

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): April 24, 2006 (April 21, 2006)

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)

(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 04/21/06](#)

Table of Contents

ITEM 8.01 Other Events.

On April 21, 2006, GTx, Inc. issued a press release announcing it is initiating a separate Phase IIIb clinical trial as an extension of the pivotal Phase III ADT clinical trial of ACAPODENE® (toremifene citrate) in an 80mg dose for the treatment of multiple serious 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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release issued by GTx, Inc. dated April 21, 2006

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: April 24, 2006

By: /s/ Henry P. Doggrell

Name: Henry P. Doggrell

Title: Vice President, General Counsel and Secretary

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

GTX, INC. ANNOUNCES INITIATION OF PHASE IIIB EXTENSION TRIAL OF ACAPODENE
FOR THE TREATMENT OF SIDE EFFECTS OF ANDROGEN DEPRIVATION THERAPY

MEMPHIS, TENN. -- April 21, 2006--GTx, Inc. (Nasdaq: GTXI), the Men's Health Biotech Company, today announced it is initiating a separate Phase IIIb clinical trial as an extension of the pivotal Phase III ADT clinical trial of ACAPODENE(R) (toremifene citrate) in an 80mg dose for the treatment of multiple serious side effects of androgen deprivation therapy.

Prostate cancer patients in the pivotal Phase III ADT trial who have completed the full two year treatment will be eligible to participate in the Phase IIIb extension trial for an additional year. The purpose of this study is to collect additional efficacy and safety data that could further support the current Phase III clinical study. This additional Phase IIIb clinical study is considered to be a separate clinical trial and will not affect the current timeline for the completion of the ongoing Phase III clinical trial in the second half of 2007 and the potential submission of the new drug application.

"This new clinical trial is a unique opportunity to continue to follow in a blinded fashion ADT patients completing our two year pivotal Phase III study. It will allow us not only to obtain additional data regarding fractures and safety, but also to evaluate other possible benefits of ACAPODENE in this population," said Mitchell S. Steiner, M.D., CEO of GTX.

Approximately 1,400 men have been enrolled into the pivotal Phase III clinical trial evaluating ACAPODENE for the treatment of side effects of androgen deprivation therapy for advanced prostate cancer. GTx completed enrollment of the trial in the fall of 2005. The primary endpoint of the trial, which is being conducted under a Special Protocol Assessment with the United States Food & Drug Administration, is a reduction in vertebral fractures. Secondary endpoints include improvements in bone mineral density and cholesterol levels, a reduction in hot flashes, and the treatment of gynecomastia. In December 2005, GTx conducted an interim analysis of bone mineral density in the first 200 men to complete one full year of treatment. The interim

analysis demonstrated a highly statistically significant positive change in bone mineral density in patients treated with ACAPODENE versus patients on placebo.

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, two essential classes of hormones. GTX is developing ACAPODENE(R) (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 PIN. GTX also is developing ostarine, a selective androgen receptor modulator, or SARM, for a variety of indications including muscle wasting and bone loss in frail elderly patients, osteoporosis, muscle wasting in end stage renal disease patients, and severe burn wounds and associated muscle wasting. GTX has licensed to Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, another of its SARMS, andarine, under a joint collaboration and license agreement.

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 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 annual report on form 10-K filed with the U.S. Securities and Exchange Commission on March 2, 2006, contains 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.