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): December 30, 2008

GTx, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of Incorporation)

005-79588	**62-1715807**
(Commission File Number)	(I.R.S. Employer Identification No.)

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

(Address of Principal Executive Office, Including Zip Code)

(901) 523-9700

(Registrant's Telephone Number, Including Area Code)

Not Applicable

(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):

o 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))

o 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 December 30, 2008, GTx, Inc. issued a press release announcing the submission of a New Drug Application with the U.S. Food and Drug Administration (FDA) for toremifene 80 mg, an oral selective estrogen receptor modulator (SERM), for the prevention of bone fractures in men with prostate cancer on androgen deprivation therapy (ADT). 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

Exhibit Number	**Description**
99.1	Press Release issued by GTx, Inc. dated December 30, 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: December 30, 2008

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

Exhibit 99.1

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

GTx Submits New Drug Application for Toremifene 80 mg for the Prevention of Bone Fractures in Men with Prostate Cancer on Androgen Deprivation Therapy

Memphis, Tenn. — December 30, 2008 — GTx, Inc. (Nasdaq: GTXI) today announced the submission of a New Drug Application with the U.S. Food and Drug Administration (FDA) for toremifene 80 mg, an oral selective estrogen receptor modulator (SERM), for the prevention of bone fractures in men with prostate cancer on androgen deprivation therapy (ADT).

“ADT has helped improve survival for men with advanced prostate cancer. Unfortunately, ADT may cause unintended serious estrogen deficiency side effects, such as a high risk of fractures, which can shorten survival,” said Dr. Mitchell Steiner, CEO of GTx. “If approved, toremifene 80 mg could become the first cancer care agent for the prevention of fractures in men receiving ADT.”

Ipsen Group has licensed European toremifene rights from GTx and is planning to submit a marketing application in 2009 in its licensed territories for the use of toremifene 80 mg for this indication.

The submission is supported by results from a two year, double blind, placebo controlled, randomized Phase III clinical trial of 1,382 men with advanced prostate cancer on ADT. The clinical trial, the first ever fracture prevention study in men on ADT, was conducted under a special protocol assessment with FDA. Toremifene 80 mg met the primary endpoint of the clinical trial, a reduction in new morphometric vertebral fractures compared to placebo, as well as other key secondary endpoints related to estrogen deficiency side effects of ADT. Because there are no FDA approved treatments for this indication, GTx has requested priority review for toremifene 80 mg.

Additionally, in the Phase III clinical trial, toremifene 80 mg was generally well tolerated. Among the most common adverse events that occurred in over 2 percent of study subjects in the toremifene and placebo groups were joint pain, dizziness, back pain, and extremity pain.

Toremifene has been marketed for the treatment of advanced breast cancer in more than 60 countries including the U.S. “The Phase III ADT clinical trial safety data are consistent with the existing 17 year pharmacovigilance database which includes approximately 480,000 patient years use of toremifene citrate,” said Ronald A. Morton Jr., MD, Chief Medical Officer of GTx.

About Prostate Cancer

Prostate cancer is the second most common type of cancer diagnosed in men in the U.S. An estimated 186,000 new cases of prostate cancer were diagnosed in the U.S. in 2008. Two out of every three prostate cancer diagnoses are in men over the age of 65.

About ADT

ADT is the primary treatment for advanced prostate cancer in the U.S. Approximately 700,000 men with prostate cancer are being treated with ADT and an estimated 100,000 are anticipated to initiate ADT each year.

Of patients on ADT, up to 77 percent develop significant bone loss, making them susceptible to fracture. Recent studies indicate that the annual risk of fracture in men on ADT is 5% to 8%, or three times higher than the risk of fracture for postmenopausal women. Fractures are serious and can reduce survival in men on ADT by more than three years.

About estrogen deficiency side effects of ADT

Although estrogen is commonly thought of as a female sex hormone, it plays a critical role in men's health. Estradiol is the primary hormone responsible for bone turnover and bone quality. It is also important for cognition and the regulation of certain central nervous system functions and metabolism. Testosterone, through the process of aromatization, is converted to estrogen, and healthy elderly men actually have higher levels of estrogen than do postmenopausal women. However, ADT reduces testosterone by up to 95% to castrate levels, thereby also depleting estrogen levels. Depletion of estrogen can result in serious side effects of ADT, including a high risk of bone fractures, adverse lipid changes and increased risk of cardiovascular disease, as well as common symptomatic side effects such as growth of breast tissue often accompanied by tenderness and pain, and hot flashes.

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 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 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 in all indications except breast cancer for Europe and the Commonwealth of Independent States (CIS). GTx has made application for marketing approval and, if approved, plans to commercialize toremifene 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. Merck and GTx are evaluating additional muscle loss indications for potential SARM clinical development. GTx also is developing its preclinical compound GTx-758, an oral luteinizing hormone inhibitor, for advanced prostate cancer.

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 November 6, 2008 contain 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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