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) December 15, 2005

GTx, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

000-50549

(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)

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))

TABLE OF CONTENTS

ITEM 8.01 Other Events.
ITEM 9.01 Financial Statements and Exhibits.

SIGNATURE EX-99.1 PRESS RELEASE

Table of Contents

ITEM 8.01 Other Events.

On December 15, 2005, GTx, Inc. issued a press release announcing positive results from an interim analysis of the first 200 patients completing one year of treatment in the company's Phase III clinical trial of Acapodene® to treat multiple side effects of androgen deprivation therapy, 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

Exhibit

Number Description

99.1 Press Release issued by GTx, Inc. dated December 15, 2005

Table of Contents

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: December 15, 2005

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

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

GTX REPORTS POSITIVE PHASE III TRIAL INTERIM ANALYSIS RESULTS

o Conference call scheduled for 10 a.m. EST to discuss the interim analysis o

MEMPHIS, TENN. - December 15, 2005 -- GTx, Inc. (Nasdaq: GTXI), the Men's Health Biotech Company, today reported that men with prostate cancer on androgen deprivation therapy (ADT) experienced highly statistically significant increases in bone mineral density (BMD) after one year of treatment with ACAPODENE(R) (toremifene citrate) 80 mg dose.

Patients treated with ACAPODENE demonstrated statistically significant increases in BMD versus patients receiving placebo for each of the three different skeletal sites measured. In lumbar spine, BMD increased +2.3% (p < 0.001); in hip, +2% (p = 0.001); and in femoral neck, +1.5% (p=0.009), versus placebo.

The planned interim analysis of BMD, a secondary endpoint of the trial, was conducted in accordance with a Special Protocol Assessment with the FDA for the company's pivotal Phase III trial for the use of ACAPODENE, a selective estrogen receptor modulator, or SERM, to treat the multiple serious side effects of ADT. The analysis examined BMD in the first 200 patients to complete one full year of treatment in order to give confidence that ACAPODENE would deliver at two years the trial's primary endpoint, a 40% reduction in fractures. This interim analysis is the largest prospective study reported to date of osteoporosis and bone loss in men with hormone sensitive prostate cancer on ADT.

Matthew Smith, MD, PhD, an Associate Professor of Medicine at Harvard Medical School, said "ACAPODENE's BMD changes are of a magnitude that should deliver the desired fracture benefit, as they are consistent with BMD changes that have translated into greater than 50% fracture reductions in other SERM trials of post-menopausal women. I believe ACAPODENE will fill an important unmet medical need, as there are no other FDA approved treatments available to reduce fractures in men with hormone sensitive prostate cancer on ADT." Dr. Smith is a lead physician investigator for GTx's ADT Phase III trial.

Mitchell Steiner, MD, CEO of GTx, said "Based on our Phase II data and the supporting scientific literature, we expected ACAPODENE to build bone in men on ADT. These results have confirmed the significant bone activity of ACAPODENE and offer hope that ACAPODENE will reduce life threatening fractures in the approximately 1 million men on ADT in the US. We also remain confident that our Phase III trial of ACAPODENE will show benefits in the trial's other secondary endpoints, including improvements in the lipid profile of the men receiving ACAPODENE, as cardiovascular disease is a leading cause of death for men on ADT."

Patients in the double blind, pivotal Phase III ADT trial are randomized to receive daily either an 80 mg dose of toremifene citrate or matching placebo for 24 months. The primary endpoint of the trial is the occurrence of radiographic vertebral fractures. Secondary endpoints include reduction of hot flashes and improvement in gynecomastia, lipid profiles, bone mineral density, and quality of life. 1,394 subjects are currently enrolled at 150 clinical sites in the United States and Mexico. GTx reached its enrollment goal in the third quarter of 2005.

CONFERENCE CALL

GTx will host a conference call this morning at 10 a.m. Eastern Standard Time to review the data. Dr. Matthew Smith, a lead investigator of the Phase III trial, will participate on the call along with members of GTx's senior management. To listen to the conference call, please dial:

- 800-901-5213 from the United States and Canada or
- 617-786-2962 (International) The access code for the call is 31470781.

A playback of the call will be available from approximately 2:00 p.m., Eastern Time, on December 15 through December 29, and may be accessed by dialing:

- 888-286-8010 from the United States and Canada or
- 617-801-6888 (International), referencing reservation number 35973442.

Additionally, you may access the live and subsequently archived webcast of the conference call from the Investor Relations section of the company's website at http://www.gtxinc.com.

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 (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 the precancerous prostate lesion called high grade prostatic intraepithelial neoplasia, or PIN. In its third clinical program, GTx is developing ostarine for the treatment of acute muscle wasting conditions associated with burns. GTx is also evaluating clinical development of ostarine for the treatment of chronic muscle wasting conditions, such as testosterone deficiency in aging men, or andropause. In its fourth clinical program, GTx and its collaborating partner, Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, are developing andarine, another 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 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 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 its 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 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.