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): March 6, 2009 (March 5, 2009)

GTx, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**005-79588**	**62-1715807**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

175 Toyota Plaza
7th Floor
Memphis, Tennessee 38103
(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)

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 March 5, 2009, GTx, Inc. issued a press release announcing that the United States Food and Drug Administration (FDA) will target a Prescription Drug User Fee Act agency action date of October 30, 2009 for the toremifene 80 mg New Drug Application (NDA), which is within 10 months of the submission of the NDA, 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	Description
99.1	Press Release issued by GTx, Inc. dated March 5, 2009

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: March 6, 2009

By: /s/ Mark E. Mosteller
Name: Mark E. Mosteller
Title: Vice President, Chief Financial Officer and Treasurer

FDA Provides PDUFA Target Agency Action Date For GTx's Toremifene 80 mg NDA

MEMPHIS, Tenn.—(BUSINESS WIRE)—March 5, 2009—GTx, Inc. (Nasdaq: GTXI), today announced that the United States Food and Drug Administration will target a Prescription Drug User Fee Act agency action date of October 30, 2009 for the toremifene 80 mg New Drug Application (NDA), which is within 10 months of the submission of the NDA.

Toremifene 80 mg is an oral selective estrogen receptor modulator which GTx seeks to market for the prevention of bone fractures in men with prostate cancer on androgen deprivation therapy (ADT).

About Androgen Deprivation Therapy (ADT) for Prostate Cancer
ADT is primary treatment for advanced prostate cancer. In the United States, approximately 700,000 men with prostate cancer are being treated with ADT and an estimated 100,000 initiate ADT each year.

ADT has improved survival for men with advanced prostate cancer. ADT works by reducing testosterone, a primary growth factor of prostate cancer, to castrate levels. The reduction in testosterone from ADT also results in very low estrogen levels, because estrogen is derived from testosterone in men. Estrogen deficiency side effects associated with ADT include high risk of skeletal fractures, adverse lipid changes, hot flashes, gynecomastia, depression, and memory loss. 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%, which is 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 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 loss 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 prevention of bone fractures and treatment of other estrogen side effects in men with prostate cancer on androgen deprivation therapy, 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 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 has applied for marketing approval in the United States for toremifene 80 mg for the prevention of bone fractures in men with prostate cancer on ADT 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, or 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, as well as cancer cachexia (cancer induced muscle loss) and other musculoskeletal wasting conditions. Merck and GTx are evaluating multiple SARM product

candidates, including Ostarine™ (designated by Merck as MK-2866) and MK-0773 for sarcopenia in several Phase I and II clinical trials. Merck and GTx will initiate an Ostarine™ cancer cachexia clinical trial in 2009. GTx also is conducting a Phase I clinical trial evaluating 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 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 quarterly report on Form 10-K filed March 3, 2009 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.

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