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): July 12, 2007

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)

(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 July 12, 2007, GTx, Inc. issued a press release announcing that a per protocol interim safety review by an independent Data Safety Monitoring Board (DSMB) recommended that GTx continue clinical development as planned with its two pivotal Phase III clinical trials of ACAPODENE® (toremifene citrate), 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

99.1

Description

Press Release issued by GTx, Inc. dated July 12, 2007

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: July 12, 2007

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

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

GTx's Phase III Clinical Development of ACAPODENE on Course Following Planned Safety Review

MEMPHIS, Tenn., July 12, 2007, GTx, Inc. (Nasdaq: GTXI), today announced that a per protocol interim safety review by an independent Data Safety Monitoring Board (DSMB) recommended that GTx continue clinical development as planned with its two pivotal Phase III clinical trials of ACAPODENE® (toremifene citrate). The DSMB meets regularly every six months to review unblinded safety data from the two pivotal Phase III clinical trials.

"The DSMB reviewed safety data of the approximately 3,000 patients enrolled in the two pivotal Phase III ACAPODENE clinical trials and recommended that GTx continue with the trials as planned under the existing protocols," said Mitchell S. Steiner, MD, Chief Executive Officer of GTx. "This was the final planned DSMB review prior to the last patient's completion of the ADT clinical trial in late November of this year and the anticipated release of top line results from this trial in the first quarter of 2008. The extensive safety database aggregated in the two large ACAPODENE clinical trials, along with the more than 350,000 patient years of experience with toremifene citrate 60 mg, which has already been approved for the treatment of advanced breast cancer, will be a critical component of the applications for marketing approval of ACAPODENE which, if efficacy and safety criteria are met, we are planning to submit beginning in 2008."

GTx is developing ACAPODENE in two Phase III clinical trials for two separate indications in men. GTx is conducting a pivotal Phase III clinical trial evaluating ACAPODENE 80 mg for the treatment of multiple side effects of androgen deprivation therapy (ADT) for prostate cancer. Approximately 1,400 patients were enrolled in the trial, which is being conducted under a Special Protocol Assessment (SPA) with the United States Food & Drug Administration. The primary endpoint of the trial is a reduction in vertebral fractures. Other endpoints include improvements in bone mineral density (BMD), hot flashes, lipid profile, and gynecomastia. The last patient will complete the Phase III ADT clinical trial late in the fourth guarter of 2007. GTx

anticipates that it will release the top line results from the Phase III ADT trial in the first quarter of 2008.

GTx is conducting a separate pivotal Phase III clinical trial evaluating ACAPODENE 20 mg for the prevention of prostate cancer in men with high grade prostatic intraepithelial neoplasia (PIN). Nearly 1,600 patients with high grade PIN have been enrolled in the trial, which is being conducted under a SPA with the FDA. The primary endpoint of the trial is a reduction in prostate cancer incidence. The Phase III clinical trial evaluating ACAPODENE 20 mg for the prevention of prostate cancer in men with high grade PIN provides for an interim efficacy analysis after a critical number of cancer events have occurred. GTx anticipates that sufficient cancer events will have occurred to conduct this interim efficacy analysis by the first quarter of 2008. If the interim efficacy analysis reveals that ACAPODENE 20 mg treatment reduces prostate cancer and achieves the pre-specified level of statistical significance, GTx plans to submit a New Drug Application.

About GTx

GTx, 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 for the treatment of serious side effects of androgen deprivation therapy for advanced prostate cancer, and second, a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia, or PIN. GTx has licensed to Ipsen Limited exclusive rights in Europe to develop and commercialize ACAPODENE®. GTx also is developing Ostarine™, a first-in-class selective androgen receptor modulator, or SARM. GTx has initiated a Phase IIb Ostarine™ clinical trial for cancer cachexia and plans to initiate a Phase IIb Ostarine™ clinical trial for the treatment of chronic kidney disease muscle wasting by the end of 2007. GTx believes that Ostarine™ also has the potential to treat a variety of other indications associated with muscle wasting and bone loss including sarcopenia and osteoporosis.

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 will not be able to commercialize its 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 its product candidates; (iii) GTx's clinical trials 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 with the U.S. Securities and Exchange Commission on May 7, 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.