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**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): **September 7, 2005**

# GTx, Inc.

(Exact name of registrant as specified in its charter)

| **Delaware** | **005-79588** | **62-1715807** |
|---|---|---|
| (State or other jurisdiction of incorporation or organization) | (Commission File Number) | (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 8.01 Other Events.

On September 7, 2005, GTx, Inc. announced results of its Phase I clinical trials and its Phase II development plans for ostarine, GTx's second selective androgen receptor modulator 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 and is incorporated herein by reference.

ITEM 9.01 Financial Statements and Exhibits.

(c) Exhibits

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release issued by GTx, Inc. dated September 7, 2005 |

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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: September 7, 2005

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

Exhibit 99.1

Contact:
Marc S. Hanover
GTx, Inc.
President and Chief Operating Officer
901-523-9700

GTX, INC. ANNOUNCES POSITIVE CLINICAL RESULTS AND DEVELOPMENT PLANS FOR OSTARINE

MEMPHIS, TENN. - September 7, 2005 - GTx, Inc. (Nasdaq: GTXI), The Men's Health Biotech Company, announced today that results from its Phase I clinical trials for ostarine, its second selective androgen receptor modulator (SARM), were consistent with anabolic activity without evidence of unwanted androgenic side effects on prostate and skin sebaceous glands. GTx intends to begin a Phase II clinical trial of ostarine for the treatment of muscle wasting associated with burns during the fourth quarter of 2005.

"We are excited with the outcome of our Phase I clinical trials of ostarine. Now that ostarine is poised to enter Phase II clinical trials, it becomes our lead SARM compound," said Mitchell Steiner, MD, chief executive officer of GTx. "Results from our recently completed multiple-ascending dose clinical trial have allowed us to pick doses of ostarine to advance into Phase II clinical trials. We have also zeroed in on developing ostarine for muscle wasting associated with an acute condition, burns, for which we believe ostarine fills an unmet medical need and which may provide us with an efficient path to market. We remain excited by other, broader market possibilities for ostarine, such as muscle wasting associated with andropause, and we intend to initiate a second Phase II clinical trial of ostarine for this indication in the first half of 2006."

About Ostarine

Ostarine is a non-steroidal, oral SARM, all rights to which are held by GTx. GTx believes that ostarine has the potential to treat muscle wasting associated with chronic conditions, such as end-stage renal disease, frailty and andropause, as well as muscle wasting associated with acute conditions, such as burns.

Ostarine is the second SARM that GTx has brought from discovery into clinical trials. GTx also discovered andarine, a SARM that GTx and its collaborator, Johnson & Johnson's subsidiary, Ortho Biotech Products L.P., are developing to treat cancer cachexia.

Planned Phase II Clinical Trials for Ostarine

GTx plans to initiate Phase II clinical trials of ostarine first for muscle wasting associated with burns because acute indications have a relatively expeditious and defined clinical development and regulatory pathway. Burn patients are hypermetabolic and lose significant lean body weight, which adversely affects their healing and recovery. GTx expects to begin its Phase II clinical trial of ostarine for muscle wasting associated with burns in the fourth quarter of 2005. Studies have already established proof-of-concept for the use of anabolic agents in the treatment of burns. Because ostarine has a long half life (24 hours) and provides levels of circulating androgens unattainable with anabolic steroidal agents, GTx believes that this selective, potent, non-steroidal anabolic agent would be an important step forward in the treatment of burn patients.

"We believe that the treatment of burn patients represents an excellent first path for GTx to pursue for ostarine," said Dr. Steiner. "A powerful anabolic agent without unwanted steroidal side effects could help speed the recovery of burn victims. For GTx, the treatment of burn patients offers a relatively expeditious route to market for its lead SARM."

GTx plans to continue clinical development of ostarine for chronic muscle wasting due to low testosterone in aging men (a condition also known as andropause). Between 30 and 60 years of age, men on average gain a pound of fat and lose a half pound of muscle, and muscle loss accelerates after age 60. This loss of muscle mass can lead to frailty and loss of independence. GTx plans to initiate Phase II clinical testing for the treatment of andropause during the first half of 2006.

About Ostarine's Phase I Multiple Ascending Dose Clinical Trial Results

The Phase I multiple-ascending dose clinical trial evaluated the safety, tolerability and specific pharmacodynamic characteristics of ostarine in a double-blind, placebo-controlled study in 48 healthy male volunteers, 18-45 years of age, and 12 elderly males with truncal obesity, who averaged 68 years of age. Safety and pharmacodynamic measurements were taken at the beginning of the study and after 14 days of daily oral dosing. These measurements included routine blood chemistry and hematology, sex hormones and gonadotropins, serum prostate specific antigen, metabolic markers of bone and muscle, cutaneous sebum analysis and DEXA scanning for body composition.

Ostarine is designed to have anabolic building activity without unwanted androgenic side effects on prostate and skin sebaceous glands. Overall, clinical laboratory values and hormonal effects determined from the study were consistent with anabolic activity. Comparisons of DEXA assessments from the beginning of the study to DEXA assessments after 14 days showed positive changes in body composition, with lean body mass and fat mass in study patients moving in a direction consistent with anabolic activity. Based on other tests, ostarine did not appear to have unwanted side effects on the prostate or the skin. GTx believes that these observations support the potential ability of ostarine to selectively modulate androgen receptors in a tissue-specific manner.

There were no drug-related serious adverse events related to ostarine in the clinical trial. Doses that were found to be safe in this study were selected to enter Phase II testing later this year.

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(R) (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 precancerous prostate lesions. In its third clinical program, GTx is developing ostarine for the treatment of muscle wasting associated with acute conditions such as burns and chronic conditions such as andropause. GTx expects to begin Phase II clinical trials of ostarine for muscle wasting associated with burns in the fourth quarter of 2005 and for andropause during

the first half of 2006. In its fourth clinical program, GTx and its collaborator, Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, are developing andarine, another one 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, including, without limitation, statements related to GTx's planned 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 and other important factors, which include, without limitation, risks that GTx will not be able to commercialize its product candidates if clinical trials do not demonstrate safety and efficacy in humans; risks related to GTx's dependence on third parties; 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-A with the U.S. Securities and Exchange Commission (the "SEC") on August 3, 2005 contains under the heading "Additional Factors That Might Affect Future Results," a more comprehensive description of these and other important factors and 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.