



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): **February 2, 2005 (February 1, 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)

---

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

---

## **TABLE OF CONTENTS**

[ITEM 8.01 Other Events.](#)

[ITEM 9.01 Financial Statements and Exhibits.](#)

[SIGNATURE](#)

[PRESS RELEASE](#)

---

## Table of Contents

### ITEM 8.01 Other Events.

On February 1, 2005, GTX, Inc. announced that it has initiated a Phase I clinical trial for ostarine, GTX's second selective androgen receptor modulator (SARM) compound to be tested in clinical trials. 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<br/>Number</u> | <u>Description</u>                                       |
|---------------------------|--|
| 99.1                      | Press Release issued by GTX, Inc. dated February 1, 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: February 2, 2005

By: /s/ Henry P. Doggrell

Name: Henry P. Doggrell

Title: Vice President, General Counsel/Secretary

Contact:  
GTx, Inc.  
Carney Duntsch  
Investor and Media Relations  
901-523-9700  
cduntsch@gtxinc.com

Burns McClellan, Inc.  
Jonathan M. Nugent (investors)  
Kathy L. Jones-Nugent, Ph.D. (media)  
212-213-0006

GTx, INC. INITIATES PHASE I CLINICAL TRIAL  
FOR ITS SECOND SARM OSTARINE

Memphis, Tenn.--February 1, 2005 - GTx, Inc. (Nasdaq: GTXI), a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for serious men's health conditions, today announced that it has initiated a Phase I clinical trial for ostarine, GTx's second selective androgen receptor modulator (SARM) compound to be tested in clinical trials.

"We are very excited about the promising preclinical ostarine data and are pleased to initiate this clinical trial," stated Mitchell Steiner, M.D., Vice Chairman and CEO of GTx. "This shows that we have the proven ability to create compounds in the laboratory and move them into the clinic as we continue to position GTx as the lead SARM company."

The Phase I study will evaluate the safety, tolerability and pharmacokinetic profile of ostarine using a single ascending dose, double-blind, placebo-controlled design in healthy volunteers.

Ostarine is a nonsteroidal SARM that is designed to have positive anabolic effects without having an impact on the prostate and is being developed for andropause as well as other conditions associated with aging, such as sarcopenia. Sarcopenia is defined as the loss of muscle mass associated with aging leading to frailty and loss of independence.

As people age they undergo hormonal and metabolic changes. Each year after age 30 people gain an average of a pound of fat every year and lose a half a pound of muscle every year. Thus, men may lose 50% of muscle between the ages of 30 and 90. Muscle provides strength and endurance, supports the skeletal system and helps protect the body from illness. Loss of muscle can cause frailty, loss of independence, and worsens other conditions such as osteoarthritis and osteoporosis. There are 17 million Americans alive over the age of 75 who suffer from sarcopenia and currently there are no approved treatment options available.

GTx's SARM Discovery Program

GTx believes that the ability to selectively target and modulate the androgen receptor will allow the development of many new drugs that are crucial for men's health. In fact, different compounds within the SARM class have demonstrated in preclinical studies unique pharmacologic activities, with varying effects on endocrine feedback, prostatic stimulation, spermatogenesis, muscle growth, bone growth and sexual behavior, highlighting the untapped potential of these novel drugs for treatment of other diseases, including benign prostatic hyperplasia (BPH), male infertility, and low libido.

## About GTX

GTX is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for 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 four clinical programs. In two of the clinical programs, the company is developing ACAPODENE(TM), its most advanced product candidate, through clinical trials for two separate indications: (1) a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men and (2) a pivotal Phase III clinical trial for the treatment of serious side effects of androgen deprivation therapy for advanced prostate cancer. In its third clinical program, GTX and its partner, Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, are developing andarine, a selective androgen receptor modulator (SARM), which is expected to enter a Phase II clinical trial in 2005. In its fourth clinical program, GTX is developing its own SARM, ostarine, for andropause and other conditions related to aging, including sarcopenia. In addition, GTX has a deep pipeline generated from its own discovery program which includes specific preclinical product candidates prostarine, a SARM, for benign prostatic hyperplasia (BPH), and andromustine, an anticancer drug, for hormone refractory prostate cancer.

## Forward-Looking Information is Subject to Risk and Uncertainty

This press release contains forward-looking statements, including, without limitation, statements related to GTX's current and anticipated clinical trials of ostarine 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 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 this press release. The annual report filed on Form 10-K with the U.S. Securities and Exchange Commission (the "SEC") 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.