

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): September 7, 2006 (September 5, 2006)

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):

- 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 September 5, 2006, GTx, Inc. issued a press release announcing that a per protocol interim safety review by an independent Drug Safety Monitoring Board (DSMB) recommended that GTx continue clinical development as planned with its two pivotal Phase III trials of ACAPODENE® (toremifene citrate), a copy of which is furnished as Exhibit 99.1 to this Current Report.

This release is furnished by GTx pursuant to Item 2.02 of Form 8-K and is not to be considered “filed” under the Exchange Act, and shall not be incorporated by reference into any previous or future filing by the Registrant under the Securities Act or the Exchange Act.

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 September 5, 2006

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: September 7, 2006

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

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

**GTx's PHASE III CLINICAL DEVELOPMENT OF ACAPODENE ON COURSE FOLLOWING
PLANNED SAFETY REVIEW**

MEMPHIS, TENN., September 5, 2006 — GTx, Inc. (Nasdaq: GTXI), the Men's Health Biotech Company, today announced that a per protocol interim safety review by an independent Drug Safety Monitoring Board (DSMB) recommended that GTx continue clinical development as planned with its two pivotal Phase III 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 more than 2,700 patients enrolled in our two pivotal Phase III trials and recommended that GTx continue with the trials as planned. This welcome news reduces the risk in ACAPODENE's clinical development and improves the prospects that we will be able to submit these product candidates for marketing approval," said Mitchell Steiner, MD, Chief Executive Officer of GTx.

GTx is developing ACAPODENE in two pivotal 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 for prostate cancer. Approximately 1,400 patients are participating 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 fractures. Other endpoints include improvements in bone mineral density (BMD), hot flashes, lipid profiles, and gynecomastia. In December 2005, GTx conducted a planned interim analysis of BMD in the first 197 patients to complete a full year of treatment. In each of three measurements (lumbar spine, hip and femoral neck), highly statistically significant positive changes in BMD were observed in patients on ACAPODENE, when compared to patients on placebo, who on average lost bone. In June 2006, GTx conducted a lipid interim analysis of the same cohort of patients. Patients treated with ACAPODENE had statistically significantly lower levels of total cholesterol, LDL, and

triglycerides, a reduction in the ratio of total cholesterol to HDL, and higher HDL, when compared to patients on placebo. GTX expects to receive final data from the trial in the second half of 2007.

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). More than 1,340 patients with high grade PIN are enrolled in the trial, which is being conducted under a SPA with the FDA. The endpoint of the trial is a reduction in prostate cancer incidence. GTX expects to conduct an interim efficacy analysis between the fourth quarter of 2007 and the first quarter of 2008. If the statistical parameters are achieved, GTX will proceed with the filing of a New Drug Application.

About GTX

GTX, headquartered in Memphis, Tenn., is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for cancer and serious conditions related to men's health. GTX's lead drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens, two essential classes of hormones. 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 is developing ostarine, a selective androgen receptor modulator, or SARM, for muscle wasting and bone loss indications. Ostarine is currently being evaluated in a Phase II clinical trial in 120 elderly men and postmenopausal women. GTX expects to have data from the Phase II ostarine trial in the fourth quarter of 2006. GTX has licensed to Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, another of its SARMS, andarine, under a joint collaboration and license agreement.

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 August 9, 2006, contains 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.