



UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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**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): **October 19, 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)

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

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### ITEM 8.01 Other Events.

On October 19, 2005, GTx, Inc. announced it has attained its enrollment goal in its pivotal Phase III clinical trial for the use of ACAPODENE (toremifene citrate) 80 mg for the treatment of the serious side effects of androgen deprivation therapy (ADT) for men with advanced prostate cancer

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 October 19, 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: October 19, 2005

By: /s/ Henry P. Doggrell

Name: Henry P. Doggrell

Title: Vice President, General Counsel/Secretary

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

#### GTx INC. ATTAINS PATIENT ENROLLMENT OF ITS PHASE III ADT TRIAL

MEMPHIS, TENN. - Oct. 19, 2005 - GTx, Inc. (Nasdaq: GTXI), the Men's Health Biotech Company, today announced it has attained its enrollment goal in its pivotal Phase III clinical trial for the use of ACAPODENE (toremifene citrate) 80 mg for the treatment of the serious side effects of androgen deprivation therapy (ADT) for men with advanced prostate cancer.

"More than 1,300 patients in the United States and Mexico are now participating in our Phase III ADT trial. We are on track to have final data from this trial in the second half of 2007," said Mitchell Steiner, MD, CEO of GTx. "Men on ADT are at high risk for developing osteoporosis and life threatening fractures. Studies have shown that average survival is reduced by 39 months in ADT patients who do develop fractures."

Patients in the randomized, double blind, pivotal Phase III ADT study receive daily for two years either an 80 mg tablet of toremifene citrate or placebo. The primary endpoint of the trial is the occurrence of lumbar vertebral fractures. Secondary endpoints include hot flashes, gynecomastia, improvement in lipid profiles, and bone mineral density. GTx is conducting this two year study in accordance with a Special Protocol Assessment (SPA) from the United States Food and Drug Administration.

Later in this quarter, GTx plans to conduct an interim analysis of bone mineral density in the first 200 patients to have completed a full year of treatment in this Phase III trial.

GTx is conducting under a separate SPA another pivotal Phase III trial of ACAPODENE in a 20 mg dose for the prevention of prostate cancer in high risk men who have high grade prostatic intraepithelial neoplasia, or high grade PIN. Under the PIN trial SPA, the timing for the interim efficacy analysis is driven by the rate of prostate cancer events among study patients. GTx expects the interim efficacy analysis will occur within 24 months after completing enrollment of the approximately 1,260 study subjects for the trial. If the interim efficacy analysis reveals a statistically significant reduction in prostate cancer, GTx expects to be able to file the New Drug Application (NDA). GTx will continue to collect efficacy and safety data during the NDA review process. Patient enrollment for the PIN trial began in the first quarter 2005 and is on track to be completed by the first quarter 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 and (2) a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with high grade PIN. In its third clinical program, GTx is developing ostarine, a selective androgen receptor modulator, or SARM, for the treatment of muscle wasting associated with acute conditions such as burns and is evaluating the drug's development to treat muscle wasting associated with andropause. GTx plans to initiate its first Phase II clinical trial of ostarine for burn patients in the fourth quarter of 2005. 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 GTx's clinical trials 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 clinical trials do not demonstrate safety and efficacy in humans; 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. GTx's prospectus supplement filed with the U.S. Securities & Exchange Commission. (the "SEC") pursuant to Rule 424(b)(5) on October 12, 2005, 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.