

**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: **June 3, 2004**
(Date of earliest event reported)

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)

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

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ITEM 7 Financial Statements and Exhibits

(c) Exhibits

Exhibit Number	Description
99.1	Press Release issued by GTx, Inc. dated June 2, 2004

ITEM 9 Regulation FD Disclosure

On June 2, 2004, GTx announced information regarding the positive results of its Phase IIb clinical trials 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.

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: June 3, 2004

By: /s/ Henry P. Doggrell

Name: Henry P. Doggrell

Title: General Counsel/Secretary

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GTx, Inc. Announces Positive Phase IIb Data for ACAPODENE(TM)
for the Prevention of Prostate Cancer in High Risk Men

MEMPHIS, TENN. - JUNE 2, 2004 -- GTx, Inc. (Nasdaq: GTXI), a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for serious men's health conditions announced today positive Phase IIb results for its lead product ACAPODENE(TM) (toremifene citrate) tablets. The data demonstrated that ACAPODENE(TM) was well tolerated and reduced the incidence of prostate cancer in men who are at high risk for prostate cancer. Patients were classified as being at high risk because they had biopsy proven precancerous lesions of the prostate called high grade prostatic intraepithelial neoplasia (PIN). GTx plans to initiate a Phase III clinical trial in 2004 following discussions with the Food and Drug Administration (FDA). ACAPODENE(TM), GTx's lead product candidate, is a nonsteroidal selective estrogen receptor modulator (SERM).

STUDY RESULTS

The ACAPODENE(TM) Phase IIb study was double-blind, placebo-controlled, one year clinical trial in 514 men at high risk for prostate cancer and high grade PIN. The primary endpoint was the incidence of prostate cancer. This is the largest prospective study of the natural history of patients with high grade PIN. This well controlled study confirmed that men who have high grade PIN are at high risk as 31% of placebo patients were diagnosed with prostate cancer by 1 year. The intent-to-treat analysis, defined as any patient who had at least one on-study biopsy, showed that ACAPODENE(TM) 20 mg had a 20% reduction in prostate cancer incidence. The reduction of prostate cancer incidence improved in men who received ACAPODENE(TM) 20mg for one year with a 46% reduction in this high risk population compared to the placebo group, which is consistent with the interim analysis GTx conducted last year. For men who developed prostate cancer, those treated with ACAPODENE(TM) had similar tumor grades to those of placebo patients. ACAPODENE(TM) was well tolerated as the number of adverse events were similar between those patients receiving ACAPODENE(TM) compared to placebo.

"This study confirms that men who have high grade PIN are indeed high-risk patients for prostate cancer with 31% of the men receiving placebo being diagnosed with cancer within one year. Developing a successful treatment option to prevent prostate cancer in high risk patients will have a positive clinical impact" said Mitchell Steiner MD, FACS, Vice-Chairman and CEO of GTx. "ACAPODENE 20mg showed a significant reduction in prostate cancer incidence in men who had taken ACAPODENE for 12 months compared to placebo. ACAPODENE at all doses tested was well tolerated. While we need to discuss the results of this study with the FDA and continue analyzing the data, we are excited about these results and plan to begin the Phase III trial later this year" said Dr. Steiner.

ABOUT THE STUDY

The Phase IIb clinical study was a 4-arm, double blind, placebo controlled, one year treatment study at 64 clinical sites in the United States involving 514 patients. The four arms included in this study were 20mg, 40mg and 60mg of ACAPODENE(TM) and placebo given orally once a day. There were approximately 125 patients per arm. The primary entry criterion for the study was men with biopsy proven and confirmed high grade PIN. All patients were rebiopsied at 6 and 12 months from randomization.

ABOUT PIN

High grade PIN has been established as a premalignant lesion that has strong potential to progress to prostate cancer. In the United States, approximately 1,300,000 prostate biopsies are performed annually to detect 230,000 new cases of prostate cancer. There are approximately 115,000 new cases of high grade PIN diagnosed each year, representing an estimated 9% of prostate biopsies. Currently, patients diagnosed with high grade PIN have to be followed closely by their urologist and are subjected to repeat prostate biopsies.

ABOUT ACAPODENE(TM)

ACAPODENE(TM) is a nonsteroidal SERM, a small molecule that binds and selectively modulates the estrogen receptor. SERMs have been shown to block estrogen receptors in the prostate. GTx has licensed the right to develop, market and distribute toremifene citrate, the active ingredient of ACAPODENE(TM) tablets, worldwide in the field of prevention and treatment of prostate cancer from Orion Corporation, Finland.

ABOUT PROSTATE CANCER

In the United States, there is estimated to be over 230,000 new prostate cancer cases and 30,000 prostate cancer deaths this year. This makes prostate cancer the most commonly diagnosed cancer and the second leading cause of cancer-related deaths in men in the United States.

CONFERENCE CALL

There will be a conference call today at 10:00 a.m. Eastern Time to discuss GTx's Phase II data for ACAPODENE(TM) for the prevention of prostate cancer in high risk men. If you would like to participate in the call, please dial 800-915-4836 from the United States or Canada or 973-317-5319 from outside North America. A playback of the call will be available today from approximately 12:00 p.m. Eastern Time through June 9, 2004 and may be accessed by dialing 800-428-6051 from the United States or Canada or 973-709-2089 from outside North America. The rebroadcast code is 359201

ABOUT GTX

GTx is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics primarily related to the treatment of serious men's health conditions. GTx's drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens. GTx currently has two product candidates that are in human clinical trials. The company is developing ACAPODENE(TM), its most advanced product candidate, through clinical trials for two separate indications: (1) its now completed Phase IIb clinical trial for the reduction in the incidence of prostate cancer in high risk men with precancerous prostate lesions and (2) a pivotal Phase III clinical trial for the treatment of serious side effects of advanced prostate cancer therapy. GTx is developing its second product candidate, andarine, and other specified backup compounds, with its partner, Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson. Andarine will be entering a planned Phase II clinical trial this year. GTx retains all rights to the discovery, development, and commercialization of the rest of its SARM program including its other specific product candidates ostarine, prostarine and andromustine.

FORWARD LOOKING STATEMENTS

This press release contains forward-looking statements, including, without limitation, statements related to GTx's current and anticipated clinical trials of ACAPODENE(TM) 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 neither GTx nor its collaboration partners will not be able to commercialize its product candidates if preclinical studies do not produce successful results or clinical trials do not demonstrate safety and efficacy in humans; if third parties do not manufacture the Company's product candidates in sufficient quantities and at an acceptable cost, clinical development and commercialization of its product candidates would be delayed; use of third-party manufacturers may increase the risk that the Company will not have adequate supplies of its product candidates; if third parties on whom the Company relies do not perform as contractually required or expected, the Company may not be able to obtain regulatory approval for or commercialize its product candidates; the Company is dependent upon collaborative arrangements to complete the development and commercialization of some of its product candidates, and these collaborative arrangements may place the development of its product candidates outside its control, may require it to relinquish important rights or may otherwise be on terms unfavorable to the Company; 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 the press release. The annual report filed on Form 10-K with the U.S. Securities and Exchange Commission on March 26, 2004 contains under the heading "Additional Factors That Might Affect Future Results" 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.

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