



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) **February 26, 2007 (February 23, 2007)**

**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,)

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(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 February 23, 2007, GTX, Inc. issued a press release announcing that interim data revealing oral, once daily ACAPELENE® (toremifene citrate) 80mg increases bone mineral density and lowers cholesterol in prostate cancer patients on androgen deprivation therapy (ADT) were announced during a press briefing at the American Society of Clinical Oncology (ASCO) Prostate Cancer Symposium, 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 February 23, 2007

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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: February 26, 2007

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

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

**GTx's ACAPODENE Interim Bone Mineral Density and Lipid Data Highlighted at Press Briefing at Prostate Cancer Symposium of the American Society of Clinical Oncology**

Orlando, February 23 — GTx, Inc. (Nasdaq: GTXI), announced that a press briefing held this morning by the American Society of Clinical Oncology (ASCO) at its annual Prostate Cancer Symposium highlighted Phase III interim data revealing oral, once daily ACAPODENE® (toremifene citrate) 80mg increases bone mineral density and lowers cholesterol in prostate cancer patients on androgen deprivation therapy. The two interim analyses were conducted in the first 197 men who completed one year of treatment in GTx's pivotal Phase III clinical trial evaluating ACAPODENE for the treatment of multiple serious side effects of androgen deprivation therapy (ADT) for advanced prostate cancer.

"Awareness of the multiple serious side effects of androgen deprivation therapy has been growing rapidly. This peer review recognition at the ASCO Prostate Cancer Symposium, along with the recent attention in the scientific literature and lay press, underscores the importance of having a treatment for these multiple serious side effects of ADT," said Mitchell S. Steiner, MD, Chief Executive Officer of GTx.

ADT, the primary treatment for advanced prostate cancer, acts by reducing testosterone to castrate levels, effectively putting hormone sensitive prostate cancer into remission. Because estrogen in men comes from testosterone, an unintended consequence of ADT is that it also reduces estrogen in men on ADT to levels well below even postmenopausal women. These low estrogen levels may result in multiple serious side effects, including osteoporosis, increased risk for life threatening fractures, adverse lipid changes, hot flashes and gynecomastia. GTx estimates that by 2008 there will be one million prostate cancer patients on ADT in the United States.

"ADT, along with early detection, has been effective in prolonging survival for prostate cancer patients. However, the serious side effects of ADT have become major causes of morbidity and potentially mortality," said Matthew Smith, MD, PhD, an Associate Professor at Massachusetts General Hospital Cancer Center and the lead principal investigator of the Phase III ADT clinical trial. "These serious ADT side effects include osteoporosis and fractures as well as adverse lipid changes. ACAPODENE has demonstrated the potential to increase bone mineral density, and the lipid interim analysis shows that ACAPODENE lowers cholesterol and triglycerides. If ACAPODENE does ultimately gain approval to treat multiple side effects of ADT, it would mark important progress in the care of prostate cancer patients."

In the bone mineral density interim analysis, originally reported by GTx in December 2005, there were highly statistically significant increases in BMD in all three skeletal sites

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assessed in patients receiving ACAPODENE compared to placebo: lumbar spine (+2.3%; p<0.001); hip (+2.0%; p=0.001); and femur neck (+1.5%; p=0.009). The magnitude of these positive changes in BMD provides increasing confidence that ACAPODENE should show efficacy in the primary endpoint of the trial, a reduction in vertebral morphometric fractures by two years.

In the lipid interim analysis, originally reported by GTx in June 2006, 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 triglycerides (-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.

GTx is conducting a Phase III clinical trial of ACAPODENE 80 mg 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 morphometric fractures. Secondary endpoints include improvements in BMD, lipid profiles, hot flashes, and gynecomastia. The last patient will complete the trial at the end of November, 2007. GTx will then evaluate the data and prepare the trial results for public release.

#### **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. 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 has licensed to Ipsen Limited exclusive rights in Europe to develop and commercialize ACAPODENE®. GTx also is developing ostarine, a first-in-class selective androgen receptor modulator, or SARM. GTx plans to initiate a Phase IIb ostarine clinical trial for cancer cachexia by the summer of 2007. GTx plans to initiate a Phase IIb ostarine clinical trial for the treatment of chronic kidney disease and end stage renal disease muscle wasting by the end of 2007. GTx believes that ostarine also has the potential to treat a variety of other indications associated with muscle wasting and bone loss including frailty and osteoporosis.

#### **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

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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 prospectus supplement filed with the U.S. Securities and Exchange Commission (the "SEC") pursuant to Rule 424(b)(5) on December 14, 2006, 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.