, 2008

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

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

**GTx's Toremifene Citrate 80 mg Meets Primary and Key Endpoints in Phase III Trial in  
Advanced Prostate Cancer Patients on Androgen Deprivation Therapy**

***Results Show a 50 Percent Reduction in Incidence of Androgen Deprivation Induced  
Osteoporosis Related Vertebral Fractures***

Memphis, TN — February 25, 2008 — GTx, Inc. (Nasdaq: GTXI) today announced Phase III clinical data for toremifene citrate 80 mg, the Company's investigational therapy for the treatment of multiple side effects of androgen deprivation therapy (ADT) for advanced prostate cancer. Results show that toremifene citrate 80 mg reduced vertebral fractures and met other key endpoints, including bone mineral density, lipid profiles, and gynecomastia.

Based on these findings, GTx plans to file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) by the summer of 2008. In addition, GTx plans to present the full data set at an upcoming medical meeting.

"The toremifene citrate 80 mg Phase III ADT clinical trial is the first fracture prevention study in men receiving ADT for prostate cancer. The study confirms that men receiving ADT are at high risk for fractures. The rate of vertebral fracture in the placebo group in this study was about 10 times greater than that expected for men of a similar age not receiving ADT, as reported in other studies," said Matthew R. Smith, MD, PhD, Director, Genitourinary Medical Oncology, Massachusetts General Hospital Cancer Center, Associate Professor of Medicine at Harvard Medical School, and Lead Principal Investigator of the Phase III ADT clinical trial.

"Androgen deprivation therapy is the cornerstone treatment for men with advanced prostate cancer, but has been associated with serious side effects. The results from this exciting study demonstrate that toremifene citrate 80 mg reduced fractures and other side effects in men taking ADT," added Dr. Smith.

**About the Disease**

Androgen deprivation therapy is the most common treatment for advanced prostate cancer, used in approximately 800,000 men. ADT (e.g. leuprolide/triptorelin injections) is hormone therapy that works by reducing testosterone and estrogen. This may result in multiple estrogen related side effects, including bone loss and fractures, hot flashes, lipid changes and increased cardiovascular risk, and gynecomastia. Studies have shown that men on ADT are at risk for fractures, and ADT patients who develop a fracture have a 39 month shorter median survival. ADT has also been associated with increased risk of cardiovascular disease and death. There are no drugs approved by the FDA to treat multiple side effects of ADT for prostate cancer. Men with prostate cancer of a similar age who are not on ADT have a vertebral fracture rate of approximately 0.3% over two years.

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## About the Study

The two year double-blind, placebo-controlled study randomized 1,389 ADT patients at approximately 150 clinical sites in the United States and Mexico. The primary endpoint was new morphometric vertebral fractures read by an independent third party. Other key endpoints included bone mineral density, lipid changes, hot flashes, and gynecomastia.

## Fracture endpoints

In a modified intent to treat analysis which included all patients with at least one evaluable study radiograph and a minimum of one dose of study drug or placebo, toremifene citrate 80 mg demonstrated a 50% reduction in morphometric vertebral fractures ( $p < 0.05$ ; 5% fracture rate in the placebo group). The estimated two year fracture rate for new morphometric vertebral fractures in the placebo group was 6.2%. In an intent to treat analysis which included all patients randomized into the trial, toremifene citrate 80 mg demonstrated a 53% reduction in new morphometric vertebral fractures ( $p = 0.034$ ; 3.6% fracture rate in the placebo group).

In prespecified subset analyses, in study patients who were greater than 80% treatment compliant, toremifene citrate 80 mg reduced vertebral morphometric fractures by 61% ( $p = 0.017$ ). When study patients who had greater than 7% bone loss at one year and new morphometric vertebral fractures were considered as treatment failures, toremifene citrate 80 mg compared to placebo demonstrated a 56% reduction ( $p = 0.003$ ).

## Other key endpoints

Patients treated with toremifene citrate 80 mg compared to placebo demonstrated statistically significant increases in bone mineral density in the lumbar spine, hip, and femur skeletal sites (each site demonstrating  $p < 0.0001$ ). Toremifene citrate 80 mg treatment compared to placebo also resulted in a decrease in total cholesterol ( $p = 0.011$ ), LDL ( $p = 0.018$ ), and triglycerides ( $p < 0.0001$ ), and an increase in HDL ( $p = 0.001$ ). There were also statistically significant improvements in gynecomastia ( $p = 0.003$ ). As for the effect of toremifene citrate 80 mg on hot flashes, the evaluation of these data is still ongoing and will be reviewed with the final data set.

## Safety

Toremifene citrate 80 mg had a favorable safety profile and was well tolerated. Among the most common adverse events that occurred in over 2% of study subjects were joint pain (treated 7.3%, placebo 11.8%), dizziness (treated 6.3%, placebo 5.0%), back pain (treated 5.9%, placebo 5.2%), and extremity pain (treated 5.0%, placebo 4.4%).

Venous thromboembolic events (VTE), which included both deep venous thrombosis and pulmonary embolism, were 17 (2.4 %) in the toremifene citrate 80 mg treated group and 7 (1.02 %) in the placebo group. The majority of VTEs occurred in men at high risk for a VTE including: age >80 years, history of VTE, recent surgical procedure and immobilization. In men without major risk factors for VTE, there were 3 VTE in the toremifene citrate 80 mg treated group and 2 VTE in the placebo group. The most significant VTE risk occurred in the first year of treatment. In year two, the VTE event rate in the toremifene citrate 80 mg treated group was similar to the rate observed in the placebo group.

"GTx has successfully reached an important corporate milestone event by meeting the primary and key secondary objectives of the Phase III ADT clinical trial," said Dr. Mitchell Steiner, Chief Executive Officer of GTx. "We now can move forward with our plans to prepare and submit the NDA for toremifene citrate 80 mg."

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## **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 ACAPODENE® (toremifene citrate), a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: first, a 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, a 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.

GTx licensed from Orion Corporation the rights to toremifene citrate for all indications worldwide, except breast cancer outside the United States. 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). Ipsen is the leading marketer of ADT (triptorelin) in Europe. Under the agreement, Ipsen will be responsible for filing for marketing approval with regulatory authorities and commercializing toremifene citrate in Europe and CIS. GTx will file for marketing approval and plans to commercialize toremifene citrate 80 mg in the United States.

GTx has formed a strategic collaboration with Merck & Co., Inc. for the development and global commercialization of selective androgen receptor modulators, or SARMS, a new class of drugs with the potential to treat a variety of indications associated with muscle wasting and bone loss, including frailty or sarcopenia, muscle wasting associated with chronic diseases, osteoporosis, and cancer cachexia. GTx also has announced that it 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 be 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 registration statement on Form S-3 (file no. 333-148325) filed December 26, 2007 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.*

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