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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 14, 2005**

GTx, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**005-79588**	**62-1715807**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(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 September 14, 2005, GTx, Inc. announced that the Company has received a response letter from the Division of Oncology Drug Products of the United States Food and Drug Administration related to GTx's Special Protocol Assessment (SPA) on the design of its pivotal Phase III clinical trial of ACAPODENE® 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

Exhibit Number	Description
99.1	Press Release issued by GTx, Inc. dated September 14, 2005

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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: September 14, 2005

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

Exhibit 99.1

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

GTx Receives FDA Response on Special Protocol Assessment for ACAPODENE for Prevention of Prostate Cancer

Memphis, Tenn, Sept. 14, 2005 - GTx, Inc. (Nasdaq: GTXI), the Men's Health Biotech Company, today announced it has received a response letter from the Division of Oncology Drug Products of the United States Food and Drug Administration related to GTx's Special Protocol Assessment (SPA) on the design of its pivotal Phase III clinical trial of ACAPODENE(R) for the prevention of prostate cancer in high risk men. GTx agrees with and will implement the FDA's recommendations under the SPA, which GTx expects will be sufficient to support the submission of the effectiveness portion of a New Drug Application.

The pivotal Phase III trial is a randomized, double-blind, placebo-controlled study of 1,260 patients who receive daily either an oral 20 mg dose of ACAPODENE or placebo. Trial participants have high grade prostatic intraepithelial neoplasia (PIN), a premalignant lesion of the prostate. The primary endpoint of the trial is a reduction in prostate cancer incidence as determined by prostate biopsy. GTx will evaluate efficacy endpoints at 36 months, with an interim analysis at 24 months. If a sufficient reduction in prostate cancer at 24 months is achieved, GTx could potentially file a New Drug Application, provided that GTx is also able to submit as part of the filing safety data for 36 months for a majority of patients and other safety data, as requested by the FDA. The statistical assumptions for the design of this Phase III trial are based on the positive results of the Phase IIb high grade PIN trial in 514 patients completed in June 2004.

Enrollment of the trial began in early 2005 and is on schedule to be completed in the first quarter of 2006.

About GTx

GTx 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, headquartered in Memphis, Tenn., currently has four clinical programs. GTx is developing ACAPODENE(R) (toremifene citrate), a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: (1) a pivotal Phase III clinical trial for the treatment of serious side effects of androgen deprivation therapy for advanced prostate cancer and (2) a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with precancerous prostate lesions. In its third clinical program, GTx is developing ostarine for the treatment of muscle wasting associated with acute conditions such as burns and chronic conditions such as andropause. GTx expects to begin Phase II clinical trials of ostarine for muscle wasting associated with burns in the fourth quarter of 2005 and for andropause during the first half of 2006. In its fourth clinical program, GTx and its collaborator, Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, are developing andarine, another one of

GTx's SARMs, for the treatment of cancer cachexia. GTx is working with Ortho Biotech to plan a Phase II clinical trial of andarine.

Forward-Looking Information is Subject to Risk and Uncertainty

This press release contains forward-looking statements, including, without limitation, statements related to the regulatory approval process for ACAPODENE, the timing of the filing of an New Drug Application for ACAPODENE, GTx's planned clinical trials of ACAPODENE, the date by which enrollment in GTx's Phase III trial of ACAPODENE for the prevention of prostate cancer in high risk men is expected to be completed, 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 and other important factors, which include, without limitation, risks that GTx will not be able to commercialize its product candidates if clinical trials do not demonstrate safety and efficacy in humans; risks related to GTx's dependence on third parties; 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/A with the U.S. Securities and Exchange Commission (the "SEC") on August 3, 2005 contains under the heading "Additional Factors That Might Affect Future Results," a more comprehensive description of these and other important factors and 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.