# 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): June 22, 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):

- 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))

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#### ITEM 8.01 Other Events.

On June 22, 2006, GTx, Inc. issued a press release announcing the results of a lipid interim analysis of the pivotal Phase III ADT clinical trial evaluating oral, once daily ACAPODENE® (toremifene citrate) 80mg for the treatment of the multiple serious side effects of androgen deprivation therapy (ADT) in men with advanced prostate cancer.

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

Exhibit	
Number	Description
99.1	Press Release issued by GTx, Inc. dated June 22, 2006

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#### **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: June 22, 2006 By: /s/ Mark E. Mosteller

Name: Mark E. Mosteller

Title: Vice President, Chief Financial Officer

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

IN A PHASE III LIPID INTERIM ANALYSIS, ACAPODENE TREATMENT LOWERED CHOLESTEROL AND RAISED HDL IN PROSTATE CANCER PATIENTS ON ANDROGEN DEPRIVATION THERAPY

Memphis, Tenn., June 22, 2006 -- GTx, Inc. (Nasdaq: GTXI), the Men's Health Biotech Company, announced today the results of a lipid interim analysis of the pivotal Phase III ADT clinical trial evaluating oral, once daily ACAPODENE(R) (toremifene citrate) 80mg for the treatment of the multiple serious side effects of androgen deprivation therapy (ADT) in men with advanced prostate cancer.

The lipid interim analysis was performed in the first 197 subjects who completed one year of the trial. Prostate cancer patients on ADT who received ACAPODENE compared to placebo had lower total cholesterol (-7.1%; p=0.001), LDL (-9.0%; p=0.003), and triglyceride (-20.1%; p=0.009) levels, a reduction in the total cholesterol/HDL ratio (-11.7%; p<0.001), and higher HDL levels (+5.4%; p=0.018). Although patients who were also taking statins had further reduction of total cholesterol, the magnitude of these lipid changes was greater in patients who were not concomitantly taking statins. The final lipid data set will be evaluated before any conclusions may be made on the clinical significance of these findings.

"Androgen deprivation therapy is quite effective in turning prostate cancer into a chronic disease in many patients," said Matthew R. Smith, M.D., Ph.D., Associate Professor of Medicine, Harvard Medical School. Dr. Smith is the lead Principal Investigator of the Phase III ADT clinical trial. "As patients are living longer with prostate cancer because of ADT, serious side effects have become major causes of morbidity and even death. These serious ADT side effects include osteoporosis and fractures as well as adverse lipid changes and cardiovascular disease. A medicine that is able to address multiple side effects of ADT would mark important progress in the care of prostate cancer patients."

GTx is conducting a pivotal Phase III clinical trial of ACAPODENE for the treatment of multiple serious side effects of ADT in approximately 1,400 men at over 150 sites in the United States and Mexico. The primary endpoint of the trial is a reduction in vertebral fractures. Secondary endpoints include improvements in bone mineral density (BMD), hot flashes, gynecomastia, and lipid profiles. Final data from the trial, which is being conducted under a Special Protocol Assessment with the United States Food & Drug Administration, is expected in the second half of 2007.

In December 2005, GTx conducted an interim analysis of the bone loss that leads to fractures which is another serious side effect of ADT. BMD was measured in the first 197 patients to complete one year of treatment. The per protocol analysis revealed highly statistically significant increases in BMD in all three skeletal sites assessed in patients receiving ACAPODENE compared to placebo: lumbar spine (+2.3%; p<0.001); hip (+2.0%; p=0.001); and femoral neck

( $\pm$ 1.5%; p=0.009). The magnitude of these positive changes in BMD provides increased confidence that ACAPODENE should show efficacy in the trial's primary endpoint, a 40% reduction in vertebral fractures at two years.

"ACAPODENE has demonstrated the potential to increase bone mineral density, and the lipid interim analysis suggests that ACAPODENE may lower cholesterol," said Mitchell S. Steiner, M.D., CEO of GTx. "We continue to be confident in the Phase III ADT clinical trial. If ACAPODENE can treat multiple serious side effects of ADT, it has the potential to become the mainstay of prostate cancer supportive care for patients on ADT."

#### 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(R) (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 ADT 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 also is developing ostarine, a selective androgen receptor modulator, or SARM, for a variety of indications including muscle wasting and bone loss in frail elderly patients, osteoporosis, muscle wasting in end stage renal disease patients, and severe burn wounds and associated muscle wasting. 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 on May 5, 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.