

---

**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):** November 2, 2009

**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.)

**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)

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))
- 
-

ITEM 8.01 Other Events.

On November 2, 2009, GTx, Inc. issued a press release announcing that it has received a Complete Response Letter from the FDA for its toremifene 80 mg New Drug Application (NDA), 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 November 2, 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: November 2, 2009

By: /s/ Henry P. Doggrell

Name: Henry P. Doggrell

Title: Vice President, General Counsel and  
Secretary

Contact:  
 GTx, Inc.  
 McDavid Stilwell  
 Director, Corporate Communications & Financial Analysis  
 901-507-2667

#### GTx Receives Complete Response Letter from FDA for Toremifene 80 mg New Drug Application

MEMPHIS, November 2, 2009 — GTx, Inc. (NASDAQ: GTXI) today announced that it has received a Complete Response Letter issued by the United States Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for toremifene 80 mg to reduce fractures in men with prostate cancer receiving androgen deprivation therapy (ADT).

The FDA identified two deficiencies in the Complete Response Letter and recommended that the following information be provided to the FDA to address these clinical deficiencies: (i) results of a second adequate and well controlled Phase III trial demonstrating the safety and efficacy of toremifene citrate 80mg to reduce fractures in men with prostate cancer on ADT and (ii) results from an adequate and well-controlled clinical trial demonstrating that toremifene treatment to reduce fractures in men with prostate cancer on ADT does not have a detrimental effect on either time-to-disease progression or overall survival. GTx is requesting a meeting with the FDA to determine the appropriate next steps regarding the NDA.

#### Conference Call and Webcast

GTx will hold a conference call and webcast today at 9:00 a.m. Eastern Time to discuss the Complete Response Letter. To listen to the conference call, please dial:

- 888-396-2369 from the United States and Canada or
- 617-847-8710 (International)  
 The access code for the call is 59484869.

A playback of the call will be available beginning today at 12:00 p.m. Eastern Time through November 16, 2009, and may be accessed by dialing:

- 888-286-8010 from the United States and Canada or
- 617-801-6888 (International)  
 The reservation number for the replay is 47774982.

Additionally, you may access the live 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 prevent and treat cancer, fractures and bone loss, muscle loss and other serious medical conditions. GTx is pursuing marketing approval in the United States for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT. GTx is also developing toremifene 20 mg in an ongoing pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia. GTx has licensed to Ipsen Developments Limited exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein, and the Commonwealth of Independent States to develop and commercialize toremifene for all indications which GTx has licensed from Orion Corporation. In December 2007, GTx and Merck & Co., Inc. entered into a collaboration to discover and develop selective androgen receptor modulators, or SARMs, a new class of drugs with the potential to treat chronic sarcopenia, which is the loss of skeletal muscle mass resulting in reduced physical strength and ability to perform activities of daily living and other musculoskeletal wasting or muscle loss conditions, including muscle loss in patients with chronic obstructive pulmonary disease. GTx and Merck are evaluating multiple SARM product candidates, including Ostarine™ (designated by Merck as MK-2866) and MK-0773, for a variety of musculoskeletal wasting indications. GTx is also developing GTx-758, an oral luteinizing hormone inhibitor for the treatment of advanced prostate cancer.

#### Forward-Looking Information is Subject to Risk and Uncertainty

*This press release contains forward-looking statements based upon GTx's current expectation, including but not limited to statements relating to GTx's plans to continue to pursue marketing approval for toremifene 80 mg and the continued development 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 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, including in any additional clinical trials required by the FDA in connection with the NDA for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT; (ii) 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) 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 August 10, 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.*