



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): **March 3, 2008**

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**GTx, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation)

**000-50549**

(Commission File Number)

**62-1715807**

(IRS Employer Identification No.)

**3 N. Dunlap Street  
Van Vleet Building  
Memphis, Tennessee 38163**

(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: **(901) 523-9700**

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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 March 3, 2008, GTx, Inc., or GTx, issued a press release announcing additional 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 the release is furnished as Exhibit 99.1 to this Current Report.

GTx previously announced data from the Phase III ADT clinical trial demonstrating that toremifene citrate 80 mg reduced new morphometric vertebral fractures, the primary endpoint of the trial, and met other key endpoints, including increasing bone mineral density, improving lipid profiles and ameliorating gynecomastia, as well as safety-related data, including the rate of venous thromboembolic events (VTEs).

GTx has also completed an analysis of the effect of excluding patients over the age of 80 years and with a history of VTEs from the modified intent to treat analysis of the primary endpoint, which included all patients with at least one evaluable study radiograph and a minimum of one dose of study drug or placebo. In this patient subset, the VTEs were 4 (1.3 %) in the toremifene citrate 80 mg treated group and 3 (1.0%) in the placebo group (p=0.679), and toremifene citrate 80 mg demonstrated a 74% reduction in new morphometric vertebral fractures (p=0.008; 5.1% fracture rate in the placebo group).

**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 March 3, 2008.

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**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.**

Dated: March 3, 2008

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

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## EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by GTx, Inc. dated March 3, 2008.

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

**GTx Announces Additional Top Line Phase III Data Demonstrating  
Toremifene Citrate 80 mg Reduced Hot Flashes in Men with Prostate Cancer on  
Androgen Deprivation Therapy**

*The most common symptomatic side effect experienced by men on ADT is hot flashes*

Memphis, TN — March 3, 2008 — GTx, Inc. (Nasdaq: GTXI) today announced that toremifene citrate 80 mg reduced hot flashes in men with prostate cancer on androgen deprivation therapy (ADT), a key secondary endpoint of the Phase III clinical trial evaluating toremifene citrate 80 mg for the treatment of multiple side effects of ADT for advanced prostate cancer.

In an analysis of hot flashes in a subset of patients in the Phase III ADT clinical trial experiencing six or more hot flashes per day at baseline and not being treated with megestrol acetate (Megace®), toremifene citrate 80 mg treatment reduced the number of hot flashes by an average of 4.7 hot flashes per day compared to placebo patients who had a reduction of 1.6 hot flashes per day (p=0.03). The reduction of hot flashes in patients treated with toremifene citrate 80 mg was durable for at least 12 months.

“Hot flashes are the most common and bothersome symptomatic side effect of ADT. Up to 80% of men on ADT report being troubled by hot flashes, which are often cited as a cause of noncompliance with hormone therapy,” 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.

GTx earlier announced data from the Phase III ADT clinical trial demonstrating that toremifene citrate 80 mg reduced new morphometric vertebral fractures, the primary endpoint of the trial, and met other key endpoints, including increasing bone mineral density, improving lipid profiles, and ameliorating gynecomastia.

“The Phase III ADT clinical trial data are important because they demonstrate the potential for toremifene citrate 80 mg as a treatment for multiple side effects of ADT, reducing fractures and improving lipid profiles while also treating symptomatic side effects such as hot flashes and gynecomastia,” added Dr. Smith.

“These hot flashes data provide additional confirmation that the multiple estrogen related side effects of androgen deprivation therapy for prostate cancer are treatable by toremifene citrate 80 mg, which binds to and selectively modulates the estrogen receptor depending on tissue type,” said Mitchell S. Steiner, MD, Chief Executive Officer of GTx.

Toremifene citrate 80 mg had a favorable safety profile and was well tolerated. Among the most common adverse events that occurred 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%).

**Conference Call**

There will be a conference call today at 9:00 a.m. Eastern Time. GTx and Dr. Smith will discuss the top line results of the toremifene citrate 80 mg Phase III ADT clinical trial. To listen to the conference call, please dial 866-770-7051 from the United States or Canada or 617-213-8064 from outside North America. The access code for the call is 82373052. A playback of the call will be available from approximately 11:00 a.m., Eastern Time today through March 10, 2008 and may be accessed by dialing 888-286-8010 from the United States or Canada or 617-801-6888 from outside North America, and referencing reservation number 39648500. Additionally, you may access the live

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and subsequently archived webcast of the conference call from the Investor Relations section of the Company's website at <http://www.gtxinc.com>.

#### **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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