



UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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**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 7, 2006**

**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)

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(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:

- 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))
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## **TABLE OF CONTENTS**

[ITEM 1.02 Termination of a Material Definitive Agreement](#)

[ITEM 8.01 Other Events.](#)

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

[SIGNATURE](#)

[EXHIBIT INDEX](#)

[Ex-99.1 December 8, 2006 Press Release](#)

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## Table of Contents

### ITEM 1.02 Termination of a Material Definitive Agreement

On December 7, 2006, GTx, Inc. (“GTx”) and Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson (“Ortho Biotech”), mutually agreed to terminate the Joint Collaboration and License Agreement, dated March 16, 2004, by and between GTx and Ortho Biotech (the “Collaboration Agreement”). Pursuant to the terms of the Collaboration Agreement, GTx and Ortho Biotech had agreed to jointly develop and commercialize andarine, a selective androgen receptor modulator (“SARM”), for indications related to men’s health and other licensed SARM compounds meeting specified criteria that Ortho Biotech may have ultimately chosen to develop instead of, or in addition to, andarine. Pursuant to the terms of the Collaboration Agreement, GTx received an up-front licensing fee and reimbursement of certain andarine development expenses totaling approximately \$6.7 million, which was being amortized into revenue over five years. In the fourth quarter 2006, GTx expects to recognize collaboration revenue of approximately \$3.3 million, which represents the unamortized balance of the up-front licensing fee paid by Ortho Biotech to GTx. Under the Collaboration Agreement, GTx was entitled to receive additional licensing fees and milestone payments prior to product launch of (1) up to an aggregate of \$76.0 million for licensed products containing andarine or any replacement compound, and (2) up to \$45.0 million for each licensed product containing any other compound developed under the Collaboration Agreement, upon achievement of specific clinical development milestones or receipt of regulatory approvals. Ortho Biotech was also obligated under the Collaboration Agreement to pay GTx up to double digit royalties on worldwide net sales of andarine and other licensed products, and an additional royalty in excess of 20% on all co-promoted net sales to urologists in the United States. As a result of the termination of the Collaboration Agreement, GTx does not expect to receive or record any portion of these additional licensing fees, milestone payments or royalties. Under the Collaboration Agreement, Ortho Biotech was responsible for the manufacture, packaging and supply of andarine for both clinical trials and commercialization.

The above description of the Collaboration Agreement is a summary of certain of the material terms of the Collaboration Agreement and does not purport to be complete, and is qualified in its entirety by reference to the Collaboration Agreement, which was filed as Exhibit 10.24 to GTx’s Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on May 7, 2004.

### ITEM 8.01 Other Events.

On December 8, 2006, GTx, Inc. issued a press release announcing positive Phase II clinical trial results for ostarine, a SARM, and announcing that it has reacquired full rights to develop and commercialize andarine and all backup compounds previously licensed to Ortho Biotech under the Collaboration Agreement. A copy of the press release is attached as Exhibit 99.1 to this current report and is incorporated herein by reference.

### ITEM 9.01 Financial Statements and Exhibits.

#### (d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release issued by GTx, Inc. dated December 8, 2006

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[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 8, 2006

By: /s/ Henry P. Doggrell

Name: Henry P. Doggrell

Title: Vice President, General Counsel/Secretary

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EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release issued by GTx, Inc. dated December 8, 2006

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

**GTx ANNOUNCES THAT OSTARINE ACHIEVED PRIMARY ENDPOINT OF LEAN BODY MASS AND A SECONDARY ENDPOINT OF IMPROVED FUNCTIONAL PERFORMANCE IN A PHASE II CLINICAL TRIAL AND REACQUISITION OF FULL RIGHTS TO GTx SARM PROGRAM**

- **Ostarine achieved the primary endpoint of increasing lean body mass and a secondary endpoint of improving functional performance**
- **Ostarine demonstrated tissue selectivity with desired effects on lean body mass (muscle) and no apparent effects on prostate, skin, or pituitary gland**
- **Ostarine continued to demonstrate a favorable safety profile, with no serious adverse events reported**
- **GTx plans to initiate a Phase IIb ostarine clinical trial for cancer cachexia in 2007**
- **GTx reacquires all rights to andarine and backup compounds from Ortho Biotech**
- **GTx will host a conference call at 9 a.m. EST today**

MEMPHIS, Tenn., December 8, 2006, GTx, Inc. (Nasdaq: GTXI), the Men's Health Biotech Company, today announced that ostarine, a first-in-class selective androgen receptor modulator (SARM), met its primary endpoint in a Phase II proof of concept double blind, randomized, placebo controlled clinical trial in 120 subjects (60 elderly men and 60 postmenopausal women). Without a prescribed diet or exercise regimen, all subjects treated with ostarine had a dose dependent increase in total lean body mass (muscle), with the 3 mg cohort achieving an increase of 1.3 kg compared to baseline and 1.4 kg compared to placebo ( $p < 0.001$ ) after three months of treatment. Treatment with ostarine also resulted in a dose dependent improvement in functional performance measured by a stair climb test, with the 3 mg cohort achieving a clinically significant improvement in both speed ( $p = 0.006$ ) and power ( $p = 0.005$ ). Ostarine continued to demonstrate a favorable safety profile, with no serious adverse events reported. Ostarine also exhibited tissue selectivity with beneficial effects on lean body mass and performance and with no apparent change in measurements for serum PSA (prostate), sebum production (skin and hair), or serum LH (pituitary) compared to placebo.

"These results are exciting," said William J. Evans, Ph.D., Professor of Geriatrics, Physiology, and Nutrition at the Donald W. Reynolds Institute of Aging of the University of Arkansas for Medical Sciences. "Not only was there a change in lean body mass in the clinically significant range, but a significant change in functional performance was also seen. A clear anabolic effect with little to no unwanted androgenic effect was demonstrated, which should be the hallmark of a SARM."

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The Phase II clinical trial evaluated four doses of ostarine (0.1 mg, 0.3 mg, 1 mg, and 3 mg) versus placebo for three months in 60 elderly men (average age 66 years) and 60 postmenopausal women (average age 63 years). The trial was conducted in five clinical sites in the United Kingdom and Germany.

**A summary of the topline data is as follows:**

**\* Primary endpoint:** total lean body mass (LBM) measured by dual energy x-ray absorptiometry (DEXA) at baseline compared to three months

- Among all subjects (n=114), ostarine treatment resulted in a dose dependent increase in total lean body mass, with an increase of 1.3 kg compared to baseline and 1.4 kg compared to placebo (p<0.001) at the 3 mg dose.
- Among females (n=56), ostarine treatment resulted in a dose dependent increase in LBM with the 3 mg dose having an increase of 1.7 kg compared to baseline and an increase of 1.4 kg compared to placebo (p=0.02).
- Among males (n=58), treatment with a 1 mg dose of ostarine resulted in a LBM increase of 0.7 kg compared to baseline and an increase of 1.2 kg compared to placebo (p=0.03), and treatment with a 3 mg dose of ostarine resulted in an increase of 1.0 kg compared to baseline and an increase of 1.4 kg compared to placebo (p=0.005).

**\*Secondary endpoints:** performance, fat mass, bone mineral density, and bone turnover markers

- In a stair climb functional performance test that measured speed (time to completion) and power exerted (watts), subjects treated with a 3 mg dose of ostarine demonstrated on average a 15.5% faster time to completion (p=0.006) and exerted on average 25.5% more power (p=0.005) than subjects receiving placebo.
- Total tissue percent fat decreased compared to placebo in a dose dependent fashion and achieved statistical significance at the 1 mg dose (p=0.02) and 3 mg dose (p=0.006) of ostarine. Total fat mass was lower in subjects receiving either the 3 mg or 1 mg ostarine dose, although not at a statistically significant level (p = 0.08 for both doses). For subjects receiving the 3 mg ostarine dose, total fat on average declined 0.6 kg compared to placebo. The site of fat loss differed among male and female subjects, with males losing fat primarily from the trunk and abdomen, and females losing fat primarily from the thighs and legs.
- In this short trial, ostarine had no apparent effect on bone mineral density, and bone turnover markers results were mixed. In preclinical *in vitro* and *in vivo* models, ostarine demonstrated both anabolic and antiresorptive activity on bone. A longer clinical study is necessary to demonstrate the actual effects of ostarine on bone.

**\* Safety**

- Ostarine continued to demonstrate a favorable safety profile, with no serious adverse events reported.
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- At the end of three months, no subject had clinically meaningful levels in liver enzyme tests. However, one female discontinued the study per protocol due to elevated liver enzymes which returned to baseline.
- Ostarine treatment resulted in a dose dependent decrease in both LDL and HDL cholesterol levels, with the average LDL/HDL ratio for all doses tested remaining in the low cardiovascular risk category.

**\* Selectivity**

- Ostarine treatment resulted in no apparent effect on serum PSA (prostate), sebum production (skin and hair), or serum LH (pituitary).

“The use of anabolic agents has previously been limited because of concerns over unwanted androgenic and steroidal side effects and oral bioavailability,” said Mitchell S. Steiner, MD, CEO of GTx. “Ostarine’s safety, tissue selectivity profile, and efficacy results demonstrated in our Phase II clinical trial, combined with oral dosing, distinguish this drug candidate from existing anabolic steroids and testosterone analogues. This opens the door for its potential use in both males and females in a multitude of diseases, including cancer cachexia, end stage renal disease muscle wasting, frailty and osteoporosis.”

GTx recently conducted discussions with various divisions of the United States Food & Drug Administration to investigate the required regulatory pathways for several indications under consideration for ostarine’s ongoing clinical development. With more clarity regarding the required regulatory pathway and with proof of concept Phase II clinical data, GTx has selected cancer cachexia as the initial acute indication for ostarine development. GTx plans to initiate a Phase IIb ostarine clinical trial for cancer cachexia by the summer of 2007.

Cachexia, or muscle wasting, is a serious result of many cancers, causing selective muscle loss, fatigue, and deteriorating quality of life which adversely impacts response to treatment and overall survival. Cancer cachexia has been identified as one of the two most frequent and devastating problems affecting individuals with advanced malignancies. It has been estimated that a third of the approximately 1.3 million patients diagnosed with cancer in the United States each year will suffer from cancer cachexia. A drug with the ability to increase lean body mass and improve functional performance would address significant unmet needs for the millions of patients living with cancer.

GTx also intends to evaluate the ability of ostarine to treat chronic disease indications including end stage renal disease muscle wasting, frailty and osteoporosis.

**Collaboration with Ortho Biotech for andarine**

GTx has reacquired full rights to develop and commercialize andarine and all backup compounds previously licensed to Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson (Ortho Biotech), through a Joint Collaboration and License Agreement executed between GTx and Ortho Biotech in March 2004, which has been terminated by mutual agreement of the parties. GTx now has full ownership and control of its SARM portfolio.

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“With GTx’s reacquisition of all rights to andarine, we are now free to pursue any indication for ostarine, including cancer cachexia, without a concern that andarine could become a potential competitor,” said Dr. Steiner. “Having positive ostarine proof of concept data and the full rights to all of our SARMs, we are now in position to maximize the value of our SARM program through clinical development and potential partnerships.”

In the fourth quarter 2006, GTx expects to recognize collaboration revenue of approximately \$3.3 million, which represents the unamortized balance of the upfront licensing fee paid by Ortho Biotech to GTx in April 2004.

### **Conference Call**

GTx will host a conference call and webcast this morning at 9:00 a.m. EST. To listen to the conference call, please dial:

— 866-202-4367 from the United States and Canada or

— 617-213-8845 (International)

The access code for the call is 32056343.

A playback of the call will be available beginning today at 11:00 a.m., Eastern Time through December 22, and may be accessed by dialing:

— 888-286-8010 from the United States and Canada or

— 617-801-6888 (International)

The reservation number for the replay is 89704161.

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, 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. GTx is developing ACAPODENE® (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 prostatic intraepithelial neoplasia, or PIN. GTx has licensed to Ipsen Limited exclusive rights in Europe to develop and commercialize ACAPODENE®. GTx also is developing ostarine, a first-in-class selective androgen receptor modulator, or SARM. GTx believes that ostarine has the potential to treat a variety of indications, including cancer cachexia, end stage renal disease muscle wasting, frailty and osteoporosis. GTx plans to initiate a Phase IIb ostarine clinical trial for cancer cachexia by the summer of 2007.

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

This press release contains forward-looking statements based upon GTX's current expectations, including, without limitation, the statements related to future clinical and other development of, and potential applications for, ostarine and expected collaboration revenue to be recognized in the fourth quarter 2006. 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, including ostarine, 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 Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission on November 3, 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.