

**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): **February 1, 2005 (January 26, 2005)**

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

**3rd Floor, Van Vleet Building
Memphis, Tennessee 38163
(901) 523-9700**

(Address, including zip code, and telephone number,
including area code, of registrant's principal executive offices)

(Former name or former address, if changed since last report)

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ITEM 8.01 Other Events.

On January 26, 2005, GTx, Inc. announced that the Company has initiated a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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 January 26, 2005

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: February 1, 2005

By: /s/ Henry P. Doggrell

Name: Henry P. Doggrell

Title: Vice President, General Counsel/Secretary

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GTx, INC. INITIATES PIVOTAL PHASE III CLINICAL TRIAL FOR
THE PREVENTION OF PROSTATE CANCER IN HIGH RISK MEN

Memphis, Tenn. -- January 26, 2005 - GTx, Inc. (Nasdaq: GTXI), a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for serious men's health conditions, today announced that the company has initiated a pivotal Phase III clinical trial for ACAPODENE(TM) for the prevention of prostate cancer in high risk men.

The company had an investigators meeting January 21-22, 2005, with approximately 100 U.S. clinical sites for its Phase III PIN trial. The pivotal Phase III trial is a double blind, placebo controlled, multicenter study. Patients with high grade prostatic intraepithelial neoplasia (PIN), the precancerous lesion in prostate cancer, will be randomized into two treatment groups: 20 mg toremifene or placebo. The primary endpoint of the clinical trial is the incidence of prostate cancer.

GTx has received initial comments from the Food and Drug Administration (FDA) on the preliminary review of the Special Protocol Assessment (SPA). As part of the SPA process, GTx plans to address these comments and resubmit the revised SPA.

"We are excited about the initiation of GTx's pivotal Phase III trial for ACAPODENE(TM) in men who are at high risk for prostate cancer," stated Mitchell Steiner, M.D., Vice Chairman and CEO of GTx. "Providing a prevention option for men who are at high risk for this premalignant disease is a top priority as there are no treatment options currently available for these patients."

About ACAPODENE(TM)

ACAPODENE(TM) is a nonsteroidal SERM, a small molecule that binds and selectively modulates the estrogen receptor. SERMs have been shown to block estrogen receptors in the prostate. GTx has licensed the right to develop, market and distribute toremifene citrate, the active ingredient of ACAPODENE(TM) tablets, in all indications in the United States.

About High Grade PIN

It has been well established that patients with high grade PIN are at high risk for developing prostate cancer. PIN is detected in approximately 9% of the patients who undergo prostate biopsies. Prostate cancer is found in approximately 30-70% of high grade PIN patients within one year of diagnosis, and in 45-80% of high grade PIN patients within five years.

About GTx

GTx is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for serious men's health conditions. GTx's drug discovery and development programs are focused on small molecules that selectively modulate the effects of

estrogens and androgens. GTx currently has four clinical programs. In two of the clinical programs, the company is developing ACAPODENE(TM), its most advanced product candidate, through clinical trials for two separate indications: (1) a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men and (2) a pivotal Phase III clinical trial for the treatment of serious side effects of androgen deprivation therapy for advanced prostate cancer. In its third clinical program, GTx and its partner, Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, are developing andarine, a selective androgen receptor modulator (SARM), which is expected to enter a Phase II clinical trial in 2005. In its fourth clinical program, GTx is developing its own SARM, ostarine, for andropause and other conditions related to aging, including sarcopenia. In addition, GTx has a deep pipeline generated from its own discovery program which includes specific preclinical product candidates prostarine, a SARM, for benign prostatic hyperplasia (BPH), and andromustine, an anticancer drug, for hormone refractory prostate cancer.

Forward-Looking Information is Subject to Risk and Uncertainty

This press release contains forward-looking statements, including, without limitation, statements related to GTx's current and anticipated clinical trials of ACAPODENE(TM) and its other research and development programs. These forward-looking statements are 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, risks that GTx will not be able to commercialize its product candidates if preclinical studies do not produce successful results or clinical trials do not demonstrate safety and efficacy in humans; if third parties do not manufacture the Company's product candidates in sufficient quantities and at an acceptable cost, clinical development and commercialization of its product candidates would be delayed; use of third-party manufacturers may increase the risk that the Company will not have adequate supplies of its product candidates; if third parties on whom the Company relies do not perform as contractually required or expected, the Company may not be able to obtain regulatory approval for or commercialize its product candidates; the Company is dependent upon collaborative arrangements to complete the development and commercialization of some of its product candidates, and these collaborative arrangements may place the development of its product candidates outside its control, may require it to relinquish important rights or may otherwise be on terms unfavorable to the Company; and if the Company is not able to obtain required regulatory approvals, the Company will not be able to commercialize its product candidates. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this press release. The annual report filed on Form 10-K with the U.S. Securities and Exchange Commission (the "SEC") on March 26, 2004 contains under the heading "Additional Factors That Might Affect Future Results," 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.